The History of PDA

65 years of *Connecting People, Science and Regulation®*

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Acknowledgements

Longtime PDA member and now President Richard M. Johnson had the vision and took the initiative to create this PDA 65th Anniversary Book in order to capture and commemorate the explosive growth in PDA's activities since the Golden Anniversary in 1996. If not for his support, knowledge of PDA and vision for this book, we would not have been able to produce it.

No PDA History can be written without the input of our members, without whom there is no PDA. Since this book focuses on the 15-year period spanning 1997 to the present, we assembled a volunteer team of members who have been active throughout this time frame. This group helped shape the book and reviewed drafts and proofs. We want to thank the following volunteers for their help in shaping the content and for providing valuable feedback and insight: Maik Jornitz, Nikki Mehringer and Glenn Wright.

PDA staff also contributed and deserves recognition. James Lyda, Robert Dana, and James Wamsley proved to be excellent sources of information about the growth of PDA internationally and about the founding and ongoing activities of the Training and Research Institute. They also have a keen eye for editing, and their recommendations on that front were well appreciated! Wanda Neal, Richard Levy, Adrienne Fierro, Hassana Howe and Emily Hough also provided insights, suggestions and edits.

Credit is also due to the PDA employees who assembled the Association's Annual Reports each and every year since 1996. Most of what is included in this History came out of those excellent yearly chronicles of PDA's activities. The *PDA Letter* served as another invaluable source, not only for chronicling events and activities, but for serving as a source for many of the photos included in this volume.

Finally, Katja Yount contributed many hours to this project. She designed the entire book, matching the style established with the 50th Anniversary booklet published in 1996. She attained the high quality scans of the 50th Anniversary booklet and a companion history, which are included as appendices to this book; she foraged for new artwork, often scanning images from old *PDA Letters* and applying some PhotoShop magic; and she shepherded the material through the printing process.

PDA hopes members will enjoy this book for years to come.

PDA Director of Publishing
September 2011

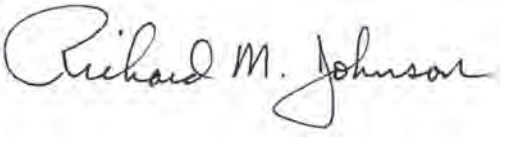
Foreword

The Parenteral Drug Association has been an active organization longer than my lifetime, and over that span of time has reflected the vision, drive and contributions of literally tens of thousands of members, volunteers, staff and professionals from the pharmaceutical and biopharmaceutical industry. As an organization with such a proud lineage, it can be instructive, rewarding and entertaining to look back on just a brief overview of that history.

We are indebted to our predecessors, who preserved for us the first 50 years of the history of PDA, but copies of that are now hard to come by. We wanted to capture that and make it available to our members, and to supplement it with the information from the period since the 50th Anniversary. To that end, we have tried to capture some of the key activities and events over the past fifteen years in this book and added the original 50 year history. While no effort of ours could comprehensively capture all of the people, accomplishments and activities that our organization has had, we hope that this sampling will capture the spirit of those people and efforts. We would also like to encourage any of you to send to us any additional material, photographs or information about PDA that you would like the organization to preserve. We will add it to the archive and maybe include it in future editions.

We hope that you will enjoy revisiting some of the activities, places, and accomplishments of the first 65 years of PDA. Most of all, we hope you enjoy visiting with old friends and colleagues, some of who are no longer with us. We hope, like us, you take pride in our accomplishments and inspiration to continue the legacy that they have built.

Best Regards,



Richard M. Johnson

The History of PDA

65 years of *Connecting People, Science and Regulation®*

CHAPTER 1

INTRODUCTION

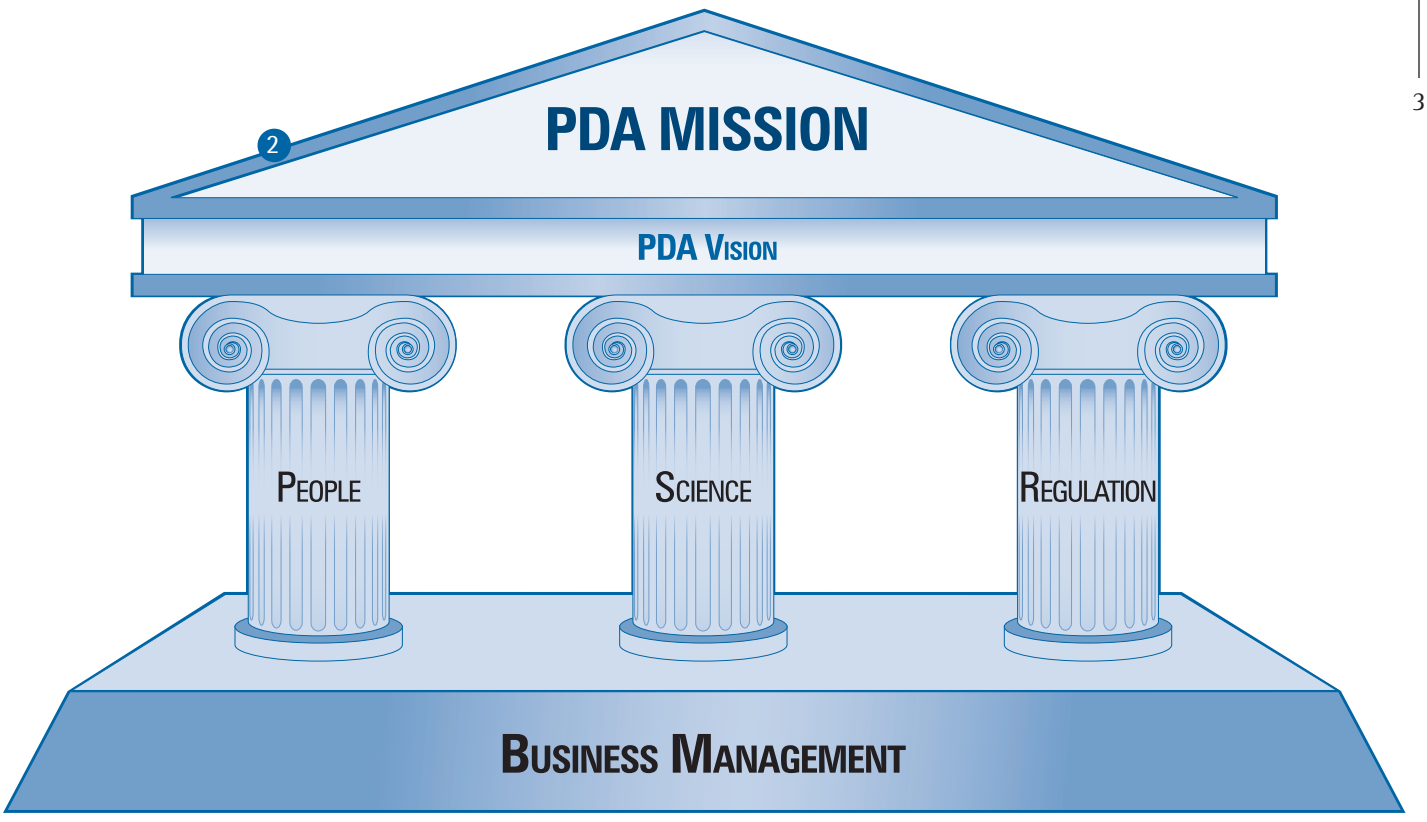
Since its humble beginnings in New York in 1946, the Parenteral Drug Association (PDA) has grown into an internationally active, influential and respected professional association representing the diverse interests of those working in and contributing to the pharmaceutical and biopharmaceutical industry. Echoing words from the introduction to PDA's 50th Anniversary booklet, PDA has undergone dramatic change in the years leading up to the 65th Anniversary. Yet, certain themes are unchanged!

Dramatic changes are reflected in the rapid growth in member volunteers outside of the United States. Whereas the first five decades saw the membership in the United States driving most activities, over the last fifteen years, participation of members in Europe and Asia has had major impact on every facet of PDA's offerings and programs. Another dramatic change has been the opening of the PDA Training and Research Institute in 1997. This milestone allowed PDA to offer hands-on industry training in a cleanroom environment—the first of its kind. After all this time, PDA remains the only professional association in the industry with its own training facility.

What is unchanged? For one, PDA had gained a reputation of providing forums for its members to meet with officials from the U.S. FDA and/or the U.S. Pharmacopeia to discuss issues in a collegial, scientific manner to help shape regulations, guidances and compendial standards. PDA has excelled at providing this connection over the last fifteen years with the forging of relationships with the European Medicines Agency and various other regulatory authorities in Europe, Asia, Canada and elsewhere.

But it is not a group of professional advocates that allow these links to grow. Instead, it is the volunteer membership. In 2011, PDA can boast that over 10% of its members are actively involved with planning and speaking at conferences, serving on advisory boards, committees and task forces, and leading chapters and interest groups.

The last 15 years have seen tremendous growth in PDA's activities to meet its members' unique needs. From the growing number of specialized events held each



PEOPLE — Enhance the Value of the PDA Membership

SCIENCE — Be recognized as a leading organization for manufacturing science, quality and innovation

REGULATION — Our regulatory activities are scientifically and technically focused, and current information is communicated to our members

year to the purpose-driven technical publications, PDA is working on multiple fronts to serve the membership. A true strength of the organization is its ability to bring together volunteer experts to influence regulation with strong scientific principles. In 2005, PDA's Board of Directors adopted the tagline *Connecting, People, Science and Regulation®* as a reflection of this strength.

As PDA looks forward, its leadership adopted a new Strategic Plan to ensure that the Association will continue to operate and serve members globally with publications, conferences, training and other activities, as well as continue to serve as the foremost organization for membership networking and sharing of best practices among colleagues in industry, regulatory agencies, and academia. This plan touches on the three pillars of PDA and will strengthen PDA's ability to connect people, science and regulation.

1. The Bethesda Towers, PDA's Global Headquarters since 2006
2. The Pillars of PDA's 2011-2015 Strategic Plan
3. TRI Instructor David Matsuhiro addresses students during a hands-on laboratory course

PDA MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA VISION

To be the foremost global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical industry

CHAPTER 2

People

1

PDA is people. And not just any group of people. It is composed of well educated, highly trained scientists, regulatory experts, businessmen/women, lawyers, doctors and academicians, who seek to serve the greater good by manufacturing or contributing to the manufacture of safe, effective and quality medications. PDA was formed by these individuals, grew because of them and exists today to continue serving them.

PDA is truly an Association of the members, by the member and for the members. Nearly every initiative undertaken in its history was driven by a volunteer champion.

This chapter celebrates PDA's members and, in particular, those volunteers who have gone above and beyond in the years 1997-2011. It includes a listing of all Honor Award Winners, Board of Director members, Advisory Board participants and Chapter Leaders. The chapter concludes with photos of various staff members who have worked with members to advance all of PDA's projects.

PDA Chairs 1998-2010

1997	Raymond Shaw, Jr., PhD Wyeth–Ayerst Labs
1998	Joyce H. Aydlett, Catalytica Pharmaceuticals
2000	Robert B. Myers, Schering-Plough
2002	Floyd Benjamin, Keystone Pharmaceuticals, Inc.
2004	Nikki Mehringer, Eli Lilly and Company
2006	Vincent Anicetti, Genentech, Inc.
2008	John Shabushnig, Pfizer Inc.
2010	Maik Jornitz, Sartorius Stedim Biotech

Honor Award Winners

The PDA Honor Awards are bestowed on members who provide exceptional leadership and service to the Association, and have been awarded at the Annual Meeting since 1958. Over the years, the number of awards has grown to recognize the various activities of PDA's members and staff, with new awards created over the last 15 years in recognition of Chapter leaders, PDA-DHI authors/editors and PDA staff.

1. Vince Anicetti presents Stephanie Gray with the Frederick J. Carleton Award
2. Raymond Shaw presents Doris Conrad with the prestigious Honorary Membership Award
3. Russell Madsen (right) presents William Whyte with the 2002 Michael S. Korcynski Lecture Award
4. The 2000 Honor Award winners

Honorary Membership

This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award has usually been given in recognition of very long service, of a very significant nature, to PDA. The award requires unanimous approval of the PDA Board of Directors.

1997	Doris L. Conrad
1999	Irving J. Pflug, PhD
2000	Clarence A. Kemper, PhD
2001	Michael S. Korczynski, PhD
2002	Joseph R. Robinson, PhD, and R. Michael Enzinger, PhD
2003	Frederick Gudtafson
2004	Robert Myers
2005	Kunio Kawamura, PhD and Russell Madsen
2007	Bengt Ljungqvist, PhD and Berit Reinmuller, PhD
2008	Julius Knapp
2009	Edmund Fry
2010	Nikki V. Mehringer

Gordon R. Personeus Award

Presented in memory of the late Gordon Personeus, past PDA President and long-time volunteer, this award is intended to honor a PDA member, other than a Board member, for long-term acts or contributions that are of noteworthy or special importance to PDA.

1997	James D. Wilson
1998	Kunio Kawamura, PhD and Toshinobu Aoyama, PhD
1999	Bernard Kronenberg and Carol Lampe
2000	Frank Bing and Robert Pazzano
2001	Regina McCairns
2003	Julius Knapp
2004	Daniel Gold, PhD
2005	John Geigert, PhD
2006	Susan Schniepp
2007	Richard Johnson
2008	Karen Ginsbury
2009	Susan Schniepp
2010	Edward H. Trappler

Frederick J. Carleton Award

Presented as a tribute to lifetime contributor, past President, past Executive Director and Honorary Member Frederick J. Carleton, this award is designated for a past or present member of the PDA Board of Directors whose services on the Board are determined by his/her peers as worthy of such recognition.

1997	Clarence A. Kemper, PhD
1998	James E. Akers, PhD
1999	Floyd Benjamin
2000	Raymond Shaw, Jr.
2001	Joyce H. Aydlett
2002	Robert B. Myers
2003	Henry Kwan, PhD
2004	Glenn Wright
2005	Richard Levy, PhD
2006	Stephanie Gray
2007	Jennie Allewell and Nikki Mehringer
2008	Lisa Skeens, PhD
2009	Vince Anicetti and Yoshihito Hashimoto
2010	Robert Dana

PDA Presidents 1997-2009

1997	Edmund M. Fry
2002	Neal G. Koller
2005	Robert B. Myers
2009	Richard M. Johnson

Frederick D. Simon Award for Best Paper in the PDA Journal of Pharmaceutical Science & Technology

This award is named in honor of the late Fred Simon, who was PDA's Director, Scientific Affairs, and is given to the authors of the for best paper published in the *PDA Journal of Pharmaceutical Science and Technology*

1997	Dexi Liu, Young K. Song, Kazuo Maruyama, and Tomoko Takizawa
1998	Lee E. Kirsch, PhD, Linda Nguyen, Graig S. Moeckly, and Ronald Gerth
1999	Feroz Jameel, PhD, Frank Mauri, PhD, and Robin Bogner, PhD
2000	Hongkee Sah
2001	Petra Merker, Jutta Ladewig, Klaus-Peter Gerbling, Lutz Grohmann, Roger Petersen, and Frank-Roman Lauter
2002	Robert A. Bellantone, Mustafa Kamal, Sivarama K. Nutalapati, Theodore Jochsberger, and Fotios M. Plakogiannis
2003	David Watling, PhD; Gunnel Lundahl
2004	Wei Wang, PhD, Tian-Yi Cui, MD, Y. John Wang, PhD, and Sheryl Martin-Moe, PhD
2005	Dennis Jenke, PhD, Molly Chacko, Tom Couch, Eric Edgcomb, Liqiong Fang, Mary Jo Garber, and Steve Swanson
2006	Brian Meyer, PhD and Diego Vargas
2007	Yves Mayeresse, Cyrille Nomine, Philippe Sibille and Romain Veillon
2008	Manuela Bini, Gilberto Dalmaso, PhD, Michela Ferrari, and Roberto Paroni
2009	Bruce Eu, Xiaolin Cao, Aylin Vance, Fabian Vega, Robert Schultheis, and Zai-Qing Wen
2010	Janice M. Davis, PhD, Erwin Freund, PhD, Yijia Jiang, PhD, Wei Liu, PhD, Anthony Mire-Sluis, PhD, Yasser Nashed-Samuel, PhD, Gianpiero Torraca, Zai-Qing Wen, PhD, Linda Narhi, Robert Swift, and Aylin Vance

James P. Agalloco Award

Presented to the PDA faculty member each year who exemplifies outstanding performance in education. Named for James P. Agalloco in honor of his work in developing the PDA education program.

1997	Lynn D. Torbeck
1998	William V. Collentro
1999	Robert G. Kieffer
2000	John M. Lindsay
2001	James L. Vesper
2002	Göran Bringert
2003	Jörg Neuhaus, PhD
2004	John Brecker
2005	David Matsuhiro
2006	Lynn Torbeck
2007	Jeanne E. Moldenhauer, PhD
2008	Harold Baseman
2009	Barry A. Friedman, PhD
2010	Arthur Vellutato Jr.

8

5. 2002 James P. Agalloco Award winner Göran Bringert (center) with Russell Madsen and Floyd Benjamin (right)
6. Four-time Distinguished Editor/ Author Award winners Maik Jornitz and Ted Meltzer
7. The 2004 Honor Award winners
8. PDA 60th Anniversary "Oustanding PDA Scientists" plaque. Honorees include (clockwise from top right) Theodore Meltzer, Julius Knapp, Bengt Ljungqvist, Berit Reinmuller and Irving Pflug (not pictured)
9. The 2005 Honor Award winners


2005
9

Distinguished Service Award

Given for special acts, contributions or service that have contributed to the success and strength of PDA.

1997	Stanley Sklar, PhD and Daniel Gold, PhD, and Donald E. Baker
1998	Martin W. Henley and Robert Dana
1999	Joyce L. DeYoung
2000	Julius Knapp, Jeanne E. Moldenhauer, PhD, and Duncan McVean
2001	Robert L. Garnick, PhD, John Geigert, PhD, Charles J. Cherundolo, Edmund J. Fitzgerald, Simon Rusmin, PhD, and Richard T. Wood, PhD
2002	Raymond Gabler, PhD
2003	Don Elinski, Taiichi Mizuta, PhD, and Thomas Wilkins, EdD
2004	Robert Coleman, Amy Davis, Richard Johnson, and Ronald Tetzlaff, PhD
2005	Louise Johnson, Michael Miller, PhD, James Lyda, Edmund Fry, Martin Van Trieste, and Toshiaki Nishihata, PhD
2006	Harold Baseman, Jerold Martin, and Gabriele Gori, PhD
2007	Rafik Bishara, PhD, Yoshiaki Hara, Vince Mathews, and Susan Schniepp
2008	Myron Dittmer, Masashi Imamura, Zena Kaufman, Daikichiro Murakami, Mathias Romacker, Thomas Schoenknecht, PhD, and Louis Zaczkiewicz
2009	Amy Scott-Billman, Peter Rauenbuehler, PhD, Stephan Rönninger, and Jean-Louise Saubion, PhD
2010	Stephen Brown, PhD, Ursula Busse, PhD, Lee Kirsch, PhD, David Matsuhiro, and Kevin Trupp

Michael S. Korczynski Grant

This grant recognizes the contribution made toward the development of PDA's international activities by Michael S. Korczynski, PhD. The grant funds travel expenses for an international guest to deliver the "Korczynski Paper" at a PDA meeting.

1997	Vivienne Christ
1998	Alan Tallentire
1999	Olavi Kajander
2001	Brian Matthews
2002	William Whyte, D.Sc
2003	Anders Vinther, PhD
2004	Stephen Bellis
2007 2008	Hannelore Willkommen, PhD

Chapter Volunteer Award

The Chapter Volunteer Award recognizes the contributions of PDA members who participate at the chapter level. Starting in 2007, outstanding leaders were issued the Service Appreciation Award.

2002	Rande Leibowitz, Capital Area Chapter; Mitchell Garber, PhD, Delaware Valley Chapter; Marco Budini, Italy Chapter
2003	Robert Pazzano, New England Chapter; Susan Moore, Southeast Chapter; Jong Hwa Oh, Korea Chapter; Anthony Rowland, Australia Chapter
2004	Allen Burgenson, Capitol Area Chapter; Markus Lankers, PhD, Central Europe Chapter; Arun Malaviya, Canada Chapter; Jason Mattis, Delaware Valley Chapter; Taraneh Roshan, Southern California Chapter
2005	Lisa Hollis McCulley and Thomas Quinn, Delaware Valley Chapter; Byong Ho Youn, PhD, Korea Chapter; James P. Agalloco, Metro Chapter; Spyros Fetsis, Midwest Chapter; Joachim Leube, PhD, Italy Chapter; Randall Tedder, West Coast Chapter; Maggie Sparhawk, Mountain States Chapter
2006	Mary Carver, Southeast Chapter; Jong-Kuk Kim, Korea Chapter; Leonard Mestrandrea, PhD, Metro Chapter; Claudio Puglisi, Italy Chapter; Traute Ryan, Delaware Valley Chapter; Mark Staples, PhD, New England Chapter; Kikoo Tejwani, Southern California Chapter; Amy Twitty, Mountain States Chapter

Distinguished Editor/Author Award

This award is presented annually for the best editor/author of PDA-DHI co-published books as selected by PDA members.

2004	James P. Agalloco, Lucia Clontz, Maik Jornitz and Theodore Meltzer, PhD, and Jeanne E. Moldenhauer, PhD
2005	Maik Jornitz and Theodore Meltzer, PhD, and Jeanne E. Moldenhauer, PhD
2006	Destin LeBlanc, Theodore Meltzer, PhD, and Maik Jornitz, and Susan Schniepp
2007	Stephan O. Krause, PhD, and Scott Sutton, PhD
2008	Anne Booth and Siegfried Schmitt, PhD
2009	Maik Jornitz and Theodore Meltzer, PhD, and Jack Lysfjord
2010	Jeanne E. Moldenhauer

Service Appreciation Award

The Service Appreciation Award is presented annually for special acts, contributions or services that have contributed to the success and strength of PDA.

2003	Thomas Handel
2005	Howard Drake
2008	Patrick Bronsard, John Ferreira, Frank Hallinan, Sara Hendricks, Nate Manco, and Art Vellutato, Jr.
2009	Robert Buchholz, Robert Caunce, Louise Johnson, Stefan Köhler, and John Shabushnig
2010	Raphael Bar, PhD, Gerard Boudreault, Colman J. Casey, PhD, Michele F. Creech, Véronique D. Davoust, PhD, Lothar Hartmann, PhD, Manuel Melendez, Lara A. Soltis, and Laura A. Thoma, Pharm.D.

10. Raymond Shaw presents Clarence Kemper with the 1997 Frederick J. Carleton Award
11. 2001 James P. Agalloco Award winner James Vesper
12. 2006 Honor Award winners
13. 2007 Honor Award winners
14. 2008 Honor Award winners
15. 2009 Honor Award winners

President's Award	
This award recognizes a PDA staff member, other than Senior Staff, whose exemplary performance has contributed to PDA's success during the previous year.	
2006	Janny Chua and Ludy Yo
2007	James Wamsley and Pateresa Day
2008	Jason Brown, Leslie Edmonds, and Hassana Howe
2009	Feng Chen and Antje Petzholdt
2010	Leon Lewis and Dirk Stelling

16. The Honorary Membership plaque displaying the names of past recipients
17. The Frederick J. Carelton Award plaque displaying the names of past recipients
18. (l-r) Theodore Meltzer, Julius Knapp and Frederick Carleton at a PDA Annual Meeting
19. Immediate Past Chair Bob Myers passes the gavel to incoming Chair Floyd Benjamin

Board of Directors 1997 – 2011

The PDA membership elects volunteers to serve on the PDA Board of Directors and Executive Committee. In the 1990's, PDA redrafted its bylaws, establishing a system of elections, terms and officers still in use today. Currently, the PDA Chair serves six full years on the Executive Committee, two years as Chair-Elect, two as Chair, and two as Immediate-Past-Chair. The Treasurer and Secretary are elected for two-year terms. Twelve additional directors serve on the Board, elected by the membership for three-year terms. The Board of Directors is involved with approving members for the PDA Advisory Boards, approving final publication of PDA Technical Reports, and establishing PDA's Strategic Plans.

1997

Chair
Raymond Shaw, Jr., PhD
Wyeth–Ayerst Labs

Chair-elect
Joyce H. Aydlett
Catalytica Pharmaceuticals

Secretary
Floyd Benjamin
Taylor Pharmaceuticals

Treasurer
Raymond Gabler, PhD
Millipore

Immediate Past Chair
Clarence A. Kemper, PhD
KMI/Parexel

James E. Akers, PhD
Akers Kennedy & Assoc.

Jennie Allewell
Cell Therapeutics, Inc.

Peter T. Bigelow
Wyeth–Ayerst Labs

Joyce L. DeYoung, PhD
Ortho-McNeil Pharmaceutical

R. Michael Enzinger, PhD
Pharmacia and Upjohn

John Geigert, PhD
IDEC Pharmaceuticals

Martin W. Henley
Merck

Kunio Kawamura, PhD
Otsuka Pharmaceutical

Nikki Mehringer
Eli Lilly and Company

Robert F. Morrissey, PhD
Johnson & Johnson

Terry E. Munson
KMI/Parexel

Robert B. Myers
Schering-Plough

1998





Chair
Joyce H. Aydlett
Catalytica Pharmaceuticals

Chair-elect
Robert B. Myers
Schering–Plough

Secretary
Floyd Benjamin
Taylor Pharmaceuticals

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R. Micharl Enzinger, PhD
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Cell Therapeutics, Inc.

Joyce L. DeYoung, PhD
Ortho-McNeil Pharmaceutical

Stephanie R. Gray
FDA

Frederick A. Gustafson
Abbott Laboratories

Martin W. Henley
Merck

Henry K. Kwan, PhD
Kwan Consulting

Nikki Mehringer
Eli Lilly and Company

Robert F. Morrissey, PhD
Johnson & Johnson

Terry E. Munson
KMI/Parexel

Toshiaki Nishihata, PhD
Santen Pharmaceutical

Glenn E. Wright
Eli Lilly and Company

1999





Chair
Joyce H. Aydlett
Catalytica Pharmaceuticals

Chair-elect
Robert B. Myers
Schering–Plough

Secretary
Floyd Benjamin
Akorn Inc.

Treasurer
R. Micharl Enzinger, PhD
Pharmacia and Upjohn

Immediate Past Chair
Raymond Shaw, Jr., PhD
Wyeth–Ayerst Labs

Jennie Allewell
Cell Therapeutics, Inc.

Joyce L. DeYoung, PhD
Ortho-McNeil Pharmaceutical

Stephanie R. Gray
FDA

Frederick A. Gustafson
Abbott Laboratories

Henry K. Kwan, PhD
Warner-Lambert

Suzanne Levesque
Sabex

Richard V. Levy, PhD
Millipore

Nikki Mehringer
Eli Lilly and Company

Robert F. Morrissey, PhD
Johnson & Johnson

Terry E. Munson
KMI/Parexel

Kenneth B. Seamon, PhD
Immunex

Glenn Wright
Eli Lilly and Company

2000

Chair
Robert B. Myers
Schering-Plough

Chair-elect
Floyd Benjamin
Akorn, Inc.

Secretary
Jennie Allewell
Cell Therapeutics, Inc.

Treasurer
Nikki Mehringer
Eli Lilly and Company

Immediate Past Chair
Joyce H. Aydlett
Aydlett and Associates

Vincent R. Anicetti
Genentech

Stephanie R. Gray
GlaxoSmithKline

Henry K. Kwan, PhD

Suzanne Levesque
Sabex

Richard V. Levy, PhD
Millipore Corporation

P. Michael Masterson, PE
NewcoGen Group

Robert J. Mello, PhD
RJM Pharmaceutical Consultants

Taiichi Mizuta, PhD
Shionogi & Co.

Robert F. Morrissey, PhD
Johnson & Johnson

Georg Rössling
Schering AG

Kenneth B. Seamon, PhD
Immunex Corporation

Glenn Wright
Eli Lilly and Company

2001

Chair
Robert B. Myers
Schering-Plough

Chair-elect
Floyd Benjamin
Keystone Pharmaceuticals

Secretary
Jennie Allewell
Cell Therapeutics, Inc.

Treasurer
Nikki Mehringer
Eli Lilly and Company

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Aydlett and Associates

Vincent R. Anicetti
Genentech

Robert Dana
Elkhorn Associates

Stephanie R. Gray
GlaxoSmithKline

Henry K. Kwan, PhD
Kwan Consulting

Suzanne Levesque
Sabex

Richard V. Levy, PhD
KMI/PAREXEL

Robert J. Mello, PhD
RJM Pharmaceutical Consultants

Taiichi Mizuta, PhD
Shionogi & Co.

Georg Rössling
Schering AG

Kenneth B. Seamon, PhD
Immunex Corporation

Lisa M. Skeens, PhD
Baxter Healthcare Corporation

Glenn Wright
Eli Lilly and Company

20. Joyce Aydlett received the 2001 Frederick J. Carleton Award

21. Stephanie Gray in one of her many speaking engagements with PDA

2002

Chair
Floyd Benjamin
Keystone Pharmaceuticals

Chair-elect
Nikki Mehringer
Eli Lilly and Company

Secretary
Jennie Allewell
Cell Therapeutics, Inc.

Treasurer
Richard V. Levy, PhD
KMI/PAREXEL

Immediate Past Chair
Robert B. Myers
Beacon Pointe Group

Vincent R. Anicetti
Genentech

Joyce H. Aydlett
Aydlett and Associates

Robert Dana
Elkhorn Associates

Stephanie R. Gray
GlaxoSmithKline

Kathleen S. Greene
Novartis Pharmaceuticals

Henry K. Kwan, PhD
Kwan Consulting

Suzanne Levesque
Sabex

Tim Marten, DPhil
AstraZeneca

Robert J. Mello, PhD
PDA

Taiichi Mizuta, PhD
Shionogi & Co. Ltd.

Lisa M. Skeens, PhD
Baxter Healthcare Corporation

Glenn Wright
Eli Lilly and Company

2003

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Floyd Benjamin
Keystone Pharmaceuticals

Chair-elect
Nikki Mehringer
Eli Lilly and Company

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Cell Therapeutics, Inc.

Treasurer
Richard V. Levy, PhD
KMI/PAREXEL

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Beacon Pointe Group

Vincent R. Anicetti
Genentech

Joyce H. Aydlett
Aydlett and Associates

Robert Dana
Elkhorn Associates

Stephanie R. Gray
GlaxoSmithKline

Kathleen S. Greene
Novartis Pharmaceuticals

Yoshito Hashimoto
Chiyada Corporation

Suzanne Levesque
Sabex

Tim Marten, DPhil
AstraZeneca

Georg Rössling
Schering AG

John Shabushnig, PhD
Pfizer

Lisa M. Skeens, PhD
Baxter Healthcare Corporation

Glenn Wright
Eli Lilly and Company

22. Henry Kwan (standing, right) at the PDA/AAPS Joint Workshop on clinical supplies in 1997

23. Glenn E. Wright, Rebecca Devine and Nikki Mehringer at the 1997 PDA/FDA Joint Regulatory Conference

2004

Chair
Nikki Mehringer
Eli Lilly and Company

Chair-elect
Richard V. Levy, PhD
PAREXEL Consulting

Secretary
Stephanie R. Gray
Pharmaceutical Strategies

Treasurer
Georg Rössling, PhD
Schering AG

Immediate Past Chair
Floyd Benjamin
Keystone Pharmaceuticals

Jennie Allewell
Wyeth Research

Vincent R. Anicetti
Genentech

Robert Dana
Elkhorn Associates

Rebecca A. Devine, PhD
Regulatory Consultant

Kathleen S. Greene
Novartis Pharmaceuticals

Yoshito Hashimoto
Chiyada Corporation

Maik Jornitz
Sartorius Corporation

Suzanne Levesque
Sabex

Tim Marten, DPhil
AstraZeneca

John Shabushnig, PhD
Pfizer

Lisa M. Skeens, PhD
Baxter Healthcare Corporation

Anders Vinther, PhD
CMC Biopharmaceuticals

2005

Chair
Nikki Mehringer
Eli Lilly and Company

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Richard V. Levy, PhD
PAREXEL Consulting

Secretary
Stephanie R. Gray
Pharmaceutical Strategies

Treasurer
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Schering AG

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Floyd Benjamin
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Jennie Allewell
Wyeth Research

Vincent R. Anicetti
Genentech

Rebecca A. Devine, PhD
Regulatory Consultant

Kathleen S. Greene
Novartis Pharmaceuticals

Yoshito Hashimoto
Chiyada Corporation

Maik Jornitz
Sartorius Corporation

Tim Marten, DPhil
AstraZeneca

John Shabushnig, PhD
Pfizer

Eric Sheinin, PhD
United States Pharmacopeia

Lisa M. Skeens, PhD
Baxter Healthcare Corporation

Laura Thoma, PharmD
University of Tennessee

Anders Vinther, PhD
CMC Biopharmaceuticals

24. Board members attend the opening of the new Training and Research Institute facility in Bethesda, Md. in 2007

25. John Shabushnig (center left) networks between sessions

2006

Chair
Vincent Anicetti
Genentech

Chair-elect
John Shabushnig, PhD
Pfizer

Secretary
Lisa Skeens, PhD
Baxter Healthcare Corporation

Treasurer
Maik Jornitz
Sartorius Corporation

Immediate Past Chair
Nikki Mehringer
Eli Lilly and Company

Jennie Allewell
Wyeth Research

Stephen Bellis
IVAX Pharmaceuticals UK

Rebecca A. Devine, PhD
Regulatory Consultant

Kathleen S. Greene
Novartis Pharmaceuticals

Yoshito Hashimoto
Chiyada Corporation

Tim Marten, DPhil
AstraZeneca

Steven Mendivil
Amgen

Amy Scott-Billman
GlaxoSmithKline

Eric Sheinin, PhD
United States Pharmacopeia

Gail Sofer
GE Healthcare

Laura Thoma, PharmD
University of Tennessee

Anders Vinther, PhD
CMC Biopharmaceuticals

2007

Chair
Vincent Anicetti
Genentech

Chair-elect
John Shabushnig, PhD
Pfizer

Secretary
Lisa Skeens, PhD
Baxter Healthcare Corporation

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Maik Jornitz
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Eli Lilly and Company

Rebecca A. Devine, PhD
Regulatory Consultant

Kathleen S. Greene
Novartis Pharmaceuticals

Yoshito Hashimoto
Chiyada Corporation

Louise Johnson
Vertex Pharmaceuticals

Tim Marten, DPhil
AstraZeneca

Steven Mendivil
Amgen

Amy Scott-Billman
GlaxoSmithKline

Eric Sheinin, PhD
United States Pharmacopeia

Gail Sofer
GE Healthcare

Laura Thoma, PharmD
University of Tennessee

Martin Van Trieste
Amgen

Anders Vinther, PhD
CMC Biopharmaceuticals

26. Jennie Allewell at the networking reception at the 2007 PDA Annual Meeting in Las Vegas, Nev.

27. PDA President Bob Myers (left) and Board members Yoshito Hashimoto, Jennie Allewell, Vincent Anicetti, and Stephanie Gray

2008

Chair
John Shabushnig, PhD
Pfizer

Chair-elect
Maik Jornitz
Sartorius Stedim Biotech

Secretary
Rebecca Devine, PhD
Regulatory Consultant

Treasurer
Anders Vinther, PhD
Genentech

Immediate Past Chair
Vincent Anicetti
Genentech

Harold Baseman
Valsource

Véronique Davoust, PhD
Pfizer Inc

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Yoshito Hashimoto
Chiyada Corporation

Louise Johnson
Aptuit

Stefan Köhler
AstraZeneca

Steven Mendivil
Amgen

Michael Sadowski
Baxter Healthcare

Amy Scott-Billman
GlaxoSmithKline

Gail Sofer
GE Healthcare

Laura Thoma, PharmD
University of Tennessee

Martin Van Trieste
Amgen

2009

Chair
John Shabushnig, PhD
Pfizer

Chair-elect
Maik Jornitz
Sartorius Stedim Biotech

Secretary
Rebecca Devine, PhD
Regulatory Consultant

Treasurer
Anders Vinther, PhD
Genentech

Immediate Past Chair
Vincent Anicetti
Genentech

Harold Baseman
Valsource

Véronique Davoust, PhD
Pfizer

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Louise Johnson
Aptuit

Stefan Köhler
AstraZeneca

Steven Mendivil
Amgen

Michael Sadowski
Baxter Healthcare

Junko Sasaki
Dainippon Sumitomo Pharma

Amy Scott-Billman
GlaxoSmithKline

Christopher J. Smalley
Wyeth Pharmaceuticals

Laura Thoma, PharmD
University of Tennessee

Martin Van Trieste
Amgen

28. Maik Jornitz checks in on plans during construction of the Training and Research Institute facility in Bethesda, Md.

29. Anders Vinther discusses PDA's activities at the 2003 International Congress in Prague

2010

Chair
Maik Jornitz
Sartorius Stedim Biotech

Chair-elect
Anders Vinther, PhD
Genentech

Secretary
Rebecca Devine, PhD
Regulatory Consultant

Treasurer
Hal Baseman
ValSource

Immediate Past Chair
John Shabushnig, PhD
Pfizer

Véronique Davoust, PhD
Pfizer

Gabriele Gori
Novartis

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Zena G. Kaufman
Abbott Laboratories

Steven Mendivil
Amgen

Michael Sadowski
Baxter Healthcare

Junko Sasaki
Dainippan Sumitomo Pharma

Amy Scott-Billman
GlaxoSmithKline

Lisa Skeens, PhD
Baxter Healthcare

Christopher Smalley
Pfizer

Laura Thoma
PharmD, Univeristy of Tennessee

Martin VanTrieste
Amgen

2011

Chair
Maik Jornitz
Sartorius Stedim Biotech

Chair-elect
Anders Vinther, PhD
Genentech

Secretary
Rebecca Devine, PhD
Regulatory Consultant

Treasurer
Hal Baseman
ValSource

Immediate Past Chair
John Shabushnig, PhD
Pfizer

Jette Christensen
Novo Nordisk

Gabriele Gori
Novartis

Zena G. Kaufman
Abbott Laboratories

Steven Mendivil
Amgen

Michael Sadowski
Baxter Healthcare

Junko Sasaki
Dainippan Sumitomo Pharma

Sue Schniepp
OSO BioPharmaceuticals

Amy Scott-Billman
GlaxoSmithKline

Lisa Skeens, PhD
Baxter Healthcare

Christopher Smalley
Merck

Martin VanTrieste
Amgen

Glenn Wright
Eli Lilly and Company

30. Chris Smalley leads an Interest Group session

31. PDA leaders pose with keynote speakers Shelley Morrison (center left) and Linda Armstrong Kelly following the opening plenary session of the 2008 Annual Meeting in Colorado Springs

Advisory Boards

Immediately underneath the PDA Board of Directors are the PDA Advisory Boards. Members on the Advisory Boards must be approved by the Board of Directors. The three primary Advisory Boards are the Regulatory Affairs and Quality Advisory Board (RAQAB), the Science Advisory Board (SAB), and the Biotechnology Advisory Board (BioAB), and they sanction PDA Task Forces that develop technical reports, workshops, comments on regulations and guidances, and other PDA activities.

RAQC 1997–2011

1997

Jennie Allewell (Chair)
Cell Therapeutics, Inc.

Donald Baker, JD
Fujisawa Healthcare, Inc.

Ronald Branning
Centeon

Robert Dana
Bristol-Myers Squibb Co.

John DeFoe
Pfizer Inc.

Don Elinski
Geneva Pharmaceuticals, Inc.

Michael Gross, PhD
Becton Dickinson & Co.

Frederick Gustafson
Abbott Laboratories, Inc.

Hiltrud Horn, PhD
F. Hoffman-La Roche Ltd.

James Lyda
PDA

Nikki Mehringer
Eli Lilly and Company

Robert Mello, PhD
Chesapeake Biological Laboratories, Inc.

Steven Mendivil
Amgen, Inc.

Toshiaki Nishihata
Santen Pharmaceutical Co.

Swroop Sahota, PhD
GlaxoSmithKline

Lisa Skeens, PhD
Baxter Healthcare Corporation

Diane Zezza, PhD
Schering-Plough Corporation

1998

Jennie Allewell (Chair)
Cell Therapeutics, Inc.

Donald Baker, JD
Fujisawa Healthcare, Inc.

Ronald Branning
Centeon

Robert Dana
Bristol-Myers Squibb Co.

John DeFoe
Pfizer Inc.

Don Elinski
Geneva Pharmaceuticals, Inc.

Michael Gross, PhD
Becton Dickinson & Co.

Frederick Gustafson
Abbott Laboratories, Inc.

Hiltrud Horn, PhD
F. Hoffman-La Roche Ltd.

James Lyda
PDA

Russell Madsen
PDA

Nikki Mehringer
Eli Lilly and Company

Robert Mello, PhD
Chesapeake Biological Laboratories, Inc.

Steven Mendivil
Amgen, Inc.

Kathy Miracco
FDA

Toshiaki Nishihata
Santen Pharmaceutical Co.

Lisa Skeens, PhD
Baxter Healthcare Corporation

1999

Lisa Skeens, PhD (Chair)
Baxter Healthcare Corporation

Jennie Allewell
Cell Therapeutics, Inc.

Vince Anicetti
Genentech

Kristen Bacigalupi
Chiron Corp.

Donald Baker, JD
Fujisawa Healthcare, Inc.

Ronald Branning
Centeon

Robert Dana
Bristol-Myers Squibb Co.

John DeFoe
Pfizer Inc.

Don Elinski
Geneva Pharmaceuticals, Inc.

Michael Gross, PhD
Becton Dickinson & Co.

Frederick Gustafson
Abbott Laboratories, Inc.

Hiltrud Horn, PhD
F. Hoffman-La Roche Ltd.

James Lyda
PDA

Russell Madsen, Jr.
PDA

Nikki Mehringer
Eli Lilly and Company

Robert Mello, PhD
Chesapeake Biological Laboratories, Inc.

Steven Mendivil
Amgen, Inc.

Toshiaki Nishihata
Santen Pharmaceutical Co.

2000

Lisa Skeens, PhD (Chair)
Baxter Healthcare Corporation

Jennie Allewell
Cell Therapeutics, Inc.

Vince Anicetti
Genentech

Donald Baker, JD
Fujisawa Healthcare, Inc.

Robert Dana
Elkhorn Associates, Inc.

Rebecca Devine
Regulatory Consultant

John DeFoe
Pfizer Inc.

Don Elinski
Geneva Pharmaceuticals, Inc.

Michael Gross, PhD
Aventis Behring

Hiltrud Horn, PhD
Knoll AG

James Lyda
PDA

Russell Madsen
PDA

Tim Marten, DPhil
AstraZeneca

Nikki Mehringer
Eli Lilly and Company

Robert Mello, PhD
RJM Pharmaceutical Consultants

Steven Mendivil
Amgen, Inc.

Toshiaki Nishihata
Santen Pharmaceutical Co.

Amy Scott-Billman
GlaxoSmithKline

William Stoedter
PDA

Anders Vinther
CMC Biotech

2001

Lisa Skeens, PhD (Chair)
Baxter Healthcare Corp.

Jennie Allewell
Cell Therapeutics, Inc.

Vince Anicetti
Genentech, Inc.

Donald Baker, JD
Fujisawa Healthcare, Inc.

Robert Dana
Elkhorn Associates, Inc.

John DeFoe
Pfizer Inc.

Rebecca Devine
Regulatory Consultant

Don Elinski
Johnson & Johnson Merck

Michael Gross
Aventis Behring

Hiltrud Horn, PhD
Knoll AG

Suzanne Levesque
Sabex, Inc.

Russell Madsen
PDA

Tim Marten, DPhil
AstraZeneca

Nikki Mehringer
Eli Lilly and Company

Robert Mello, PhD
RJM Pharmaceutical Consultants

Steven Mendivil
Amgen, Inc.

David Miner
Eli Lilly and Company

Toshiaki Nishihata, PhD
Santen Pharmaceutical Co. Ltd.

Amy Scott-Billman
GlaxoSmithKline

William Stoedter
PDA

Anders Vinther
CMC Biotech A/S

2002

Suzanne Levesque (Chair)
Sabex, Inc.

Jennie Allewell
Cell Therapeutics, Inc.

Vince Anicetti
Genentech

Donald Baker, JD
Fujisawa Healthcare, Inc.

Robert Dana
Elkhorn Associates, Inc.

Rebecca Devine
Regulatory Consultant

Don Elinski
Johnson & Johnson Merck

Michael Gross, PhD
Aventis Behring

Hiltrud Horn, PhD
Cap Gemini Ernst and Young Deutschland GmbH

James Lyda
KMI, a division of PAREXEL International, LLC

Russell Madsen
PDA

Gautam Maitra
PDA

Tim Marten, PhD
AstraZeneca

Nikki Mehringer
Eli Lilly and Company

Robert Mello, PhD
PDA Training and Research Institute

Steven Mendivil
Amgen, Inc.

David Miner
Eli Lilly and Company

Toshiaki Nishihata
Santen Pharmaceutical Co.

Amy Scott-Billman
GlaxoSmithKline

Lisa Skeens, PhD
Baxter Healthcare Corporation

William Stoedter
PDA

Anders Vinther
CMC Biotech

32. (l-r) Glenn Wright, Lisa Skeens, Swroop Sahota, Nikki Mehringer, David Moyer, Robert Dana, Kristen Bacigalupi, Anders Vinther

33. RAQC circa 2000 (l-r): David Miner; Nikki Mehringer; William Stoedter; Vince Anicetti; Anders Vinther; Lisa Skeens; Michael Gross; Jennie Allewell; Robert Mello; Amy Scott-Billman; Robert Dana; Russell Madsen (Not Pictured: Kristen Bacilgalupi; Donald Baker; Rebecca Devine; John DeFoe; Don Elinski; Hiltrud Horn; James Lyda; Tim Marten; Steven Mendivil; Toshiaki Nishihata)

34. RAQC member Michael Gross (center) at a PDA conference

2003

Suzanne Levesque (Chair)
Sabex, Inc.

Jennie Allewell
Cell Therapeutics, Inc.

Vince Anicetti
Genentech

Donald Baker, JD
Fujisawa Healthcare, Inc.

Stephen Bellis
AstraZeneca

Robert Dana
Elkhorn Associates, Inc.

Rebecca Devine
Regulatory Consultant

Don Elinski
Johnson & Johnson Merck

Michael Gross, PhD
Aventis Behring

Hiltrud Horn, PhD
Cap Gemini Ernst and Young Deutschland GmbH

Richard Johnson
Abbott Laboratories

James Lyda
KMI, a division of PAREXEL International, LLC

Russell Madsen
PDA

Gautam Maitra
PDA

Steven Mendivil
Amgen, Inc.

David Miner
Eli Lilly and Company

Toshiaki Nishihata
Santen Pharmaceutical Co.

Amy Scott-Billman
GlaxoSmithKline

Lisa Skeens, PhD
Baxter Healthcare Corporation

Anders Vinther
CMC Biotech

2004

Amy Scott-Billman (Chair)
GlaxoSmithKline

Jennie Allewell
Wyeth Research

Stephen Bellis
IVAX Pharmaceuticals UK Ltd.

Robert Dana
Elkhorn Associates, Inc.

Victoria Dedrick
PDA

Rebecca Devine, PhD
Regulatory Consultant

Don Elinski
Eli Lilly and Company

Michael Gross
QLT, Inc.

Roland Guenther
Novartis Pharma AG

Hiltrud Horn
Horn Pharmaceutical Consulting

Richard Johnson
Abbott Laboratories

James Lyda
PAREXEL Consulting

Gautam Maitra
PDA

Steven Mendivil
Amgen, Inc.

Toshiaki Nishihata
Santen Pharmaceutical Co. Ltd.

David Miner
Eli Lilly and Company

Joyce Ramsbotham
Solvay Pharmaceuticals NL

George Robertson, PhD
PDA

Lisa Skeens
Baxter Healthcare Corporation

John Towns, PhD
Eli Lilly and Company

Filippo Trionfera
Bristol Myers Squibb SpA

Anders Vinther, PhD
CMC Biopharmaceuticals A/S

2005

Amy Scott-Billman (Chair)
GlaxoSmithKline

Jennie Allewell
Wyeth Research

Stephen Bellis
IVAX Pharmaceuticals UK Ltd.

Rebecca Devine, PhD
Regulatory Consultant

Don Elinski
Eli Lilly and Company

Roland Guenther
Novartis Pharma AG

Hiltrud Horn
Horn Pharmaceutical Consulting

Zena Kaufman
Abbott Laboratories

Lee Kirsch, PhD
University of Iowa

Brian Matthews, PhD
Alcon Laboratories Ltd.

Steven Mendivil
Amgen, Inc

Toshiaki Nishihata
Santen Pharmaceutical Co. Ltd

Joyce Ramsbotham
Solvay Pharmaceuticals

Stefano Salmieri
Farmabios, SPA

Lisa Skeens, PhD
Baxter Healthcare Corporation

John Towns, PhD
Eli Lilly and Company

Barbara Zinck
Cambrex Corporation

PDA Staff Liaisons

Robert Dana
VP, Quality & Regulatory Affairs

Richard Levy, PhD
Senior Vice President, Science and Regulatory Affairs

Robert Myers
PDA President

James Lyda
Acting Director, European Operations

2006

Zena Kaufman (Chair)
Abbott Laboratories

Stephen Bellis
CMC Biopharmaceuticals

Rebecca Devine, PhD
Regulatory Consultant

Don Elinski
Lachman Consultant Services, Inc.

Amy Giertych
Baxter Healthcare Corporation

Roland Guenther
Novartis Pharma. AG

Hiltrud Horn
Horn Pharmaceutical Consultants

Michihisa Inokuma, PhD
Denka Seiken

Louise Johnson
Vertex Pharmaceuticals Incorporated

Brian Matthews, PhD
Alcon Laboratories, Inc.

Steven Mendivil
Amgen

Dr.-Ing. Stephan Rönninger, PhD
F. Hoffmann-La Roche, Ltd.

Stefano Salmieri
Farmabios

Junko Sasaki
Sumitomo Pharmaceuticals Co., Ltd.

Amy Scott-Billman
GlaxoSmithKline

John Towns, PhD
Eli Lilly and Company

Barbara Zinck
Cambrex Bio Science

PDA Staff Liaisons

Robert Dana
Quality and Regulatory Affairs

James Lyda
Regulatory Affairs

2007

Zena Kaufman (Chair)
Abbott Laboratories

Steven Mendivil (Co-Chair)
Amgen, Inc.

Michihisa Inokuma, PhD
Denka Seiken Co. Ltd.

Stephen Bellis
CMC Biopharmaceuticals

Don Elinski
Lachman Consultant Services, Inc.

Amy Giertych
Baxter Healthcare Corporation

Karen Ginsbury
PCI Pharmaceutical Consulting Israel Ltd

Roland Guenther
Novartis Pharma AG

Louise Johnson
Aptuit

Brian Matthews, PhD
Alcon Laboratories, Ltd.

Dr.-Ing. Stephan Rönninger
F. Hoffmann-La Roche, Ltd.

Junko Sasaki
Sumitomo Pharmaceuticals Co., Ltd.

Susan Schniepp
Consultant

Janeen Skutnik
Pfizer Inc

John K. Towns, PhD
Eli Lilly and Company

Michael VanDerWerf
GlaxoSmithKline Biologicals

Barbara Zinck
Cambrex Bio Science

PDA Staff Liaisons

Robert Dana
Quality and Regulatory Affairs

2008

Steven Mendivil (Co-Chair)
Amgen, Inc.

Dr.-Ing. Stephan Rönninger (Co-Chair)
F. Hoffman-La Roche Ltd.

Amy Giertych
Baxter Healthcare Corporation

Karen Ginsbury
PCI Pharmaceutical Consulting Israel, Ltd.

Michihisa Inokuma, PhD
Towayakuhin

Louise Johnson
Aptuit

Zena Kaufman
Abbott Laboratories

Brian Matthews, PhD
Alcon Laboratories, Inc.

Junko Sasaki
Sumitomo Pharmaceuticals

Susan Schniepp
Consultant

Janeen Skutnik
Pfizer Inc

John Towns, PhD
Eli Lilly and Company

Michael VanDerWerf
GlaxoSmithKline Biologicals

Barbara Zinck
Zinck Consulting

PDA Staff Liaisons

Robert Dana
Quality and Regulatory Affairs

James Lyda
PDA Europe

35. (l-r) Steve Mendivil, Amy Giertych, Amy Scott-Billman, Bob Dana, Zena Kaufman, John Towns and Barbara Zink at PDA HQ

36. Stephan Rönninger (left) and Steve Mendivil (right) with regulator Tor Gråberg at the 2009 Annual Meeting

2009

Steven Mendivil (Co-Chair)
Amgen, Inc.

Dr.-Ing. Stephan Rönninger (Co-Chair)
F. Hoffmann-La Roche Ltd.

Ruhi Ahmed, PhD
BioMarin Pharmaceuticals, Inc.

Jeffrey Broadfoot
Cangene Corporation

Allan Burns
Sartorius Stedim Biotech

Robert Caunce
Hospira

Don Elinski
Lachman Consultant Services, Inc.

John Finkbohner, PhD
MedImmune

Amy Giertych
Baxter Healthcare Corporation

Karen Ginsbury
PCI Pharmaceutical Consulting Israel Ltd.

Michihisa Inokuma, PhD
Towayakuhin

Louise Johnson
Aptuit

Brian Matthews, PhD
Alcon Laboratories,(UK), Ltd.

Junko Sasaki
Dainippon Sumitomo Pharma

Siegfreid Schmitt, PhD
PAREXEL Consulting

Susan Schniepp
Antisoma

Janeen Skutnik
Pfizer Inc.

John Towns, PhD
Eli Lilly and Company

Michael VanDerWerf
GlaxoSmithKline Biologicals

Hongyan Xie
Qilu Pharmaceuticals Co., Ltd.

Barbara Zinck
Zinck Consulting

PDA Staff Liaisons

Robert Dana
Quality and Regulatory Affairs

James Lyda
Regulatory Affairs

2010

Dr. –Ing. Stephan Rönninger (Co-Chair)
F. Hoffmann-La Roche, Ltd.

Susan Schniepp (Co-Chair)
OSO Biopharmaceutical Manufacturing LLC

Ruhi Ahmed, PhD
Biomarin Pharmaceuticals, Inc.

Jeffery Broadfoot
Cangene Corporation

Alan Burns
Sartorius Stedim Biotech

Robert Caunce
Hospira

Don Elinski
Lachman Consultant Services, Inc.

John Finkbohner, PhD
Medimmune

Amy Giertych
Baxter Healthcare Corporation

Karen Ginsbury
PCI Pharmaceutical ConsultinG Israel Ltd.

Louise Johnson
Takeda Pharmaceuticals International, Inc.

Barbara Jentges
PhACT GmBH

Louise Johnson
Takeda Pharmaceuticals International, Inc.

Brian Matthews, PhD

Steven Mendivil
Amgen, Inc.

Shin-ichiro Mohri
Kyowa Hakko Kirin Co., Ltd.

Junko Sasaki
Dainippon Sumitomo Pharma

Siegfried Schmitt, PhD
PAREXEL Consulting

Janeen Skutnik
Pfizer

Michael VanDerWerf
GlaxoSmithKline Biologicals

Jacqueline Veivia-Panter
Abbott Laboratories

Hongyan Xie
Qilu Pharmaceuticals Co., Ltd.

Barbara Zinck
Zinck Consulting

PDA Staff Liaisons

Robert Dana
Regulatory Affairs and PDA TRI

James Lyda
Scientific & Regulatory Affairs

Iris Rice
Scientific & Regulatory Affairs

2011

Dr. –Ing. Stephan Rönninger (Co-Chair)
F. Hoffmann-La Roche, Ltd.

Susan Schniepp (Co-Chair)
OSO Biopharmaceutical Manufacturing LLC

Ruhi Ahmed, PhD
Biomarin Pharmaceuticals, Inc.

Jeffery Broadfoot
Cangene Corporation

Alan Burns
Sartorius Stedim Biotech

Robert Caunce
Hospira

Don Elinski
Lachman Consultant Services, Inc.

John Finkbohner, PhD
Medimmune

Amy Giertych
Baxter Healthcare Corporation

Karen Ginsbury
PCI Pharmaceutical Consulting Israel Ltd.

Barbara Jentges
PhACT GmBH

Louise Johnson
Takeda Pharmaceuticals International, Inc.

Steven Mendivil
Amgen, Inc.

Shin-ichiro Mohri
Kyowa Hakko Kirin Co., Ltd.

Junko Sasaki
Dainippon Sumitomo Pharma

Siegfried Schmitt, PhD
PAREXEL Consulting

Michael VanDerWerf
GlaxoSmithKline Biologicals

Jacqueline Veivia-Panter
Abbott Laboratories, Inc.

Hongyan Xie
Qilu Pharmaceuticals Co., Ltd.

Barbara Zinck
Zinck Consulting

PDA Staff Liaisons

Robert Dana
Regulatory Affairs and PDA TRI

James Lyda
Scientific & Regulatory Affairs

Iris Rice
Scientific & Regulatory Affairs

SAB 1997–2011

1997-2000

James Akers, PhD (Chair)
Akers Kennedy & Associates

James Agalloco
Agalloco & Associates

Joyce Aydlett
Catalytica Pharmaceuticals, Inc.

R. Michael Enzinger, PhD
Pharmacia and Upjohn, Inc.

Edmund Fry
PDA

Klaus Haberer
Hoechst Marion Roussel

Kunio Kawaura, PhD
Otsuka Pharmaceutical Company, Ltd.

Bengt Ljungqvist, PhD
Royal Institute of Technology

Russel Madsen
PDA

Robert Morrissey, PhD
Johnson & Johnson

Raymond Shaw, Jr., PhD
Wyeth-Ayers Labs., Inc.

2001

James Agalloco (Chair)
Agalloco & Associates

Michael Akers
Cook Pharmaceutical Solutions

Frank Bing
Abbott Laboratories

Roger Dabbah
U.S. Pharmacopeia Convention

Don Elinksi
Eli Lilly and Company

Nigel Halls
Glaxo Wellcome

Karl Hoffmann
Bristol-Myers Squibb Co.

Pedro Jimenez
Eli Lilly and Company

Richard Johnson
Abbott Laboratories Inc.

Kunio Kawamura
Otsuka Pharmaceutical Company Ltd.

Carol Lampe
Baxter Healthcare Corporation

Richard Levy
Millipore Corporation

Russell Madsen
PDA

Jean Olsen
GlaxoSmithKline

Georg Rössling
Schering AG

John Shabushnig
Pharmacia Corporation

Gail Sofer
BioReliance Corporation

37. RAQC members at the 2009 Annual Meeting

38. RAQC member Janeen Skutnik speaks at a PDA meeting

39. RAQC member Susan Schniepp has chaired or co-chaired the PDA/FDA Joint Regulatory Conference Planning Committee five times and served on the committee since 2002

40. James Fernandez (left) co-chaired the SAB 2003-2004

41. SAB's Bengt Ljungqvist (right) and long-time collaborator Berit Rienmuller; both were honored in 2006 as Outstanding PDA Scientists

2002

James Agalloco (Co-Chair)
Agalloco & Associates

James Fernandez (Co-Chair)
Fernandez and Associates

Michael Akers, PhD
Baxter Pharmaceutical Solutions, LLC

Frank Bing
Abbott Laboratories, Inc.

Roger Dabbah, PhD
U.S. Pharmacopeia Convention

Volker Eck, PhD
Pfizer Inc. & Italia S.p.A.

Jens Eilertsen, PhD
Novo Nordisk A/S

Don Elinski
Eli Lilly and Company

Gordon Farquharson
Bovis Lend Lease Pharmaceutical

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Karl Hofmann
Bristol-Myers Squibb Co.

David Hussong, PhD
U.S. Food and Drug Administration

Richard Johnson
Abbott Laboratories, Inc.

Kunio Kawamura, PhD
Otsuka Pharmaceutical Company, Ltd.

Carol Lampe
Baxter Healthcare Corporation

Russell Madsen
PDA

Gautam Maitra
PDA

Robert Mello, PhD
PDA Training and Research Institute

Jeanne Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

Jean Olsen
GlaxoSmithKline

Georg Rössling, PhD
Schering AG

John Shabushnig, PhD
Pfizer Inc.

Gail Sofer
BioReliance Corporation

William Stoedter, RAC
PDA

Ignacio Tintore, PhD
Tiselab SL

Lynn Torbeck
Torbeck and Associates, Inc.

Glenn Wright
Eli Lilly and Company

2003

James Agalloco (Co-Chair)
Agalloco & Associates

James Fernandez (Co-Chair)
Fernandez and Associates

Roger Dabbah, PhD
U.S. Pharmacopeia Convention

Volker Eck, PhD
Pfizer Inc. & Italia S.p.A.

Jens Eilertsen, PhD
Novo Nordisk A/S

Don Elinski
Eli Lilly and Company

Gordon Farquharson
Bovis Lend Lease Pharmaceutical

William Frieben, PhD
Pfizer Inc.

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Karl Hofmann
Bristol-Myers Squibb Co.

David Hussong, PhD
U.S. Food and Drug Administration

Richard Johnson
Abbott Laboratories, Inc.

Kunio Kawamura, PhD
Otsuka Pharmaceutical Company, Ltd.

Lee Kirsch, PhD
University of Iowa

Carol Lampe
Baxter Healthcare Corporation

Russell Madsen
PDA

Gautam Maitra
PDA

Robert Mello, PhD
PDA Training and Research Institute

Jeanne Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

Jean Olsen
GlaxoSmithKline

Georg Rössling, PhD
Schering AG

John Shabushnig, PhD
Pfizer Inc.

Gail Sofer
BioReliance Corporation

William Stoedter, RAC
PDA

Ignacio Tintore, PhD
Tiselab SL

Lynn Torbeck
Torbeck and Associates, Inc.

Glenn Wright
Eli Lilly and Company

2004

James Fernandez (Co-Chair)
Fernandez and Associates

Martin Van Trieste (Co-Chair)
Bayer HealthCare

Michael Akers, PhD
Baxter Pharmaceutical Solutions LLC

Frank Bing
Consultant

Roger Dabbah, PhD
U.S. Pharmacopeia Convention

Volker Eck, PhD
Pfizer Inc. & Italia S.p.A.

Jens Eilertsen, PhD
Novo Nordisk A/S

Don Elinski
Eli Lilly and Company

Gordon Farquharson
Bovis Lend Lease Pharmaceutical

William Frieben, PhD
Pfizer Inc.

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Karl Hofmann
Bristol-Myers Squibb Co.

David Hussong, PhD
U.S. Food and Drug Administration

Richard Johnson
Abbott Laboratories, Inc.

Kunio Kawamura, PhD
Otsuka Pharmaceutical Company, Ltd.

Lee Kirsch, PhD
University of Iowa

Carol Lampe
Baxter Healthcare Corporation

Gautam Maitra
PDA

Jeanne Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

Jean Olsen
GlaxoSmithKline

Georg Rössling, PhD
Schering AG

John Shabushnig, PhD
Pfizer Inc.

Gail Sofer
BioReliance Corporation

Lynn Torbeck
Torbeck and Associates, Inc.

Glenn Wright
Eli Lilly and Company

2005

Richard Johnson (Co-Chair)
Abbott Laboratories

Martin Van Trieste (Co-Chair)
Amgen

Michael Akers, PhD
Baxter Pharmaceutical Solutions LLC

Harold Baseman
Valsource, LLP

Roger Dabbah, PhD
U.S. Pharmacopeia Convention

Volker Eck, PhD
Pfizer Inc. & Italia S.p.A.

Jens Eilertsen, PhD
Novo Nordisk A/S

Don Elinski
Eli Lilly and Company

Gordon Farquharson
Bovis Lend Lease Pharmaceutical

Klaus Haberer, PhD
Compliance Advice and Services in Microbiology, GmbH

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Karl Hofmann
Bristol-Myers Squibb Co.

Jeanne Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

John Shabushnig, PhD
Pfizer Inc.

Gail Sofer
BioReliance Corporation

Lynn Torbeck
Torbeck and Associates, Inc.

Brenda Uratani, PhD
U.S. Food and Drug Administration

PDA Staff Liaisons

Richard Levy, PhD
Scientific and Regulatory Affairs

Robert Dana
Regulatory Affairs

2006

Martin Van Trieste (Chair)
Amgen

Michael Akers, PhD
Baxter Pharmaceutical Solutions LLC

Harold Baseman
Valsource, LLP

Roger Dabbah, PhD
U.S. Pharmacopeia Convention

Jens Eilersen, PhD
Novo Nordisk A/S

Don Elinski
Lachman Consultant Services, Inc.

Gordon Farquharson
Bovis Lend Lease Pharmaceutical

Klaus Haberer, PhD
Compliance Advice and Services in Microbiology, GmbH

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Karl Hofmann
Bristol-Myers Squibb Co.

Jeanne Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

John Shabushnig, PhD
Pfizer Inc.

Gail Sofer
BioReliance Corporation

Lynn Torbeck
Torbeck and Associates, Inc.

Brenda Uratani, PhD
U.S. Food and Drug Administration

PDA Staff Liaisons

Richard Levy, PhD
Scientific and Regulatory Affairs

Robert Dana
Regulatory Affairs

Volker Eck, PhD
Science and Technology

42. SAB member Robert Mello (standing, far right) also served on the Board of Directors and worked as PDA's Director of TRI

43. Lee Kirsch (right) served on SAB and as the Editor of the *PDA Journal of Pharmaceutical Science and Technology*

2007

Richard Johnson (Co-Chair)
Fort Dodge Animal Health

Martin VanTrieste (Co-Chair)
Amgen

Michael Akers, PhD
Baxter Pharmaceutical Solutions LLC

Harold Baseman
Valsource, LLP

Roger Dabbah, PhD
U.S. Pharmacopeia Convention

Jens Eilersen, PhD
Novo Nordisk A/S

Don Elinski
Lachman Consultant Services, Inc.

Gordon Farquharson
Bovis Lend Lease Pharmaceutical

Kristen Evans
Amgen, Inc.

Klaus Haberer, PhD
Compliance Advice and Services in Microbiology, GmbH

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Karl Hofmann
Bristol-Myers Squibb Co.

Lisa Hornback
Hornback Consulting

Michael Long
AstraZeneca

Russell Madsen
The Williamsburg Group, LLC

Jeanne Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

Ken Muhvich, PhD
Micro-Reliance

John Shabushnig, PhD
Pfizer Inc

Christopher Smalley, PhD
Wyeth Pharmaceuticals

Lynn Torbeck
Torbeck and Associates, Inc.

Brenda Uratani, PhD
U.S. Food and Drug Administration

PDA Staff Liaisons

Richard Levy, PhD
Scientific and Regulatory Affairs

Robert Dana
Regulatory Affairs

Volker Eck, PhD
Science and Technology

2008

Harold Baseman (Co-Chair)
Valsource, LLP

Jens Eilersen, PhD (Co-Chair)
Novo Nordisk A/S

Roger Dabbah, PhD

Don Elinski
Lachman Consultant Services, Inc.

Kristen Evans
Amgen, Inc.

Klaus Haberer, PhD
Compliance Advice and Services in Microbiology, GmbH

Lothar Hartmann, PhD
F. Hoffmann-La Roche Ltd.

Karl Hofmann
Hiland Pharmacon, LLC

Lisa Hornback
Hornback Consulting

Richard Johnson
RMJ Consulting

Michael Long
KPM International Associates

Russell Madsen
The Williamsburg Group, LLC

Jeanne Moldenhauer, PhD
Excellent Pharma Consulting Consultants, Inc.

Ken Muhvich, PhD
Micro-Reliance

John Shabushnig, PhD
Pfizer Inc

Christopher Smalley, PhD
Wyeth Pharmaceuticals

Lynn Torbeck
Torbeck and Associates, Inc.

Brenda Uratani, PhD
U.S. Food and Drug Administration

PDA Staff Liaisons

Richard Levy, PhD
Scientific and Regulatory Affairs

Robert Dana
Regulatory Affairs

Volker Eck, PhD
Science and Technology

Iris Rice
Scientific and Regulatory Affairs

2009

Richard Johnson (Co-Chair)
Fort Dodge Animal Health

Martin VanTrieste (Co-Chair)
Amgen

Harold Baseman
Valsource, LLP

Roger Dabbah, PhD
U.S. Pharmacopeia Convention

Jens Eilersen, PhD
Novo Nordisk A/S

Don Elinski
Lachman Consultant Services, Inc.

Kristen Evans
Amgen, Inc.

Klaus Haberer, PhD
Compliance Advice and Services in Microbiology, GmbH

Lothar Hartmann, PhD
F. Hoffmann-La Roche

Karl Hofmann
Bristol-Myers Squibb Co.

Lisa Hornback
Hornback Consulting

Michael Long
AstraZeneca

Russell Madsen
The Williamsburg Group, LLC

Jeanne Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

Ken Muhvich, PhD
Micro-Reliance

John Shabushnig, PhD
Pfizer Inc

Christopher Smalley, PhD
Wyeth Pharmaceuticals

Lynn Torbeck
Torbeck and Associates, Inc.

Brenda Uratani, PhD
U.S. Food and Drug Administration

PDA Staff Liaisons

Richard Levy, PhD
Scientific and Regulatory Affairs

Robert Dana
Regulatory Affairs

Volker Eck, PhD
Science and Technology

2010

Harold Baseman (Co-Chair)
Valsource, LLP

Jens Eilersen, PhD (Co-Chair)
Novo Nordisk A/S

Raphael Bar, PhD
BR Consulting

Joyce Bloomfield
Merck Sharp & Dohme Corporation

Jean-Luc Clavelin
Lilly France S.A.S.

Roger Dabbah, PhD

Don Elinski
Lachman Consultant Services, Inc.

Kristen Evans
Amgen, Inc.

Klaus Haberer, PhD
Compliance Advice and Services in Microbiology, GmbH

Lothar Hartmann, PhD
F. Hoffmann-La Roche Ltd.

Karl Hofmann
Hiland Pharmacon, LLC

Lisa Hornback
Hornback Consulting

Stefan Köhler
AstraZeneca

Michael Long
KPM International Associates

Russell Madsen
The Williamsburg Group, LLC

Jeanne Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

Ken Muhvich, PhD
Micro-Reliance

John Shabushnig, PhD
Pfizer Inc

Christopher Smalley, PhD
Wyeth Pharmaceuticals

Lynn Torbeck
Torbeck and Associates, Inc.

Brenda Uratani, PhD
U.S. Food and Drug Administration

2011

Harold Baseman (Co-Chair)
Valsource, LLP

Jens Eilersen, PhD (Co-Chair)
Novo Nordisk A/S

Raphael Bar, PhD
BR Consulting

Joyce Bloomfield
Merck Sharp & Dohme Corporation

Jean-Luc Clavelin
Lilly France S.A.S.

Phil DeSantis
Merck & Company, Inc.

Don Elinski
Lachman Consultant Services, Inc.

Kristen Evans
Amgen, Inc.

Tor Gråberg
Medical Products Agency

Klaus Haberer, PhD
Compliance Advice and Services in Microbiology, GmbH

Maik Jornitz
Sartorius Stedim Biotech

Joachim Leube, PhD
Crucell Holland B.V.

Michael Long
AstraZeneca

Russell Madsen
The Williamsburg Group, LLC

Walter De Matteo
Institut Biochimique SA

Grace McNally
U.S. Food and Drug Administration

Jeanne Moldenhauer, PhD
Vectech Pharmaceutical Consultants, Inc.

Ken Muhvich, PhD
Micro-Reliance

John Shabushnig, PhD
Pfizer Inc

Christopher Smalley, PhD
Wyeth Pharmaceuticals

Brenda Uratani, PhD
U.S. Food and Drug Administration

Glenn Wright
Eli Lilly and Company

44. Martin Van Trieste (right) co-chaired SAB from 2004-2009 and has served on the Board of Directors since 2007; here with fellow SAB member Georg Rössling

45. SAB members Joyce Bloomfeld and Kris Evans both worked for the U.S. FDA

46. David Hussong (right) represented FDA on the SAB

47. SAB meets at a PDA Annual Meeting

48. Ken Muhvich (left) served on SAB following his career at FDA

49. Jeanne Moldenhauer serves on the SAB, planning committees and task forces; she speaks at meetings and writes books, as well


50

BioAB 2005–2011

2005

John Geigert, PhD (Co-Chair)
BioPharmaceutical Quality Solutions

Gail Sofer (Co-Chair)
GE Healthcare

Kurt Brorson, PhD
U.S. Food and Drug Administration

Christopher Bussineau, PhD
Cambrex Bio Science

Norbert Hentschel
Boehringer Ingelheim Pharma

James Kenimer, PhD
Biologics Consulting Group

Peter Levy
Altus Pharmaceuticals

Annemarie Moëritz, PhD
Novartis Pharma AG

Barbara Potts, PhD
Genentech, Inc.

Anurag Rathore, PhD
Amgen, Inc.

Amy Scott-Billman
GlaxoSmithKline

Robert Seely, PhD
RMC Pharmaceutical Solutions

RAQC Liaison

Rebecca Devine, PhD
Regulatory Consultant

PDA Staff Liaisons

Richard Levy, PhD
Scientific and Regulatory Affairs

Robert Dana
Regulatory Affairs

James Lyda
Europe Operations

2006

John Geigert, PhD (Co-Chair)
BioPharmaceutical Quality Solutions

Gail Sofer (Co-Chair)
GE Healthcare

Kurt Brorson, PhD
U.S. Food and Drug Administration

Christopher Bussineau, PhD
Cambrex Bio Science

Norbert Hentschel
Boehringer Ingelheim Pharma

James Kenimer, PhD
Biologics Consulting Group

Peter Levy
Altus Pharmaceuticals

Annemarie Moëritz, PhD
Novartis Pharma AG

Barbara Potts, PhD
Genentech, Inc.

Anurag Rathore, PhD
Amgen, Inc.

Amy Scott-Billman
GlaxoSmithKline

Robert Seely, PhD
RMC Pharmaceutical Solutions

RAQC Liaison

Rebecca Devine, PhD
Regulatory Consultant

PDA Staff Liaisons

Richard Levy, PhD
Scientific and Regulatory Affairs

James Lyda
Europe Operations


51

2007

Norbert Hentschel (Co-Chair)
Boehringer Ingelheim Pharma

Gail Sofer (Co-Chair)
GE Healthcare

S. Robert Adamson
Wyeth Biopharma

Jeffrey Baker, PhD
Eli Lilly and Company

Kurt Brorson, PhD
U.S. Food and Drug Administration

Christopher Bussineau, PhD
Cambrex Bio Science

Anita Derks
F. Hoffman-La Roche Ltd.

Rebecca Devine, PhD
Regulatory Consultant

John Geigert, PhD
Biopharmaceutical Quality Solutions

Brian Kelley
Genentech, Inc.

James Kenimer, PhD
Biologics Consulting Group

Peter Levy
Altus Pharmaceuticals

Annemarie Moëritz, PhD
Novartis Pharma AG

Barbara Potts, PhD
Genentech, Inc.

Anurag Rathore, PhD
Amgen, Inc.

Amy Scott-Billman
GlaxoSmithKline

Robert Seely, PhD
RMC Pharmaceutical Solutions

Robert Sitrin, PhD
Merck Research Labs

PDA Staff Liaisons

Richard Levy, PhD
Scientific and Regulatory Affairs

James Lyda
Regulatory Affairs, PDA Europe

2008

Jeffrey Baker, PhD (Co-Chair)
Eli Lilly and Company

Norbert Hentschel (Co-Chair)
Boehringer Ingelheim Pharma

S. Robert Adamson
Wyeth Biopharma

Kurt Brorson, PhD
U.S. Food and Drug Administration

Christopher Bussineau, PhD
Cambrex Bio Science

Anita Derks
F. Hoffman-La Roche Ltd.

Rebecca Devine, PhD
Regulatory Consultant

John Geigert, PhD
Biopharmaceutical Quality Solutions

Brian Kelley
Genentech, Inc.

James Kenimer, PhD
Biologics Consulting Group

Peter Levy
Altus Pharmaceuticals

Rohin Mhatre, PhD
Biogen Idec

Annemarie Moëritz, PhD
Novartis Pharma AG

Jill Myers, PhD
BioPro Consulting, Inc.

Barbara Potts, PhD
Genentech, Inc.

Anurag Rathore, PhD
Amgen, Inc.

Amy Scott-Billman
GlaxoSmithKline

Karin Sewerin
Pharm.D., NDA Regulatory Service AB

Robert Sitrin, PhD
Merck Research Labs

Gail Sofer
SofeWare Associates

Søren Thuesen Pedersen
Novo Nordisk A/S

Hannelore Willkommen, PhD
RBS Consulting

2009

Jeffrey Baker, PhD (Co-Chair)
Eli Lilly and Company

Norbert Hentschel (Co-Chair)
Boehringer Ingelheim Pharma

Michael Vanderwerf (Co-Chair)
GlaxoSmithKline Biologicals

S. Robert Adamson
Wyeth Biopharma

Kurt Brorson, PhD
U.S. Food and Drug Administration

Christopher Bussineau, PhD
Cambrex Bio Science

Anita Derks
F. Hoffman-La Roche Ltd.

Rebecca Devine, PhD
Regulatory Consultant

John Geigert, PhD
Biopharmaceutical Quality Solutions

Brian Kelley
Genentech, Inc.

James Kenimer, PhD
Biologics Consulting Group

Peter Levy
Altus Pharmaceuticals

Rohin Mhatre, PhD
Biogen Idec

Annemarie Moëritz, PhD
Novartis Pharma AG

Jill Myers, PhD
BioPro Consulting, Inc.

Barbara Potts, PhD
Genentech, Inc.

Anurag Rathore, PhD
Amgen, Inc.

Amy Scott-Billman
GlaxoSmithKline

Karin Sewerin, PharmD
NDA Regulatory Service AB

Robert Sitrin, PhD
Merck Research Labs

Gail Sofer
SofeWare Associates

Søren Thuesen Pedersen
Novo Nordisk A/S

Hannelore Willkommen, PhD
RBS Consulting

2010

Jeffrey Baker, PhD (Co-Chair)
Eli Lilly and Company

Norbert Hentschel (Co-Chair)
Boehringer Ingelheim Pharma

Michael Vanderwerf (Co-Chair)
GlaxoSmithKline Biologicals

S. Robert Adamson
Wyeth Biopharma

Kurt Brorson, PhD
U.S. Food and Drug Administration

Christopher Bussineau, PhD
Cambrex Bio Science

Anita Derks
F. Hoffman-La Roche Ltd.

Rebecca Devine, PhD
Regulatory Consultant

John Geigert, PhD
Biopharmaceutical Quality Solutions

Brian Kelley
Genentech, Inc.

James Kenimer, PhD
Biologics Consulting Group

Peter Levy
Altus Pharmaceuticals

Rohin Mhatre, PhD
Biogen Idec

Annemarie Moëritz, PhD
Novartis Pharma AG

Jill Myers, PhD
BioPro Consulting, Inc.

Søren Thuesen Pedersen
Novo Nordisk A/S

Barbara Potts, PhD
Genentech, Inc.

Anurag Rathore, PhD
Amgen, Inc.

Amy Scott-Billman
GlaxoSmithKline

Karin Sewerin, PharmD
NDA Regulatory Service AB

Robert Sitrin, PhD
Merck Research Labs

Gail Sofer
SofeWare Associates

Hannelore Willkommen, PhD
RBS Consulting

50. Past Board Member and PDA Chair, James Akers (left) helped found the SAB; here he poses with Rich Levy and Teri T. C. Soli at the PDA Pharmaceutical Microbiology Conference in 2009

51. John Geigert (second from left) has served on the BioAB since its inception and served as its co-chair in 2005 and 2006

52. Jeffrey Baker co-chaired BioAB in 2009 and 2010

53. BioAB's *Technical Report No. 41: Virus Filtration*

2011

E. J. Brandreth (Co-Chair)
Althea Technologies

Barbara Potts, PhD (Co-Chair)
Potts and Nelson Consultants, LLC

Vince Anicetti
Genentech, Inc.

Jeffrey Baker, PhD
U.S. Food and Drug Administration

Stephen Brown, PhD
Vivalis

Christopher Bussineau, PhD
One Lambda, Inc.

Michael Defelippis, PhD
Eli Lilly and Company

Rebecca Devine, PhD
Regulatory Consultant

Earl Dye, PhD
Genentech, Inc.

Frank Hallinan, PhD
Pfizer

Norbert Hentschel
Boehringer Ingelheim Pharma

Kathryn King, PhD
U.S. Food and Drug Administration

Peter Levy
Principal, Technical Operations

Annemarie Möritz, PhD
Novartis Pharma, AG, Werk, Klybeck

Søren Thuesen Pedersen
Novo Nordisk A/S

Anurag Rathore, PhD
Indian Institute of Technology, Delhi

Robert Sitrin, PhD
Merck & Company, Inc.

Gail Sofer
SofeWare Associates

Rodney Thompson, PhD
BioPharm Process Associates

Michael VanDerWerf
GlaxoSmithKline Biolsogicals

Michael Wiebe, PhD
Quantum Consulting, LLC

Hannelore Willkommen, PhD
RBS Consulting

Wendy Zwolenski-Lambert
Abbott Laboratories

54. 2011 BioAB Co-Chair Barbara Potts

55. BioAB member Frank Hallinan

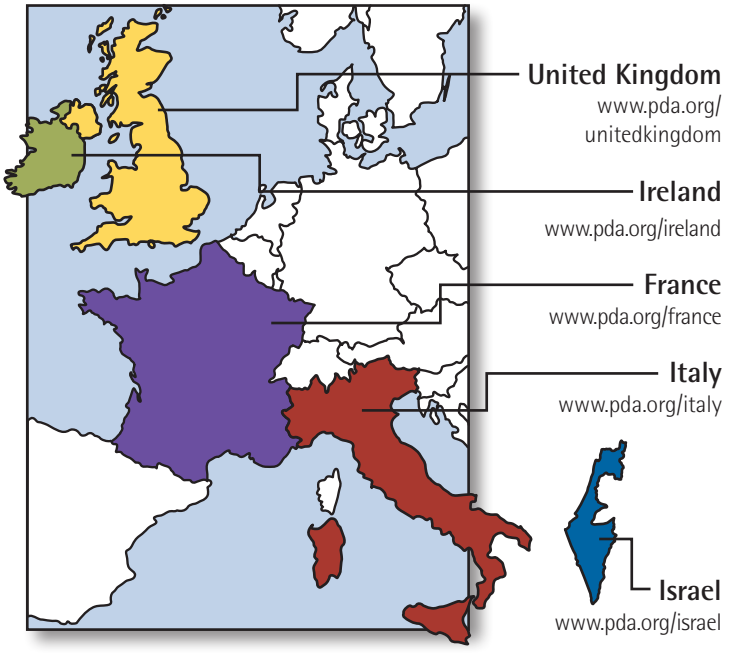
56. BioAB work session at a PDA conference

57. BioAB member Anurag Rathore also serves as an Associate Editor for the *PDA Journal of Pharmaceutical Science and Technology*

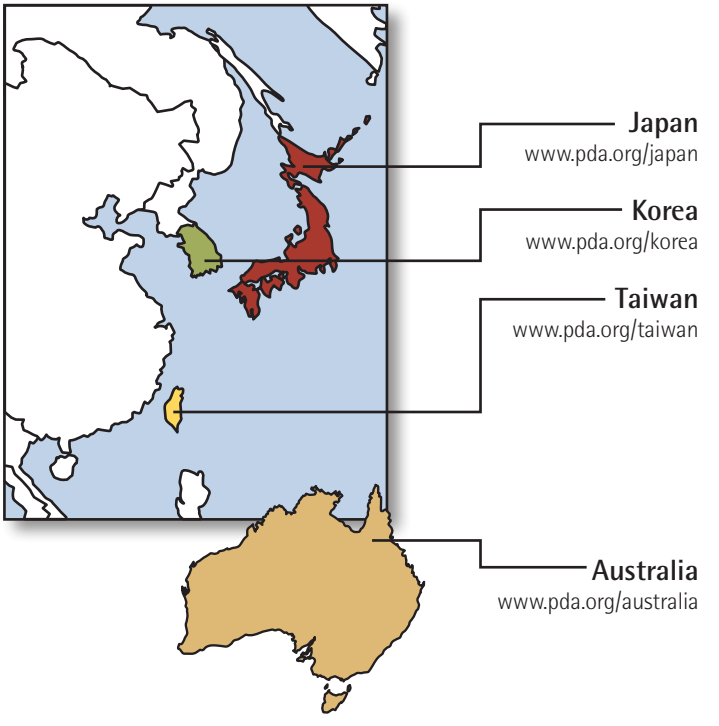
Chapters

Another layer of PDA leadership resides at the grassroots level in the Chapter organizations. Regional PDA Chapters provide unique services to their constituents, including translations of PDA publications, networking social events, student scholarship and annual regulatory and technical conferences. Each Chapter is managed by volunteer leaders.

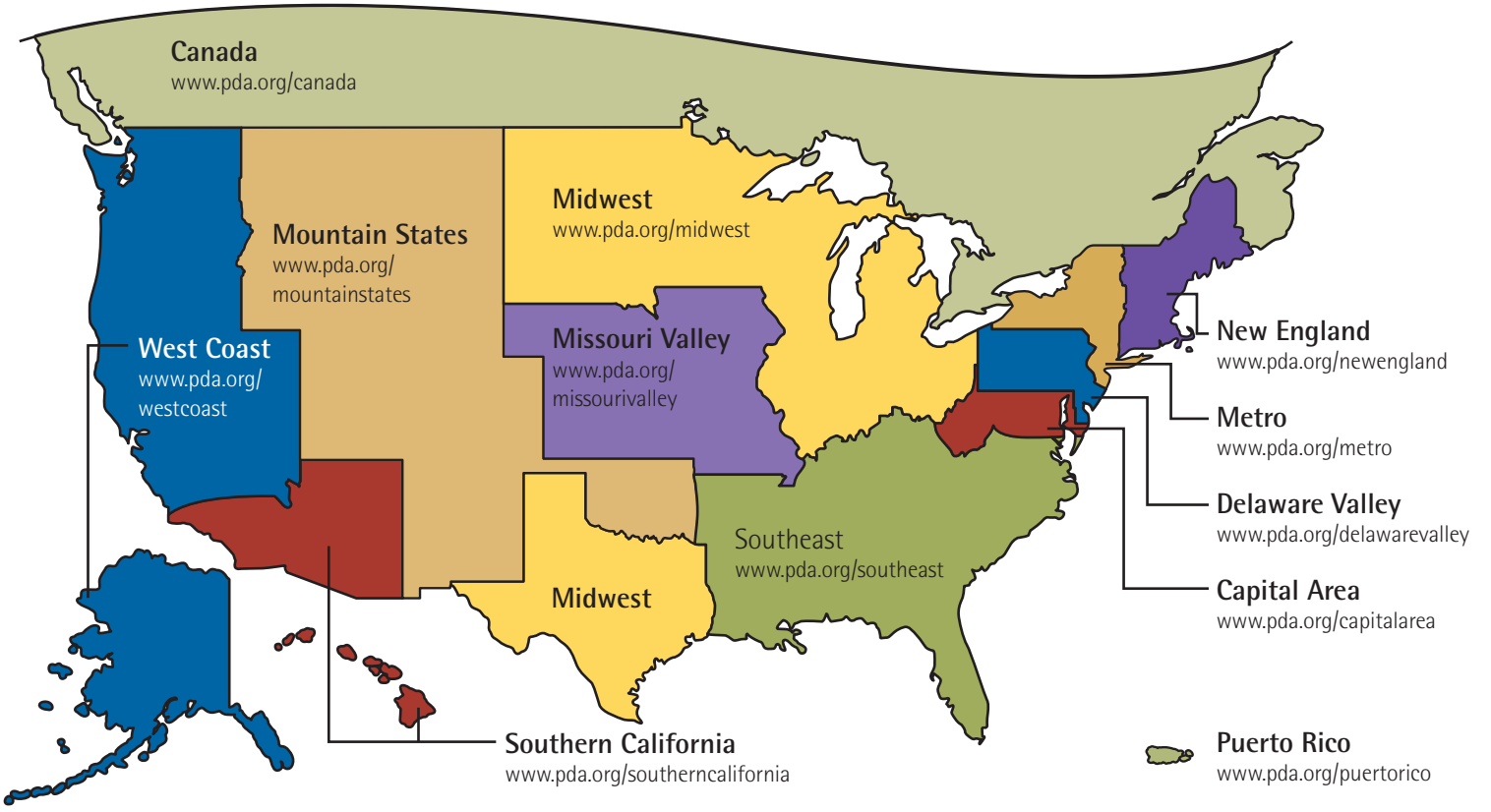
EUROPE



ASIA-PACIFIC



NORTH AMERICA



Asia-Pacific

Australia

Year	President	President-Elect	Vice-President	Secretary	Treasurer	Chapter Liaison
1997	Anthony Rowland					
1998	Mary Sontrop		Helen Efthimiou	Ken Dibble	Anthony Rowland	Norm Cheale
1999	Mary Sontrop		Helen Efthimiou	Ken Dibble	Anthony Rowland	Norm Cheale
2000	Mary Sontrop		Helen Efthimiou	Ken Dibble	Anthony Rowland	Norm Cheale
2001	Robert Sullivan		Ken Dibble	Bryan Martin	Anthony Rowland	Mary Sontrop
2002	Robert Sullivan		Ken Dibble	Bryan Martin	Anthony Rowland	
2003	Ken Dibble					
2004	Ken Dibble					
2005	Greg Jordan					
2006	Anna Corke	Vincent Chung		Malcolm Tipping	Caspar Graham	
2007	Anna Corke	Vincent Chung		Malcolm Tipping	Greg Jordan	
2009	Robert Caunce	Ano Xidias		Malcolm Tipping	Greg Jordan	
2010	Robert Caunce	Ano Xidias		Malcolm Tipping	Greg Jordan	
2011	Ano Xidias					

India (disbanded 2006)

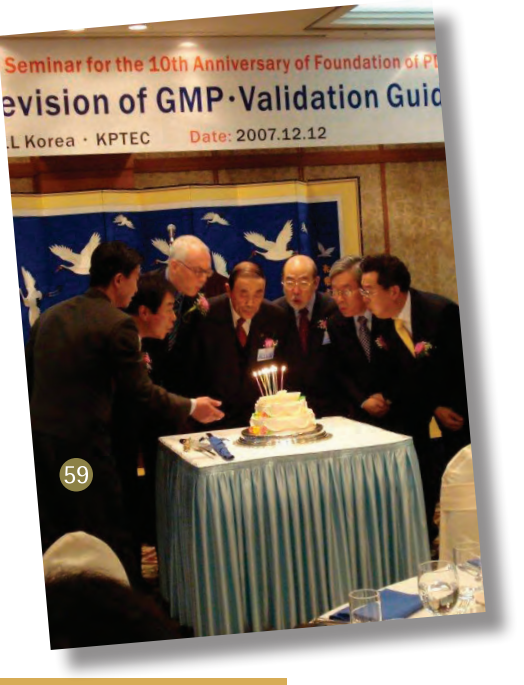
Year	President
2004	Darshan Makhey
2005	Darshan Makhey
2006	Darshan Makhey

Japan

Year	President	President-Elect	Vice-President	Secretary	Treasurer	Chapter Liaison
1997	Ken Ikeda		Kunio Kawamura Toshiaki Nishihata	Hisao Kyogoku	Masahiro Sudo	Kunio Kawamura
1998	Ken Ikeda		Kunio Kawamura	Hisao Kyogoka	Masahiro Sudo	Kunio Kawamura
1999	Kunio Kawamura		Ken Ikeda	Hisao Kyogoka	Masahiro Sudo	Ken Ikeda
2000	Ken Ikeda		Taiichi Mizuta	Hisao Kyogoku	Morihiro Sudo	Kunio Kawamura
2001	Ken Ikeda		Taiichi Mizuta	Hisao Kyogoku	Morihiro Sudo	Kunio Kawamura
2002	Ken Ikeda		Taiichi Mizuta	Hisao Kyogoku	Morihiro Sudo	Kunio Kawamura
2003	Katsutoshi Mise					
2004	Katsutoshi Mise					
2005	Katsuhide Terada					
2006	Katsuhide Terada	Shigeo Kojima Takashi Sonobe				
2007	Katsuhide Terada	Shigeo Kojima Takashi Sonobe				
2008	Katsuhide Terada					
2009	Katsuhide Terada	Shigeo Kojima				
2010	Katsuhide Terada	Shigeo Kojima				
2011	Katsuhide Terada					

Korea

Year	President	Vice-President(s)	Secretary	Treasurer
1998	Woo Hyun Paik	Hyun Tak Hong Chong Kook Kim		
1999	Woo Hyun Paik	Hyun Tak Hong Chong Kook Kim		
2000	Woo-Hyun Paik	Hyun Tak Hong Chong Kook Kim	Kang Chun Lee Sung	Gwang Soon Kim
2001	Woo-Hyun Paik	Chong Kook Kim		Gwang Soon Kim
2002	Woo-Hyun Paik	Chong Kook Kim		Gwang Soon Kim
2003	Woo-Hyun Paik			
2004	Woo-Hyun Paik			
2005	Woo-Hyun Paik			
2006	Woo-Hyun Paik			Young Kou Jeong
2007	Woo-Hyun Paik			Young Kou Jeong
2008	Woo-Hyun Paik			Young Kou Jeong
2009	Woo-Hyun Paik			Young Kou Jeong
2010	Woo-Hyun Paik			Young Kou Jeong
2011	Woo-Hyun Paik			Young Kou Jeong



Southeast Asia (disbanded 2006)

Year	President	Vice-President	Secretary	Treasurer
2002	Kanneganti Prasad	John Westbrook	Richard Ferris	Dinesh Khokal
2003	Kanneganti Prasad			
2004	Kanneganti Prasad			
2005	Kanneganti Prasad			
2006	Kanneganti Prasad			

Taiwan

Year	President	Vice-President	Secretary	Chapter Liaison
1997	SheShong Tsai	James T.S. Tu S. T. Tsai D. M. Tsan T. D. Chang		James T.S. Tu
1998	SheShong Tsai		Tuan-Tua Su	James T.S. Tu
1999	SheShong Tsai		Tuan-Tua Su	James T.S. Tu
2000	SheShong Tsai		Tuan-Tua Su	James T.S. Tu
2001	SheShong Tsai		Tuan-Tua Su	James T.S. Tu
2002	SheShong Tsai		Tuan-Tua Su	James T.S. Tu
2003	Shin-Yi Hsu			
2004	Shin-Yi Hsu			
2005	Shin-Yi Hsu			
2006	Tuan-Tua Su			
2007	Shin-Yi Hsu			
2009	Frank Wu			
2010	Frank Wu			
2011	Frank Wu			

58. Members of the Japan Chapter 2010

59. Korea Chapter leaders celebrate 10th Anniversary

60. Korean Chapter President, Woo-Hyun Paik (left) poses with PDA's Edmund Fry and Taiwan Chapter President She-Shong Tsai at the 2001 Taiwan Chapter Annual Meeting

Europe

Central Europe (disbanded 2007)

Year	President	Vice-President	Secretary	Treasurer
1997	Bernard Kronenberg	Georg Rössling	Finlay Skinner	Carlo Voellmy
1998	Bernard Kronenberg	Georg Rössling	Finlay Skinner	Carlo Voellmy
1999	Bernard Kronenberg	Georg Rössling	Finlay Skinner	Carlo Voellmy
2000	Bernard Kronenberg	Georg Rössling	Finlay Skinner	Carlo Voellmy
2001	Bernard Kronenberg	Georg Rössling	Finlay Skinner	Carlo Voellmy
2002	Bernard Kronenberg	Georg Rössling	Finlay Skinner	Carlo Voellmy
2003	Erich Sturzenegger			
2004	Erich Sturzenegger			
2005	Erich Sturzenegger			
2006	Andreas Wenng			
2007	Andreas Wenng			


61

France

Year	President	Treasurer
2003	Jean Louis Saubion	
2004	Jean Louis Saubion	
2005	Jean Louis Saubion	
2006	Jean Louis Saubion	Jean-Luc Clavelin
2007	Jean Louis Saubion	Jean-Luc Clavelin
2009	Philippe Gomez	Jean-Luc Clavelin
2010	Philippe Gomez	Jean-Luc Clavelin
2011	Philippe Gomez	Jean-Luc Clavelin

Ireland

Year	President	President-Elect	Secretary	Treasurer
2006	Frank Hallinan			Joan Fitzgerald
2007	Frank Hallinan	Coleman Casey		Joan Fitzgerald
2008				Joan Fitzgerald
2009	Coleman Casey		Paul Louge	Joan Fitzgerald
2010	Coleman Casey	Brendan Cahill	Paul Louge	Joan Fitzgerald
2011	Brendan Cahill			

62

Israel

Year	President	Vice-President	Secretary	Treasurer	Chapter Liaison
1997	Gil Bismuth	Karin Baer	Karen Ginsbury	Karin Baer	Karen Ginsbury
1998	Gil Bismuth	Karin Baer	Karen Ginsbury	Karin Baer	Karen Ginsbury
1999	Gil Bismuth	Karin Baer	Karen Ginsbury	Karin Baer	Karen Ginsbury
2000	Karen Ginsbury	Karin Baer	Eli Schmell	Karin Baer	
2001	Karen Ginsbury	Ezra Ouziel	Eli Schmell	Karin Baer	
2002	Karen Ginsbury	Ezra Ouziel	Eli Schmell	Karin Baer	
2003	Benny Klener		Karen Ginsbury	Karin Baer	
2004	Benny Klener		Karen Ginsbury	Karin Baer	
2005	Sigalit Portnoy		Karen Ginsbury	Karin Baer	
2006	Sigalit Portnoy		Karen Ginsbury	Karin Baer	

Israel (continued)

Year	President	President-Elect	Secretary	Treasurer
2007	Raphael Bar	Izar Mordechai	Karen Ginsbury	Karin Baer
2008	Raphael Bar		Karen Ginsbury	Karin Baer
2009	Raphael Bar	Izar Mordechai	Karen Ginsbury	Karin Baer
2010	Mordechai Izhar	Rina Yamin	Karen Ginsbury	Karin Baer
2011	Mordechai Izhar			

Italy

Year	President	President-Elect	Vice-President	Secretary	Treasurer	Chapter Liaison
2000						Vincenzo Baselli
2001	Vincenzo Baselli		Antonio Giannetto	Gabriele Gori	Stefano Maccio	Antonio Imperatore
2002	Vincenzo Baselli		Antonio Giannetto	Gabriele Gori	Stefano Maccio	Antonio Imperatore
2003	Vincenzo Baselli					
2004	Vincenzo Baselli					
2005	Gabriele Gori					
2006	Gabriele Gori					
2007	Stefano Maccio			Barbara Sambucco		
2008	Stefano Maccio					
2009	Stefano Maccio	Claudia Nardini		Barbara Sambucco		
2010	Stefano Maccio	Claudia Nardini		Lucia Ceresa		
2011	Stefano Maccio					

63

Prague (disbanded 2006)

Year	President
2003	Jean Louis Saubion
2004	Zdenka Mrvova
2005	Zdenka Mrvova
2006	Zdenka Mrvova

Spain (disbanded 2005)

Year	President
2003	Jordi Botet
2004	Jordi Botet
2005	Jordi Botet

United Kingdom and Ireland (split into UK and Ireland Chapters in 2007)

Year	President	Secretary	Treasurer
2000	Colin Booth	Nigel Halls	Karen Todd
2001	Colin Booth	Nigel Halls	Karen Todd
2002	Frank Talbot	Stephen Bellis	John Moys
2003	Frank Talbot		John Moys
2004	Frank Talbot		John Moys
2005	Frank Talbot		John Moys
2006	Frank Talbot		John Moys

United Kingdom

Year	President	Secretary	Treasurer
2007	Siegfried Schmitt		John Moys
2008	Siegfried Schmitt		John Moys
2009	Siegfried Schmitt		John Moys
2010	Siegfried Schmitt	Michael Baker	Mark Gibson
2011	Siegfried Schmitt		

61. Central Europe Chapter leaders

62. Ireland Chapter Leaders in 2006

63. Italy Chapter Committee during a work session in 2005

North America

Canada

Year	President	President-Elect	Vice-President	Secretary	Treasurer	Toronto Chair	Montreal Chair
1997	Shirley Gallaugher		Yves Archambault	Grace Chin	Ameera Al-Jabore		
1998	Yves Archambault		Grace Chin	Michel Roy	Ameera Al-Jabore		
1999	Yves Archambault		Grace Chin	Michel Roy	Ameera Al-Jabore		
2000	Grace Chin		Michel Soucy	Alex Montgomery	Ameera Al-Jabore	Hein Wick	Patrick Bronsard
2001	Grace Chin		Michel Soucy	Alex Montgomery	Ameera Al-Jabore	Hein Wick	Patrick Bronsard
2002	Grace Chin		Michel Soucy	Alex Montgomery	Ameera Al-Jabore	Hein Wick	Patrick Bronsard
2003	Grace Chin						
2004	Hein Wick						
2005	Hein Wick						
2006	Patrick Bronsard	Jacques Pilon		Arun Malaviya			
2007	Patrick Bronsard	Sabrina Ullah		Arun Malaviya			
2009	Vagiha Hussain			Antonella Maggio			
2010	Vagiha Hussain	Sabrina Ullah		Antonella Maggio			
2011	Vagiha Hussain						


64

Capital Area

Year	President	Vice-President	Secretary	Treasurer	President-Elect
1997	William Stoedter		Ursula Wehler	Robert Mello	Allen Burgenson
1998	William Stoedter		Ursula Wehler	Robert Mello	
1999	William Stoedter				Robert Mello
2000	Allen Burgenson		Stephen Rochelle	Dan Bauer	Robert Mello
2001	Allen Burgenson		Stephen Rochelle	Dan Bauer	Robert Mello
2002	Allen Burgenson	Robert Mello	Stephen Rochelle	Dan Bauer	
2003	Barry Friedman				
2004	Barry Friedman				
2005	Barry Friedman				
2006	Allen Burgenson		Stephen Rochelle	Barry Friedman	
2007	Allen Burgenson		Stephen Rochelle	Barry Friedman	
2008	Allen Burgenson				
2009	Allen Burgenson		Stephen Rochelle	Barry Friedman	
2010	Allen Burgenson		Stephen Rochelle	Barry Friedman	
2011	Allen Burgenson				


65

Delaware Valley

Year	President	Vice-President	Secretary	Treasurer
1997	Charles Cherundolo	Mark Kaiser	Steve Trombetta	Roger Deschenes
1998	Charles Cherundolo	Mark Kaiser	Stephen Trombetta	Roger Deschenes
1999	Arthur Vellutato, Jr.	Marlene Raschiatore	Stephen Trombetta	Jim Hallman
2000	Arthur Vellutato, Jr.	Marlene Raschiatore	Stephen Trombetta	Jim Hallman
2001	Arthur Vellutato, Jr.	Marlene Raschiatore	Stephen Trombetta	Jim Hallman
2002	Arthur Vellutato, Jr.	Marlene Raschiatore	Stephen Trombetta	Jim Hallman
2003	Arthur Vellutato, Jr.			
2004	Arthur Vellutato, Jr.			
2005	Arthur Vellutato, Jr.			
2006	Arthur Vellutato, Jr.		Stephen Trombetta	Marlene Raschiatore
2007	Arthur Vellutato, Jr.		Stephen Trombetta	Marlene Raschiatore
2008	Arthur Vellutato, Jr.		Stephen Trombetta	Marlene Raschiatore
2009	Arthur Vellutato, Jr.		Stephen Trombetta	Marlene Raschiatore
2010	Arthur Vellutato, Jr.			Marlene Raschiatore
2011	Arthur Vellutato, Jr.			


66

Metro

Year	President	President-Elect	Vice-President	Secretary	Treasurer	Chapter Liaison
1997	Benjamin Willemstyn			Frank Settineri	Linda Vollherbst	Leonard Mestrandrea
1998	Benjamin Willemstyn			Frank Settineri	Linda Vollherbst	
1999	Felicia Manganiello		Frank Settineri	Doug Kline	Linda Vollherbst	
2000	Felicia Manganiello		Frank Settineri	Doug Kline	Linda Vollherbst	
2001	Felicia Manganiello		Frank Settineri	Doug Kline	Linda Vollherbst	
2002	Frank Settineri		Carol Smith	Doug Kline	Linda Vollherbst	
2003	Frank Settineri					
2004	Natale Manco					
2005	Natale Manco					
2006	Natale Manco	Naomi Baer	Nancy Tomoney	Nancy Tomoney	Xiaoming Wang	
2007	Nate Manco	Naomi Baer	Nancy Tomoney	Nancy Tomoney	Xiaoming Wang	
2009	Lara Soltis	Robert Johnson	Robert Seltzer	Robert Seltzer	Lisa Smith	
2010	Robert Johnson	Robert Seltzer	Lara Soltis	Lara Soltis	Lisa Smith	
2011	Robert Johnson					


67

64. Canada Chapter Leaders at an event in 1998

65. Capital Area Chapter Scholarship Award 2005: Allen Burgenson, Bill Stoedter, Erin Voss (Scholarship winner), Jaime Miller (Scholarship winner) and Barry Friedman

66. Art Vellutato not only leads the Deleware Chapter, he also teaches TRI courses

67. Dana Morton Guazzo, Nate Manco, Bob Johnson are all smiles following PDA Metro's Container Closure Integrity Testing Event

Midwest

Year	President	President-Elect	Vice-President	Secretary	Treasurer	Chapter Liaison
1997	Carol Lampe			Amy Davis		Frank Bing
1998	Carol Lampe			Amy Davis		Frank Bing
1999	Michael Anisfeld		Nick Dayton	Robert Murphy	William Domansky	
2000	Michael Anisfeld		Nick Dayton	Robert Murphy	William Domansky	
2001	Amy Gotham					
2002	Amy Gotham			Peter Noverini	Ryan Skoraczewski	
2003	Amy Gotham					
2004	Amy Gotham					
2005	Madhu Ahluwalia					
2006	Madhu Ahluwalia	Peter Noverini		Matthew Anderson	Kurt Puterbaugh	
2007	Madhu Ahluwalia	Peter Noverini		Matthew Anderson	Kurt Puterbaugh	
2009	Robert Buchholz			Matthew Anderson	Kurt Puterbaugh	
2010	Peter Noverini	Jeanne Moldenhauer		Beth Kirschenheiter	Ken Paddock	
2011	Peter Noverini					

Missouri Valley

Year	President	President-Elect	Secretary	Treasurer
2010	Thomas Pamukcoglu	Kenneth Boone	Jeff Hargroves	Keith Koehler
2011	Thomas Pamukcoglu			

Mountain States

Year	President	President-Elect	Vice-President	Secretary	Treasurer	Chapter Liaison
1997	Brian Shontz			Jill Ewoldt	Ronald Branning	Donald Elinksi
1998	Deon Josephson			Jill Ewoldt	Brenda Fielding	Brian Shontz
1999	Jeffrey Beste			Shira Krivjansky	Brenda Fielding	Deon Josephson
2000	Jeffrey Beste		John Elvig	Shira Krivjansky	Deon Josephson	
2001	Jeffrey Beste		John Elvig	Paul Bilodeau	Deon Josephson	Vivian Denny
2002	Jeffrey Beste				Maggie Sparhawk	John Elvig
2003	Paul Bilodeau					
2004	Paul Bilodeau					
2005	Cathie Wilkerson					
2006	Sara Hendricks				Sheri Glaub	
2007	Sara Hendricks		Robert Buchholz		Sheri Glaub	
2009		Patricia Brown			Nikolas Burlew	
2010	Patricia Brown	Suzanne Mecalo		Karrin Hogan	Nikolas Burlew	
2011	Suzanne Mecalo					

New England

Year	President	President-Elect	Vice-President	Secretary	Treasurer	Chapter Liaison
1997	Charles Cherundolo		Mark Kaiser	Steve Trombetta	Roger Deschenes	Marlene Rashiatore
1998	Robert Pazzano		James Correia	Michelle Sceppa	Mark Staples	
1999	Robert Pazzano		James Correia	Michelle Sceppa	Mark Staples	
2000	Robert Pazzano		James Correia	Michelle Sceppa	Mark Staples	
2001	Robert Pazzano		James Correia	Michelle Sceppa	Mark Staples	
2002	Robert Pazzano		James Correia	Michelle Sceppa	Mark Staples	
2003	Mark Staples					
2004	Mark Staples					
2005	Myron Dittmer					
2006	Myron Dittmer	Louis Zaczkiewicz		Melissa Smith	Russell Morrison	
2007	Louis Zaczkiewicz	Gerald Boudreault		Melissa Smith	Russell Morrison	
2009	Gerald Boudreault	Russell Morrison			Maryellen Brown	
2010	Gerald Boudreault	Russell Morrison		Sarvang Mishra	Maryellen Brown	
2011	Russell Morrison					

Puerto Rico

Year	President	President-Elect	Vice-President	Secretary	Treasurer
1997	Brenda Rodríguez De Damiani		Joseph Mendoza	Carmen Oliver	Vivvian Negrón Luciano
1998	Brenda Rodríguez De Damiani		Joseph Mendoza	Carmen Oliver	Vivvian Negrón Luciano
2003	Silma Bladuell				
2004	Silma Bladuell				
2005	Silma Bladuell				
2006	Manuel Melendez	Evelyn Marchany		Gloria Martinez	Frederick Fontanez
2007	Manuel Melendez	Evelyn Marchany		Gloria Martinez	Frederick Fontanez
2008	Manuel Melendez				
2009	Manuel Melendez			Gloria Martinez	Frederick Fontanez
2010	Jose Cotto			Ruth Toledo	Yaritza Martinez
2011	Jose Cotto				

Southern California

Year	President	President-Elect	Vice-President	Secretary	Treasurer
1997	Glenn Wright	Sean Carnes		David Barry	Mark Mugerditchian
1998	Beth Bertelsen		David Barry		Mark Mugerditchian
1999	Jeffrey Yuen		David Barry	Dianne Gerst	Mark Mugerditchian
2000	Jeffrey Yuen		David Barry	Beth Bertelsen	Bernice Stein
2001	Kikoo Tejwani		John D'Angelo	Maria Wagner	
2002	Kikoo Tejwani		John D'Angelo	Maria Wagner	
2003	Kikoo Tejwani				
2004	Kikoo Tejwani				
2005	Kikoo Tejwani				
2006	Saeed Tafreshi	Kenneth Cairns, II			
2007	Saeed Tafreshi	Kenneth Cairns, II			
2008	Saeed Tafreshi				
2009	Saeed Tafreshi				
2010	Saeed Tafreshi				
2011	Saeed Tafreshi				

68. Mountain States chapter 2000

69. Attendees relax during a Midwest Chapter event

70. New England Chapter President Louis Zaczkiewicz mans the registration desk at a chapter event

Southeast

Year	President	President-Elect	Vice-President	Secretary	Treasurer
1997	Terri Polson		Lucia Clontz	John Shirtz	
1998	Terri Polson		William Jones	Pam Proctor-Webb	John Shirtz
1999	William Jones, Jr.		Mary Carver	Kim Hughes	John Shirtz
2000	William Jones, Jr.		Mary Carver	Kim Hughes	John Shirtz
2001	William Jones, Jr.		Mary Carver	Kim Hughes	Anthony Pavell
2002	William Jones, Jr.		Mary Carver	Kim Hughes	Anthony Pavell
2003	Mary Carver				
2004	Lisa Eklund				
2005	Lisa Eklund				
2006	Patrick Sabourin	Michele Creech		Beth Meinig	Bruce Craven
2007	Patrick Sabourin	Michele Creech		Beth Meinig	Bruce Craven
2009	Michele Creech	Beth Meinig		Shelley Preslar	Bruce Craven
2010	Michele Creech	Beth Meinig		Shelley Preslar	Bruce Craven
2011	Shelley Preslar				

West Coast

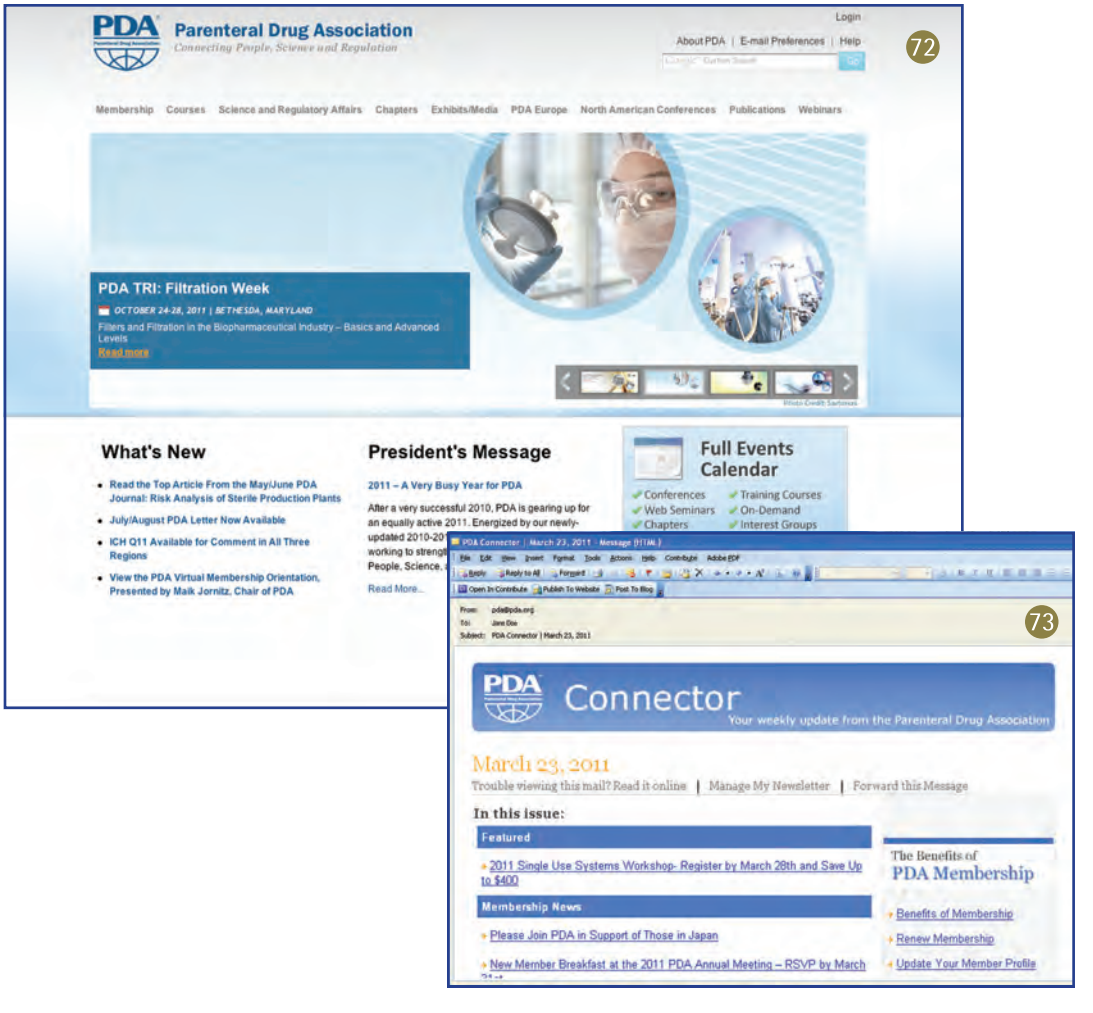
Year	President	President-Elect	Vice-President	Secretary	Treasurer
1997	Kristen Bacigalupi	Vince Anicetti	Mark Kaiser	Otis Sangster	Steve Carlson
1998	Vince Anicetti	Randall Tedder		Dan Linehan	Peter Rauenbuehler
1999	Vince Anicetti	Randall Tedder		Dan Linehan	Peter Rauenbuehler
2000	Vince Anicetti	Randall Tedder		Dan Linehan	Peter Rauenbuehler
2001	Randall Tedder				Peter Rauenbuehler
2002	Randall Tedder		John Ferreira	Beverly McCalla	Peter Rauenbuehler
2003	Randall Tedder				
2004	Randall Tedder				
2005	Peter Rauenbuehler				
2006	Peter Rauenbuehler	John Ferreira		Kristina Nordhoff	Michael Place
2007	John Ferreira	Elizabeth Leininger		Kristina Nordhoff	Michael Place
2009	Elizabeth Leininger			Kristina Nordhoff	Michael Place
2010	Elizabeth Leininger			Kristina Nordhoff	Michael Place
2011	Elizabeth Leininger				

Making the Connection

PDA utilizes a number of tools to keep its members and its volunteers connected. Since 1949, the Association leaders have issued a newsletter to keep member informed of regulatory developments. Over the last 15 years, the *PDA Letter* (so named in the 1960's) has evolved into a 52+-page, four-color magazine that offers science and technology updates, regulatory news and information on PDA members, conferences, and training activities. It is an indispensable source of information for PDA members and volunteers, issued 10 times each year. An electronic archive of issues is available online, starting with the 2001 volume year. Starting in 2006, selected articles from each *PDA Letter* are posted for the entire industry to see; this now includes an online commenting feature.

PDA embraced the electronic age with www.pda.org in the late 1990's. Like the *PDA Letter*, the website has evolved over time. The first version of the website was a useful source of information on event dates and general information about PDA. Later, it included a members-only directory of members and the capability to register online for events. A bookstore was built to sell PDA Technical Reports and PDA/DHI books. In our 65th year, the website was completely overhauled with a modern look and feel that will help members more easily find the information they need to stay engaged with PDA.

In 2005, the *PDA Connector*, a weekly email to members full of the latest regulatory news and offerings from PDA, was launched. The *PDA Connector* gives members a weekly glimpse into all things PDA and provides links back to the website



71. Saeed Tafreshi (second from left) has lead the successful Southern California Chapter since 2006
72. The PDA website's most recent design
73. The weekly PDA Connector email newsletter was launched in 2005 to keep members informed

74. The different faces of the *PDA Letter* 1997-2011

75. The Science & Technology Snapshot was added to the *PDA Letter* in 2007 to keep members informed of upcoming developments

76. New Member list added to the *PDA Letter* in 2007

77. The Volunteer Spotlight was added in 2008 to recognize the strong contributions of PDA's members

78. In the wake of a bad economy, Tools for Success column was added to the *PDA Letter* in 2009

PDA Letter Editorial Committee 2007-2011

Shelley Abrams (2007-2008)
Kamaal Anas (current)
Vincent Anicetti (current)
Michael Awe (2007–2010)
Harold Baseman (current)
Winston Brown (current)
José A. Caraballo (current)
Doris Conrad (current)
Robert Darius (current)
Miriam Estrano (current)
Martha Folmsbee (current)
Karen Ginsbury (current)
Vinod Gupta, PhD (2007-2010)
Georgiann Keyport (current)
Anastasia Lolas (current)
Mike Long (current)
Elizabeth Martinez (2007-2010)
Rainer Newman (2007-2008)
Kristina Nordhoff (2007-2008)
Matt Schmidt (current)
Susan Schniepp (current)
Scott Sutton (2007-2009)
Janeen Skutnik-Wilkinson (current)
Anita Whiteford (2009-2010)
Sandra Zoghbi-Gay (current)

Staff

Professional staff at PDA's headquarters provides the critical link in the connection. The PDA staff has grown since those early days in New York, where PDA was first founded, matching the explosive growth in membership and regions served since the 1990's. PDA staff support every activity promoted by the members—conferences, courses, publications, chapters, task forces, interest groups, etc. This section includes photos of various staff who served PDA over the last 15 years.

79. Jennifer Knode
80. Jim Lyda
81. Bill Stoedter
82. Virginia Ventura
83. Guatam Maitra
84. Iris Rice, Halleh Sameni, Hassana Howe, Feng Chen
85. George Robertson
86. Victoria Dedrick
87. Jason Brown, Bob Dana and Gail Sherman


PDA
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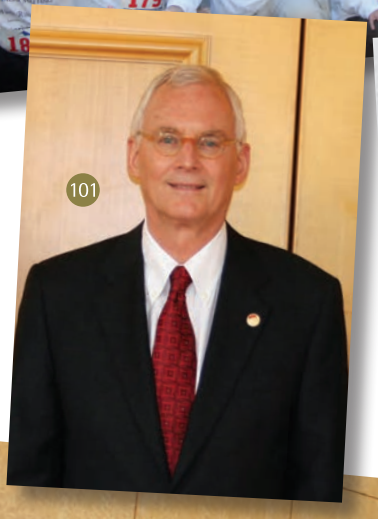
ERAL DRUG ASSOCIATION



88. Adrienne Fierro

89. Janny Chua

90. Ta-Méla Jeffries, (member) John Ferreira, Emily Alesantrino, Hassana Howe, and Lindsay Donofrio

91. Stephanie Ko, James Wamsley, and Gail Sherman

92. Russell Madsen

93. Leon Lewis and Hee-Young Park (Korean government intern)

94. Allison Caballero

95. David Hall

96. Andrea Viera and Patresa Day

97. Walter Morris

98. Craig Elliot

99. Julia Zimmerman, Trevor Swan, Dawn Marek, Hassana Howe

100. Various staff participated in the 2010 Fun Run: Walter Morris, Richard Johnson, Wanda Neal, Craig Elliott and Feng Chen

101. Richard Levy

102. Frank Sarlo

103. Shyla Fuentas, Nikki Nasabzadeh, Leslie Edmond, Luis Castro, Christina Bogyo, Jason Brown, Paula Pagino, Patresa Day, and Wanda Neal

104. Richard Johnson

105. Dirk Stelling, Nadine Gold, Katharina Keisers-Engstfeld, Georg Rössling, Ailyn Kandora and Antje Petzholdt

CHAPTER 3

SCIENCE

The first connection between our members is the science. Looking at the PDA Vision and Mission, one will see phrases like:

> *Foremost provider of science and technology information"*
>
> *Develop scientifically sound, practical technical information"*
>
> *Promote advances in pharmaceutical and biopharmaceutical science*
>
> *Facilitate development, testing and qualification of new technology*

These activities really comprise the essence of PDA. For 65 years, PDA members have shared the best and latest scientifically sound practices in the manufacturer of pharmaceutical products via face-to-face meetings and in publications. From humble origins focused solely on the sterile product manufacturing to the membership-driven growth into other product areas, including, but not limited to, biotechnology and advanced therapeutic products based on genetic technologies.

This chapter celebrates and memorializes the key contributions that PDA has made to pharmaceutical science over the last 15 years.

Sterile Processing: PDA's Core Strength

PDA continued to strongly support its core strength—aseptic processing and sterile products. PDA's expertise with the processing of sterile products was never more important than when the U.S. FDA revised its 1987 guideline on GMPs for aseptic processes in the late 1990's. The membership's rapid response to FDA's effort and their willingness to turn to PDA as their conduit demonstrates best PDA's ability to *Connect People, Science and Regulation®.*

Led by members, including James Agalloco, James Akers, Martin VanTrieste, Richard Johnson, and Glenn Wright, PDA took a proactive role. In 2000, PDA formed a task force of a dozen volunteer leaders from PDA membership, including senior industry managers and expert consultants to address a number of industry concerns with the original guideline. The task force produced a "Points to Consider" document, published as a supplement to the *PDA Journal of Pharmaceutical Science and Technology,* that presented consensus guidance on 50-plus issues deemed most critical and most likely to be controversial in the pending revised guidance.

The U.S. FDA subsequently published a "concept paper" entitled, *Sterile Drug Products Produced by Aseptic Processing.* Differences between the two documents prompted the formation of an expert committee under the auspices of the Product Quality Research Institute, of which PDA was a founding member. Many of the members of the PDA task force joined the PQRI working group, which began work in December 2002 and published a final report in March 2003. FDA considered the

1. Testing at the Training and Research Institute

PDA Aseptic Processing Task Force

David J. Miner, PhD (Co-Chair)

Glenn E. Wright, Eli Lilly and Company (Co-Chair)

James P. Agalloco, Agalloco & Associates

William R. Frieben, PhD, Pharmacia Corporation

Nigel Halls, PhD, GlaxoSmith Kline (ret.)

Richard M. Johnson, Abbott Laboratories

Carol M. Lampe, Baxter Healthcare Corporation

Russell E. Madsen, PDA

Andy Minor, Eli Lilly and Company

Kenneth Muhvich, PhD, Micro-Reliance

Terry Munson, KMI/PAREXEL, Inc.

Richard N. Prince, PhD, Richard Prince Associates

Leonard W. Mestrandrea, PhD, Pfizer Inc.

Dr. Andreas Sachse, Schering AG

Ian Symonds, GlaxoSmithKline

Martin Van Trieste, Abbott Laboratories

Richard T. Wood, PhD, Pfizer Inc.

2. TR-1 goes on tour. The Technical Report No. 1 Revision Task Force took a draft of the document on tour in 2006 for a global review; (from top, clockwise): Pavia, Italy; London; Bethesda, Md.; PDA HQ; Cork, Ireland

3. Richard Johnson on the Glass Tour, part of the Glass Defects Task Force effort to produce *Technical Report No. 43: Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing*

4. Sam Venogopal and PDA's Richard Johnson recognize the PDA/CMC-VWG Partnership at MedImmune's Gaithersburg, Md. location as members of the Vaccines Working Group look on

report and made a number of adjustments to their aseptic processing guidance, which was published in final form in 2004. Both industry and the FDA recognized that the rapid, proactive work done by PDA's members throughout the process and the Agency's willingness to engage in dialogue were instrumental to producing a scientifically sound guidance that reflected industry best practices.

PDA and FDA subsequently cosponsored four training workshops on the aseptic processing guidance with participation of PDA task force representatives and Agency officials.

A major initiative during the last 15 years was the rewrite PDA's first Technical Monograph, which addressed steam sterilization validation. The revised document—*PDA Technical Report No. 1: Validation of Moist Heat Sterilization Processes Cycle Design, Development, Qualification and Ongoing Control*—was published in 2007. Interest in the revision of this document was strong, and the Task Force participated in a number of conferences to generate consensus among a broad cross-section of the industry, including regulatory authorities in the United States and Europe.

Contributors to PDA Technical Report No. 1 — Revised 2007

Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control

James P. Agalloco, Agalloco & Associates

James E. Akers, PhD, Akers Kennedy & Associates

Wilf Allinson, GlaxoSmithKline

Thomas J. Berger, PhD, Hospira

Frank Bing, Abbott Laboratories (retired)

Göran Bringert, GE Kaye Instruments

Gary Butler, Steris Corporation

Jean-Luc Clavelin, Eli Lilly and Company

Peter Cooney, PhD, FDA (retired)

Phil DeSantis, Schering-Plough

Peter Dürr, F. Hoffmann-La Roche AG

Kristen D. Evans, FDA

John G. Grazal, AstraZeneca

Nigel Halls, PhD, IAGT. Ltd.

Nigel Halls, PhD, IAGT. Ltd.

Paul Hargreaves, MHRA

Andrew D. Hopkins, MHRA

Martin A. Joyce, PhD, GeneraMedix Inc.

David Karle, Steris Corporation

Bernard Kronenberg, Bakrona Basel AG

John W. Levchuk, PhD, FDA (retired)

Richard V. Levy, PhD, PDA

Steen Loevtrup, Novo Nordisk A/S

Timothy F. Lord, Eli Lilly and Company

Genevieve Lovitt-Wood, G.I. Lovitt & Associates, Project Manager and Technical Writer

Russell E. Madsen, The Williamsburg Group, LLC

Vittorio Mascherpa, PhD, Fedegari Autoclavi Spa (retired)

David W. Maynard, Maynard & Associates

Robert B. Myers, PDA

James E. Owens, Baxter Healthcare (retired)

Irving Pflug, PhD, University of Minnesota (retired)

Dario Pistolesi, PhD, Fedegari Autoclavi Spa (retired)

Anthony Pochiro, AG Edwards and Sons

Jarmo Saari, Leiras OY

Michael Sadowski, Baxter Healthcare

John T. Shirtz, Baxter Healthcare

Keith Shuttleworth, Keith Shuttleworth & Associates Ltd.

Finlay Skinner, Skinner Pharm-Assist

Ian Symonds, GlaxoSmithKline

Kevin D. Trupp, Hospira

Dieter Witthauer, PhD, Novartis

Richard T. Wood, PhD (retired)

William Young, Baxter Healthcare (retired)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Expanding Areas of Scope

Following the industry, PDA increased its focus on topics relevant to the manufacture of biotech pharmaceuticals. In 2004, PDA formed the Biotechnology Advisory Board to help guide these activities. Over the last eight years, PDA has published 7 technical reports to support biotech manufacturers, held workshops and conferences on various relevant topics, including virus safety, cell substrates, and adventitious viruses, and opened the biotech laboratory at the new TRI facility.

Technical Reports

Publication of technical reports is a defining activity of PDA's membership. Volunteer members come together in task forces (approved by an Advisory Board) and work for a year or more to develop these best-practice documents, which are then distributed to all members for free. Technical reports are repeatedly ranked as the top and most valuable benefit. In the last 15 years, PDA doubled the number of technical reports available to the membership.

Technical Reports 1997–2011

1997 TR–24: Current Practices in the Validation of Aseptic Processing
Blend Uniformity Analysis: Validation and In-Process Testing

1998 TR–26: Sterilizing Filtration of Liquids
TR–27: Pharmaceutical Package Integrity
TR–29: Points to Consider for Cleaning Validation

1999 TR–30: Parametric Release of Pharmaceuticals Terminally Sterilized by Moist Heat
TR–31: Validation and Qualification of Computerized Laboratory Data Acquisition Systems

2000 TR–33: Evaluation, Validation and Implementation of New Microbiogical Testing Methods

2001 TR–13 (Revised): Fundamentals of an Environmental Monitoring Program
TR–34: Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products
TR–35: A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry

2002 TR–36: Current Practices in the Validation of Aseptic Processing

2004 **TR–32:** Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations

2005 TR–39: Cold Chain Guidance for Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products Through the Transportation Environment
TR–40: Sterilizing Filtration of Gases
TR–41: Virus Filtration
TR–42: Process Validation Protein Manufacturing

2006 TR–38: Manufacturing Chromatography Systems Postapproval Changes (ChromPAC): Chemistry, Manufacturing, and Controls Documentation
TR–28 (Revised): Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals

2007 TR–39 (Revised): Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment

TR–43: Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing

TR–1 (Revised): Validation of Moist Heat Sterilization Processes Cycle Design, Development, Qualification and Ongoing Control

2008 TR–14 (Revised): Validation of Column-Based Chromatography Processes for the Purification of Proteins

TR–26 (Revised): Sterilizing Filtration of Liquids

TR–41 (Revised): Virus Filtration

TR–44: Quality Risk Management for Aseptic Processes

TR–45: Filtration of Liquids Using Cellulose-Based Depth Filters

2009 TR–15 (Revised): Validation of Tangential Flow Filtration in Biopharmaceutical Applications

TR–46 (Revised): Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User

2010 Technical Series: Filtration – A Compilation of Technical Reports on Filtration

TR–47: Preparation of Virus Spikes Used for Virus Clearance Studies

TR–48: Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance

TR–49: Points to Consider for Biotechnology Cleaning Validation

TR–50: Alternative Methods for Mycoplasma Testing

TR–51: Biological Indicators for Gas and Vapor Phase Decontamination Processes: Specification, Manufacture, Control and Use

5. PDA Technical Report projects are first championed by a volunteer or volunteers, sanctioned by an Advisory Board, drafted by a Task Force, approved by the Advisory Board and ultimately approved by the Board of Directors; they are considered the most valuable member benefit

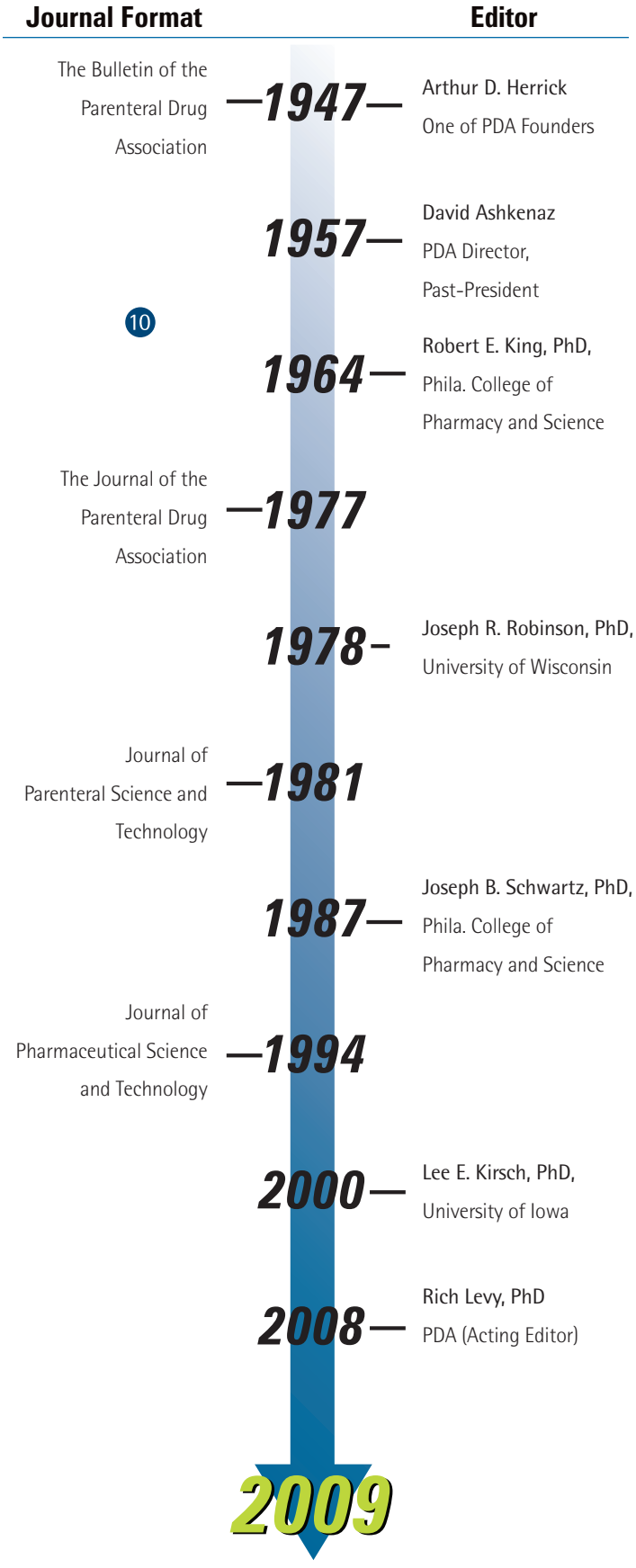
6. Members of the CVM Task Force meet at PDA's Headquarters in February 2005

7. Members of the EIA Task Force meet at PDA Headquarters in March 2005

8. In 2010, PDA bundled five Technical Reports on Filtration

9. The many faces of the PDA Journal, from a bulletin to a fully searchable online product, complete with a mobile interface

Brief History of the PDA Journal



2011 TR–52: Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain
TR–53: Guidance for Industry: Stability Testing to Support Distribution of New Drug Products

PDA Journal of Pharmaceutical Science and Technology

The *PDA Journal of Pharmaceutical Science and Technology*, better known by members as simply the Journal, consistently ranks as the second most prized benefit of PDA membership. Founded in 1947, the Journal was edited by PDA founding father Arthur D. Herrick and later by David Ashkenaz. 1957 was a milestone year in that the reins of the Journal were turned over to an academic, Prof. Robert King, which helped turn the publication into a highly rated scientific resource for researchers around the world. Prof. Joseph Robinson and Prof. Joseph Schwartz followed Dr. King as the Journal editors in PDA's first 50. In the last 15 years, the Journal has enjoyed two highly qualified editors in Prof. Lee Kirsch and Prof. Govind Rao.

In 2009, the Journal met the Internet age by becoming an online-only publication, delivering to the members a number of new tools, including the ability to conduct online searches for valuable content. In 2011, the website went mobile, as a new interface was introduced so that members and researchers on the go can easily access the website via their smartphones.

PDA/DHI Co-Published Books

PDA entered the book publishing business in this period, partnering with Davis Healthcare International Publishing in 2001 to produce high quality technical books on topics relevant to our community. As of 2011, over 80 titles have been published through this partnership on topics like environmental monitoring, filtration, QA/QC, rapid microbial methods, GMPs, to name a few.

PDA/DHI Books 2001–2011

2001 *Change Control*, Soren Schwartze

2002 *GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Third Edition*, Soren Schwartze

Validation Master Plan: The Streetwise Downtown Guide, Trevor Deeks

2003 *Analytical Method Validation in the Chemical Analysis Lab*, Robert B. Kirsch

2004 *A Basic Primer on Pharmaceutical Microbiology*, Hans van Doorne

Cleanroom Clothing Systems: People as a Contamination Source, Bengt Ljungqvist and Berit Reinmuller

Pharmaceutical Quality, Richard Prince

2005 *Computer Infrastructure Qualification: For FDA Regulated Industries*, Orlando Lopez

Encyclopedia of Rapid Microbiological Methods, Vol I, Michael Miller

Quality Assurance Workbook for Pharmaceutical Manufacturers, Michael Jahnke

Technology Transfer: An International Good Practice Guide for Pharmaceutical and Allied Industries, Mark Gibson

2006 *Encyclopedia of Rapid Microbiological Methods, Vol II & III*, Michael J. Miller

Pharmaceutical Filtration: The Management of Organism Removal, Theodore Meltzer, Maik Jornitz

Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple, James Vesper

Risk-Based Software Validation: Ten Easy Steps, David Nettleton, Janet Gough

Successfully Validating ERP Systems (and other large, configurable applications), David Stokes

2007 *Bioprocess Validation The Present and Future*, Trevor Deeks

Caveats of Bacterial Endotoxin Testing, Kevin Williams

Chinese Drug GMP An Unofficial Translation Including Related Sections of the Taiwanese, U.S., and ICH-API GMP, Steven Kuwahara, Simon Xiuwei Li

Confronting Variability: A Framework for Risk Assessment, Richard Prince, Diane Petitti

Essential Microbiology for QP Candidates, Nigel Halls, Bruce Vernon

Ethylene Oxide Sterilization: Validation and Routine Operations Handbook, Anne F. Booth

Pharmaceutical Contamination Control: Practical Strategies for Compliance, Nigel Halls

Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics, Scott Sutton

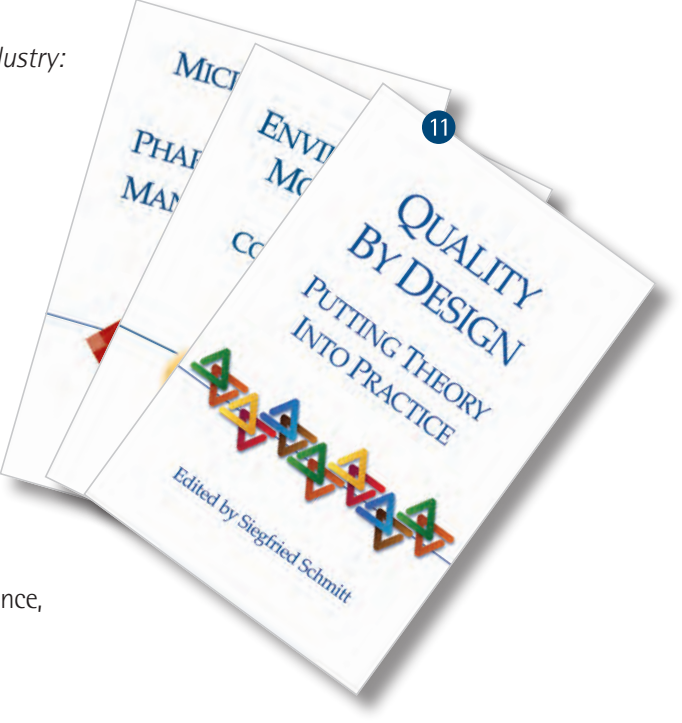
Systems Based Inspection for Pharmaceutical Manufacturers, Jeanne Moldenhauer

Validation of Analytical Methods for Biopharmaceuticals: A Guide to Risk-Based Validation and Implementation Strategies, Stephan O. Krause

10. A brief history of the Journal

11. PDA-DHI books have contributed to PDA's Mission since 2001

12. Maik Jornitz, (left) and Ted Meltzer (right) sign a book during the PDA Bookstore at the 2005 Annual Meeting



2008 *Biological Indicators for Sterilization Processes*, Jeanne Moldenhauer, Margarita Gomez

Chinese GMP Inspection Standard Checklist, Simon Xiuwei Li, Steven S. Kuwahara

Microbiology in Pharmaceutical Manufacturing, Second Edition, Revised and Expanded, Vol I & II, Richard Prince

Radiation Sterilization: Validation and Routine Operations Handbook, Anne F. Booth

Risk-Based Compliance Handbook, Siegfried Schmitt

2009 *Anatomy of a Pharmaceutical Filtration Differential Pressures, Flow Rates, Filter Areas, Throughputs and Filter Sizing*, Maik W. Jornitz, Theodore H. Meltzer

Application and Insights for Lyophilization of Parenteral Products, Edward H. Trapple

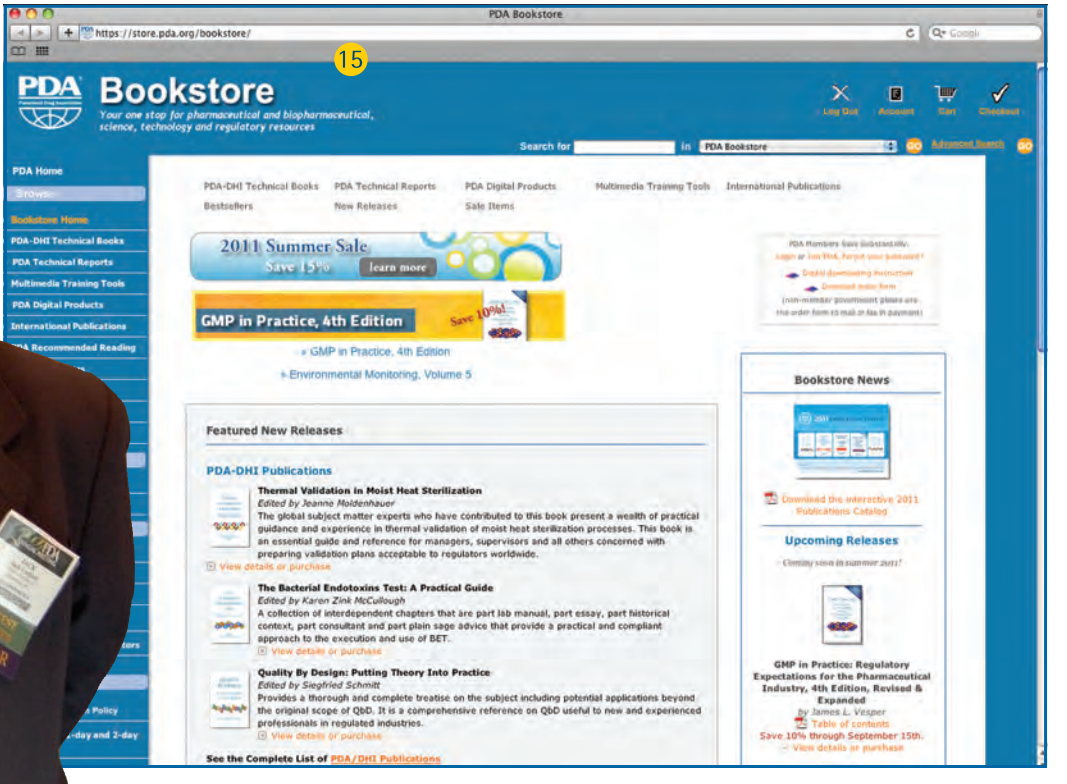
Applications of Water Activity Management in the Pharmaceutical Industry, Detlef Werner

Aseptic Process Validation and Aseptic Process Simulation Studies, Hal Baseman

Best Practices in Environmental Monitoring Automation, Robert Toal, Michael Goetter, Susan Harrison, Jeremy Tanner, Timothy A. Coleman and Robert Lutskus

Practical Aseptic Processing: Fill and Finish, Vol I & II, Jack Lysfjord

Water Activity Applications in the Pharmaceutical Industry, Anthony M. Cundell, Anthony J. Fontana, Jr.



2010 *Cleaning and Cleaning Validation, Vol I*, Paul L. Pluta

Environmental Monitoring: A Comprehensive Handbook, Vol 4, Jeanne Moldenhauer

Laboratory Design: Establishing the Facility and Management Structure, Scott Sutton

Recent Warning Letters: Review for Preparation of an Aseptic Processing Inspection, Jeanne Moldenhauer

Recent Warning Letters Review for Preparation of a Non-Sterile Processing Inspection, Volume 2, Jeanne Moldenhauer

Validation By Design®: The Statistical Handbook for Pharmaceutical Process Validation, Lynn Torbeck

2011 *Quality by Design: Putting Theory Into Practice*, Siegfried Schmitt

The Bacterial Endotoxins Test: A Practical Guide, Karen Zink McCullough

Thermal Validation in Moist Heat Sterilization, Jeanne Moldenhauer

13. Author Jeanne Moldenhauer with a fan at a PDA Annual Meeting
14. Jack Lysfjord promotes his books
15. PDA's online bookstore
16. Author Siegfried Schmitt at a PDA Annual Meeting
17. PDA was Organizational Member of ASTM
18. Members of the Single-Use Systems Task Force outside PDA Headquarters: (l-r) Eric Isberg, Bob Repetto, Robert Shaw, Jerold Martin, Ingrid Markovich, Stephen Brown, Morten Munk, Bill Hartzel

CHAPTER 4

REGULATION

The final part of the Connection is with the regulatory agencies. PDA members share a long history of coming together to participate jointly in the commenting process for new regulations, guidelines/guidances, and compendial and other official standards. The ability to impact regulatory and compendial outcomes is an important aspect of the regulatory process and a key reason why PDA's members organize under the Association's umbrella. The quality and merit of PDA's regulatory comments over the years gained it recognition by the World Health Organization, which officially approved PDA in 2003 as a commenting organization for WHO guidances and policies.

Harmonization

As large pharmaceutical companies grew into even larger multinationals, new start-up companies emerged and new and different types of therapeutic molecules arrived, the challenges posed by divergent regulatory requirements in different countries grew evermore significant.

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)GMP guidance for active pharmaceutical ingredients (quality guidance Q7A), published in 2000, opened the door for PDA's direct involvement in the harmonization process. The U.S. FDA asked PDA to cosponsor a series of trainings on Q7A, and PDA responded with five standing-room only workshops in 2002 in Europe and in the United States. PDA's Q7A training workshops were the only ones in the industry offered with U.S. FDA's imprimatur and with full participation of the ICH Expert Working Group that developed the guidance.

In 2009, PDA supported harmonization with its member-led initiative called, "Paradigm Change in Manufacturing Operations" (PCMO[SM]). The goal of the PCMO[SM] program is to drive the establishment of "best practice" documents and/or train-

ing events to assist pharmaceutical manufacturers in implementing the ICH guidelines on Pharmaceutical Development (ICH Q8, Q11), Quality Risk Management (ICH Q9) and Pharmaceutical Quality Systems (ICH Q10). PCMO[SM] projects are expected to facilitate knowledge transfer among the experts from industry, universities and regulators as well as experts from the respective ICH Expert Working Groups and Implementation Working Groups.

PDA's experience, reputation and strong member base again showed up in support of the ICH Quality Implementation Working Group (Q-IWG) on Q8, Q9 and Q10. In 2010, at the request of the Q-IWG, PDA cosponsored two training workshops in Europe and the United States for both industry and regulators.

In 2009, PDA supported harmonization with its member-led initiative called, "Paradigm Change in Manufacturing Operations" (PCMO[SM]). The goal of the PCMO[SM] program is to drive the establishment of "best practice" documents and/or training events to assist pharmaceutical manufacturers in implementing the ICH guidelines on Pharmaceutical Development (ICH Q8, Q11), Quality Risk Management (ICH Q9) and Pharmaceutical Quality Systems (ICH Q10). PCMO[SM] projects are expected to facilitate knowledge transfer among the experts from industry, universities and regulators as well as experts from the respective ICH Expert Working Groups and Implementation Working Groups.

Milestones in Compendial and Regulatory History

2000 ICH Q7A, GMPs for APIs adopted

2002 FDA publishes "Pharmaceutical GMPs for the 21st Century: A Risk-Based Approach, introducing the concept of a Quality Systems approach to compliance

2004 EU expands from 15 to 25 member states

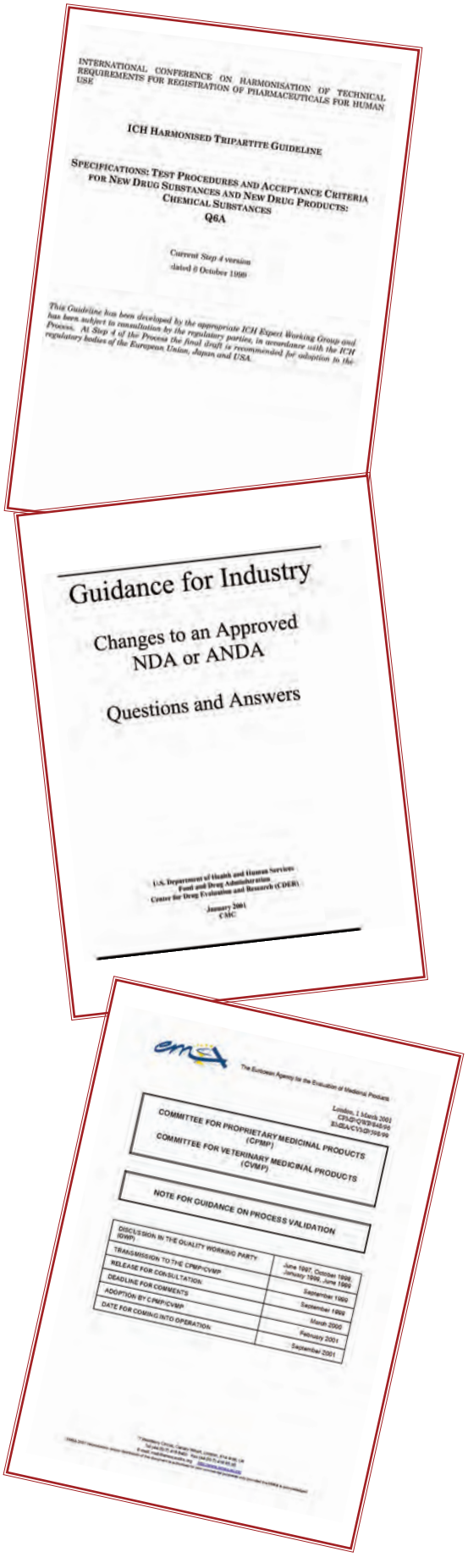
FDA publishes new Guidance for Industry on GMPs for aseptic processing of sterile drugs

2005–2008 ICH adopts Quality Guidelines on Pharmaceutical Development, Quality Risk Management and Pharmaceutical Quality Systems (Q8, Q9 and Q10)

2008 2008 EMA finalizes revised GMP Annex 1, Manufacture of Sterile Medicinal Products

2011 FDA publishes new Guidance for Industry on process validation

1. RAQC "Open Air" at the 2006 PDA/FDA Joint Regulatory Conference
2. Q7A Training in Europe
3. PDA was an early member of the Product Quality Research Institute, with the U.S. FDA and AAPS



Regulatory Comments

Over the last 15 years, PDA has formed Task Forces of volunteers to comment on numerous regulatory guidances and initiatives. The following is a complete list by year and title of regulatory documents for which RAQC and the Board of Directors approved and submitted comments.

1997

U.S. FDA Draft Guidance for Industry: GMPs for Active Pharmaceutical Ingredients

U.S. FDA Proposed Rule: Reporting Errors and Accidents in Manufacturing (CBER)

U.S. FDA Draft Guidance for Industry: Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics

1998

U.S. FDA Proposed Rule: Biological Products, Reporting Errors and Accidents in Manufacturing (CBER)

PIC Draft Guidance on GMPs for APIs

EMEA/CPMP Decision Trees for the Selection of Sterilization Methods

U.S. FDA Draft Guidance for Industry: Investigating Out-of-Specification Test Results in Pharmaceutical Production

ICH Q6A: Specifications

U.S. FDA Draft Guidance for Industry: Submitting Documentation for the Stability of Human Drugs and Biologics

1999

U.S. FDA Request for Comment: CGMP Recordkeeping Burden

USP <1> Injections

U.S. FDA Draft Guidance for Industry (ANDAs): Blend Uniformity Analysis

U.S. FDA Draft Guidance for Industry: BACPAC I: Intermediates in Drug Substance Synthesis: Bulk Actives Postapproval Changes: Chemistry, Manufacturing and Controls Documentation

U.S. FDA extended comment period regarding Site Specific Stability in regards to U.S. FDA Draft Guidance for Industry: Submitting Documentation for the Stability of Human Drugs and Biologics

U.S. FDA Proposed Rule: NDA/ANDA Post-Approval Changes

2000

EMEA/CPMP Draft Note for Guidance on Process Validation

EMEA Draft Annex 15 to EU GMP, Process Validation

EMEA Draft Annex 17 to EU GMP, Parametric Release

ICH Q7A, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

Canadian TPP Sterile Product GMP Revision

U.S. FDA Draft Guidance for Industry, Analytical Procedures and Methods Validation, CMC Documentation

2001

Proposed Rule; Good Tissue Practices for Manufacturers of Human Cellular and Tissue-Based products; Inspection and Enforcement

EU Note for Guidance on Quality of Water for Pharmaceutical Use (CPMP/QWP/158/01draft)

Canadian Draft Good Manufacturing Guidelines

"Change Tables" to open dialogue with U.S. FDA for the development of a Post-Approval changes for Sterile Products guidance

U.S. FDA Draft Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components

2002

U.S. FDA's dispute resolution process, part of Pharmaceutical CGMPs for the 21st Century—A Risk-Based Approach (comments were presented at the December 18, 2002 U.S. FDA OPS trade association meeting)

PIC/S draft recommendation on the Isolators Used for Aseptic Processing and Sterility Testing

Letter and proposal to U.S. FDA regarding PAC for sterile products

U.S. FDA's preliminary concept paper, "Sterile Drug Products Produced by Aseptic Processing"

2003

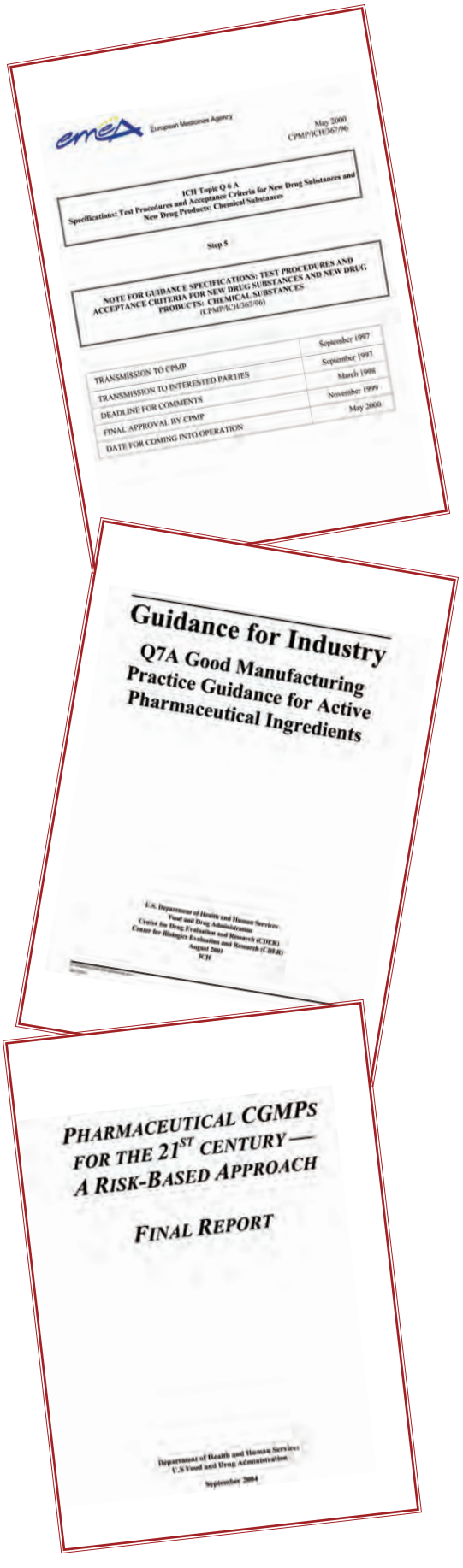
U.S. FDA Guidance for Industry: Comparability Protocols—Chemistry, Manufacturing and Controls Information

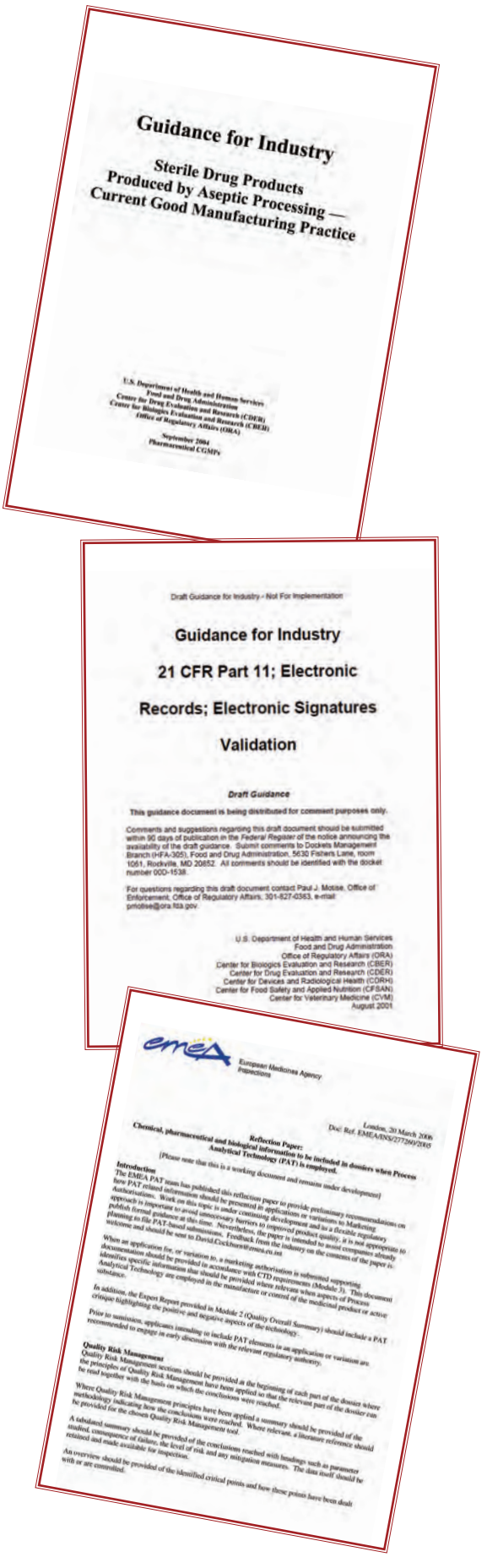
U.S. FDA Draft Guidance for Industry: Part 11, Electronic Records: Electronic Signatures—Scope and Application

U.S. FDA Draft Guidance for Industry: Sterile Products Produced by Aseptic Processing

U.S. FDA Draft Guidance for Industry: PAT—A framework for Innovative Pharmaceutical Manufacturing and Quality Assurance

U.S. FDA Draft Guidance for Industry: Comparability Protocols: Protein Drug Product





and Bilogical Products—Chemistry, Manufacturing and Controls Information

U.S. FDA Proposed Bar Code Rule

U.S. FDA Query on Reporting Biological Deviations in Manufacturing rule

EU Note for Guidance on GMP Annex II on Process Validation, Nonstandard Processes

WHO Sampling Guideline

WHO Validation Guideline

2004

U.S. FDA Draft Guidance for Industry: Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

U.S. FDA GMP in 21st Century: Risk and quality Glossary

U.S. FDA Draft Guidance for Industry: Powder Blends and Finished Dosage Units – Stratified In-Process Dosage Unit Sampling and Assessment

WHO Working Document QAS/04.068: Good Distribution Practices (GDP) for Pharmaceutical Products

WHO Guideline for Sampling of Pharmaceuticals and Related Materials, Working Document QAS/03.066/Rev. 2

EMEA Compilation of Case Studies Provided by Members of EFPIA and PDA Regarding Inspectional Issues with the EU GMP Annex 1 and the U.S. FDA Draft Guidance on Aseptic Processing

Addition to Chapter 1 to the EU Guide to Good Manufacturing Practice, Titled: Product Quality Review

Addition to Chapter 6 to the EU Guide to Good Manufacturing Practice

WHO Guidelines for Sampling of Pharmaceuticals and Related Materials: Risk Assessment with Respect to the n, r, p Plans

PDA DRAFT Proposal for Guidance for Industry ChromPAC, Manufacturing Chromatography Systems Post-approval Changes: Chemistry, Manufacturing and Controls Document submitted to Docket #03N-0059-Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach

U.S. FDA White Paper: Defining the Customer in a Regulatory Agency, submitted to Docket #2003N-0059 – Pharmaceutical cGMPS for the 21st Century: A Risk-Based Approach

U.S. FDA White Paper: Risk-Based Method for Prioritizing CGMP Inspections of Pharmaceutical Manufacturing Sites – A Pilot Risk Ranking Model. submitted to Docket #2003N-0059 – Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach

U.S. FDA Draft Guidance for Industry: Good Manufacturing Practices for Combination Products

U.S. FDA Draft Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations

U.S. FDA White Paper: Office of New Drug Chemistry Reorganization Write-Up

2005

USP proposed changes to general Chapter <1> Injections (Pharmacopeial Forum 31 (5) September/October 2005)

ICH Q9: Quality Risk Management

ICH Q8: Draft Consensus guideline Pharmaceutical Development

2006

U.S. FDA Direct and Proposed Final Rules: Current Good Manufacturing Practice Regulation and Investigational New Drugs;

U.S. FDA Draft Guidance for Industry: INDs – Approaches to Complying with CGMP During Phase 1

EU GMP Annex 1: Proposals for Amendment to the Environmental Classifi cation Table for Particles and Associated Text, Amendments to Section 42 Concerning Acceptance Criteria for Media Simulations, Amendment to Section 52 Concerning Bioburden Monitoring and Additional Guidance in Section 88 on the Sealing of Vials

EU Draft Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products

U.S. FDA Draft Guidance for Industry: Characterization and Qualifi cation of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases

EMEA Reflection Paper on Process Analytical Technology

2007

Chapter 1 (Quality Management) of the EU GMP Guideline for Human and Veterinary Products

Content of the Batch Release Certificate Referred to in Article 13.3 of Directive 2001/20/EC

Revisions to the Canadian GMPs

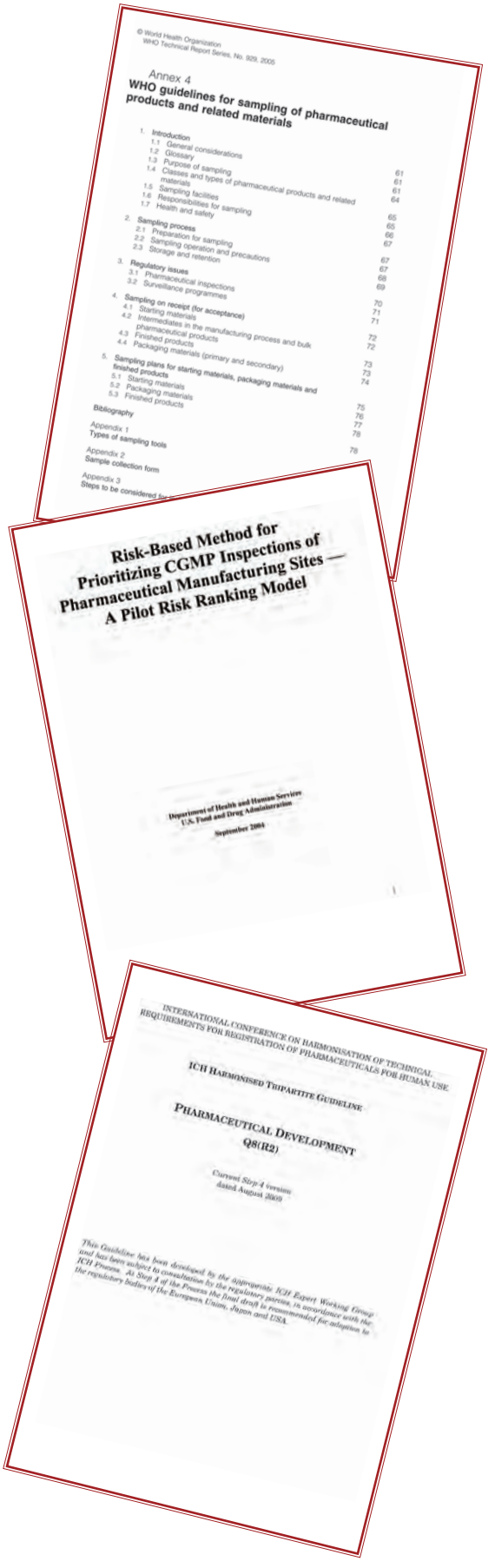
ICH Draft Guidance Q10 Pharmaceutical Quality Systems

EU Guideline on Production and Quality Control of Monoclonal Antibodies and Related Substances

2008

EMEA Guidelines to GMP, Draft Annex 11, Computerized Systems

EMEA Guidelines to GMP, Chapter 4



ICH Q8, Pharmaceutical Development

EMEA Guidelines to GMP, Draft Annex 2, Manufacture of Biological Medicinal Products for Human Use

Proposed Changes to U.S. 21 CFG 210 and 211

ICH Q4B, Evaluation and Recommendation of Pharmacopeial Tests for Use in the ICH Regions, Annex 3 on Test Particulate Contamination: Subvisible Particles

U.S. FDA Draft Guidance for Industry, Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes

2009

U.S. FDA Draft Guidance for Industry, Process Validation: General Principles and Practice

EDQM, European Pharmacopeia, Proposed revision to General Chapter XXXX:2031 Monoclonal Antibodies for Human Use

Proposed Revisions to Chapter 2.6.16. Test for Extraneous Agents in Biological Products, and Chapter 5.2.3. Cell Substrates for the Production of Biological Products

U.S. FDA Draft Guidance for Industry, Good Importer Practices

U.S. FDA Draft Guidance for Industry, Standards for Securing the Drug Supply Chain

EMEA Concept Paper on the Implementation of ICH Q10 into the EU GMP

Concept Paper on the Revision of the EU Guideline on Good Distribution Practice (GDP)

EMEA Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (Revision 4)

Draft Guidance for Industry and U.S. FDA Staff: Technical Considerations for Pen, Jet and Related Injectors Intended for Use with Drugs and Biological Products

EMEA Guidance, Use of Near Infrared Spectroscopy (NIRS) by the Pharmaceutical Industry and the Data Requirements for New Submissions and Variations

WHO Recommendations for the Evaluation of Animal Cell Cultures as Substrates for the Manufacture of Biological Medicinal Products and for the Characterization of Cell Banks

U.S. FDA's Proposed Rule, Postmarketing Safety Reporting for Combination Product

2010

WHO, Draft Good Practices for Pharmaceutical Microbiology Laboratories

U.S. FDA Draft Guidance for Industry, CMC Postapproval Manufacturing Changes

Reportable in Annual Reports

EMA/CHMP/BWP Draft Guideline on the Requirements for Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials

EMA/CHMP/BWP Draft Guideline on the Requirements for Quality Documentation Concerning Biological Investigational Medicinal Products in Clinical Trials

Eudralex, Volume 4, Good Manufacturing Practice, Draft GMP Annex 2, Manufacture of Biological Medicinal Substances and Products for Human Use

EU Guidelines to Good Manufacturing Practice, Part 1, Medicinal Products for Human and Veterinary Use, Chapter 2, Personnel

EU Guidelines to Good Manufacturing Practice, Part 1, Medicinal Products for Human and Veterinary Use, Chapter 1, Quality Management System

U.S. FDA Transparency Task Force; Request for Comments

EMA Explanatory notes for pharmaceutical manufacturers on the preparation of a Site Master File and content of a Site Master File

U.S. FDA Draft Guidance for Industry, Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products

21 CFR Part 4, Current Good Manufacturing Practice Requirements for Combination Products

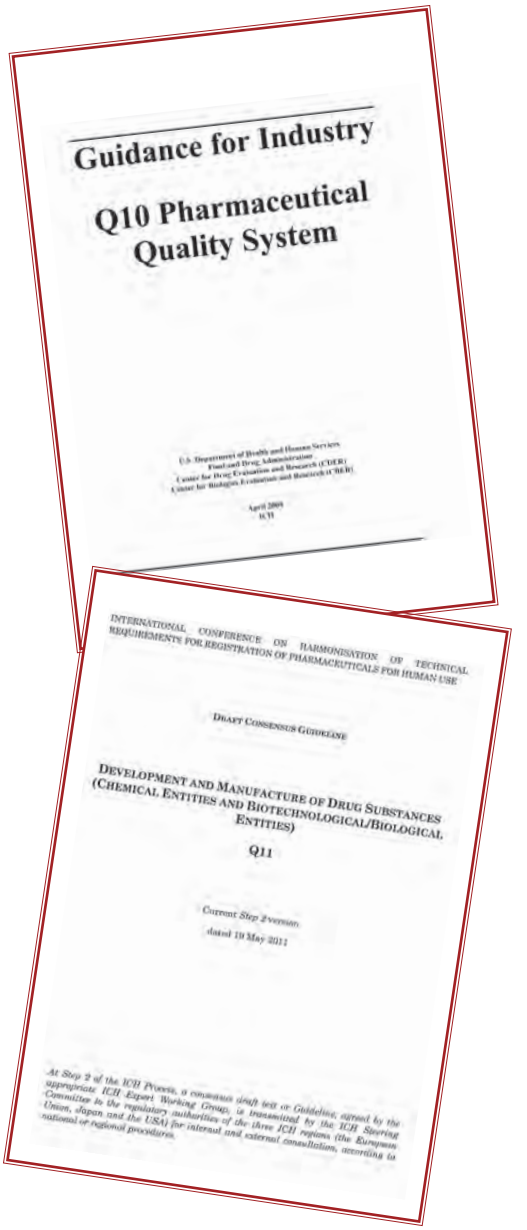
U.S. FDA Postmarketing Safety Reporting for Combination Products

2011

U.S. FDA Periodic Review of Existing Regulations; Retrospective Review under E.O. 13563

EudraLex, Volume 4, Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Revised EU GMP Chapter 5: Production

EudraLex, Volume 4, Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Revised EU GMP Chapter 7: Outsourced Activities

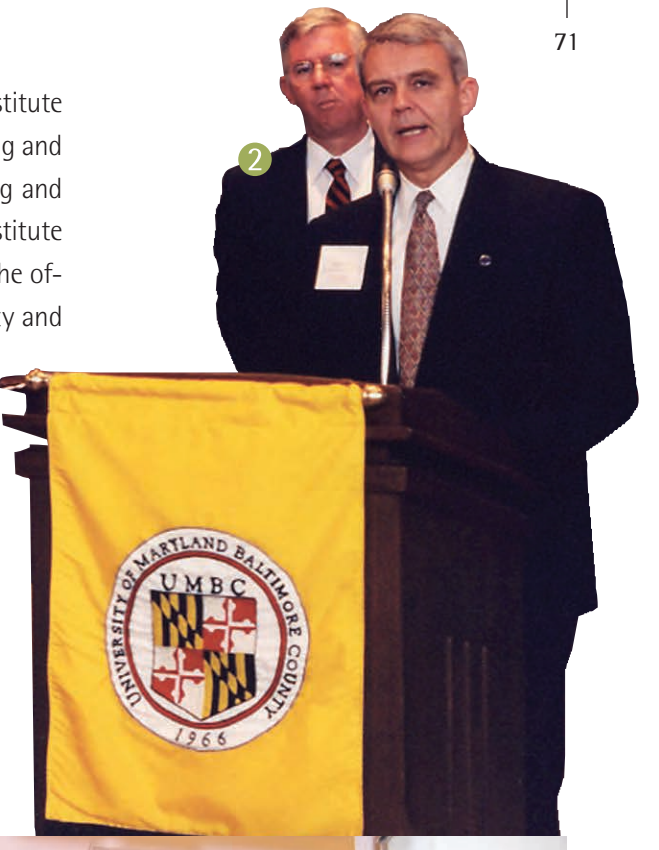


4. In 2000, PDA received the Center for Drug Evaluation and Research Director's Special Citation

CHAPTER 5

TRAINING & Research Institute

Former PDA President Ed Fry once said about the Training and Research Institute (TRI), "No event was more significant than the opening of the PDA Training and Research Institute." Indeed, over the last 15 years, the opening of the Training and Research Institute in 1997 stands out as a defining moment for PDA. The Institute is responsible for the education and training mission of PDA, which includes the offering of pharmaceutical and biopharmaceutical courses at the training facility and at off-site locations.



The 15-year history of the Training and Research Institute is really a tale of two facilities: the initial facility at University of Maryland Baltimore County Technology Center (1997-2007) and the new facility in Bethesda, Md.

The first TRI facility opened its doors on May 1, 1997. On September 18, 1997, PDA recognized the contribution and influence of former PDA Chair Dr. Kenneth Avis with the dedication of the "Kenneth Avis Aseptic Processing Laboratory" in his honor. Long-time PDA volunteer Dr. Michael S. Korczynski joined PDA's staff to lead TRI in its maiden year, overseeing 31 courses at the new facility.

By 1998, nearly all the equipment was in place to make TRI fully operational. The centerpiece of the facility was the installation of a 10 mL vial filling line, which was installed in a Class 100 flexible-walled cleanroom. This became the foundation for the two-week intensive Aseptic Processing Training Program, which was launched in 1999 and quickly became the flagship offering of TRI. The course is a massive undertaking for TRI and the dedication of the faculty and the staff to ensure a high-quality learning experience is evident with each session offered.

In 2007, TRI said goodbye to the UMBC facility and moved to 4350 East West Highway in Bethesda, Md., which also became the home to PDA's global headquarters. Now, the entire professional staff in the United States works out of the same location. PDA Chair Vincent Anicetti's view of the consolidated operations was: "This single site for PDA

1. The filling line in TRI's new fill suite in Bethesda, Md.
2. The first TRI facility opened its doors on May 1, 1997. PDA President Ed Fry addressed an audience that included members of the Board of Directors. Then Maryland Governor Parris Glendening looks on.
3. PDA Chair Vincent Anicetti cuts the ribbon to officially open TRI's new faciltiy in Bethesda, Md. in 1997. Fellow Board members and PDA staff look on.
4. Giuseppi Fedegari in front of the autoclave donated by Fedegari Autoclavi

headquarters and training operations provides our members with a state of the art production and laboratory facility to perform 'hands-on' and classroom training a few steps away from the PDA staff and FDA."

PDA staff worked closely with architects and engineers from Vectech Pharmaceutical Consultants, Inc. to design a state-of-the-art training facility, including an aseptic processing suite, a microbiology laboratory, a biotech laboratory, a clean-in-place laboratory and two classrooms.

From its very beginning, TRI's energetic staff and dedicated faculty never hesitated taking its lecture-based training to places as far away as Taiwan (inspectorate/industry training, 1997) Prague (2003), Basel, Switzerland (several times), and Japan (several times), to name a few. And it would be easier to count the number of U.S. States in which TRI has not offered lecture courses over the last 15 years than those in which it has! In 2004, TRI offered the aseptic processing program in Basel—the first time faculty and staff took a laboratory course abroad.

Over the years, TRI's reputation has grown worldwide, not only as a key source of hands-on training for professionals in the industry, but also those working with the regulatory authorities. The U.S. FDA saw immediate benefits to a hands-on training center virtually in its backyard. In July 1998, TRI hosted a two-week FDA Drug Compliance School for approximately 45 new CDER compliance inspectors. The success of that course led to a follow-up laboratory course for CDER officials in 1999 and additional trainings for FDA staff over the years.

World-class inspectorate training became an important part of the Institute's identity. In 2003, TRI staff and faculty traveled to Italy for its "Regulatory Compliance School for

the Italian Pharmaceutical Inspectorate," administered for the Italian Ministry of Health and the Instituto Supiore di Sanita. In 2005, TRI teamed up with Purdue University to provide training to members of the Kazakhstan Ministry of Health and the Kazakhstan National Center for the Assessments of Drugs, Items for Medical Purposes and Medical Equipment. TRI conducted two weeks of GMP training in a variety of areas. This training continued for the next two years, and in 2007, TRI conducted it on its own. In 2009, TRI again worked with Purdue University to provide world class GMP training in Russia, with the cooperation of the Russian Federal Service on Surveillance in Healthcare and Social Development (Roszdravnadzor). That same year, TRI conducted three training courses in Shanghai in conjunction with the PDA/FDA Asia Pacific Pharmaceutical Ingredient Supply Chain Conference.

5. The ribbon cutting in 1997, PDA Chairman Raymond Shaw, Jr., PDA President Edmund Fry, Michael Korczynski, and Antonio Moreira
6. Student receives training from John Lindsay on the proper use of a velocity meter as part of the Aseptic Process Training Program
7. Dave Matsuhiro performing a dynamic airflow evaluation with students during the "Aseptic Processing Training Program"
8. PDA TRI Dedication Plaque
9. Dedication of a TRI Lab to Kenneth Avis (holding plaque); Ed Fry (left), Raymond Shaw and Michael Korczynski
10. A student working in the cleanroom
11. A student dresses for the TRI cleanroom
12. Regulator Jeorg Neuhaus (second from right) participates in TRI Inspectorate Training in Italy
13. James Wamsley gives a tour of TRI to the visiting Kazakhstan Ministry
14. Members of the Kazakhstan Ministry of Health and the Kazakhstan National Center for the Assessments of Drugs pose with PDA's Rich Levy (photo on the left) and Bob Myers, whom they presented with a traditional, hand-made ceremonial robe (photo on right).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15. Art Vellutato discusses his TRI course at the 2009 PDA Annual Meeting

16. Students at the 2004 PDA Annual Meeting and TRI Courses in Orlando do some work outside (photo on right); TRI Director Robert Mello joins them.

17. Bob Myers (left facing) and James Wamsley (center) work with Vectech's William Bennett and Robert Ferer to develop the floor-plan for the new TRI facility

18. Students in the Micro Lab

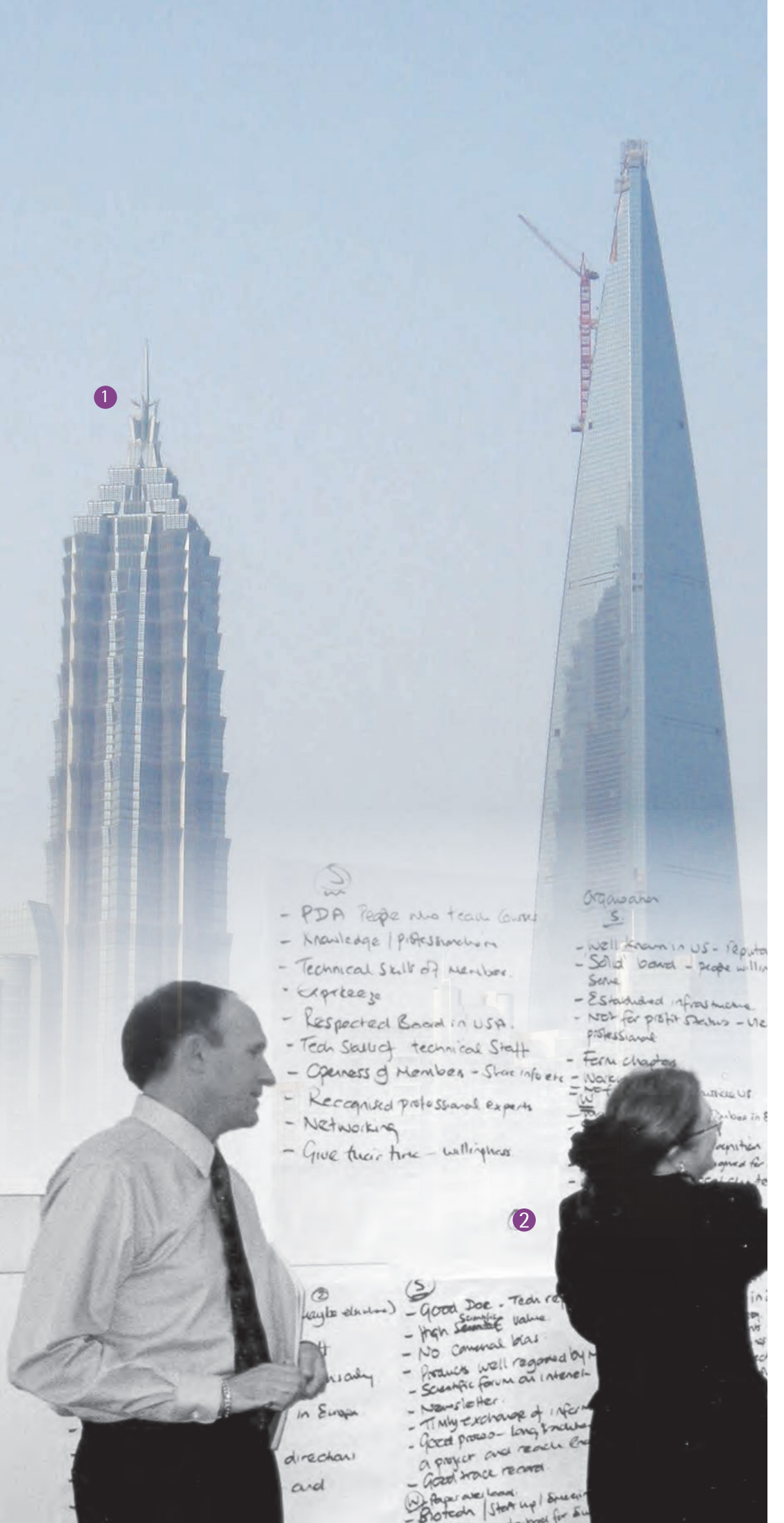
19. Dedication of a TRI lab to Theodore Meltzer (enter), with Maik Jornitz (left), Bob Dana, John Shabushnig and Richard Johnson

20. Visual Inspection Course at TRI

21. TRI demonstration at the 2008 Annual Meeting

CHAPTER 6

INTERNATIONAL Growth

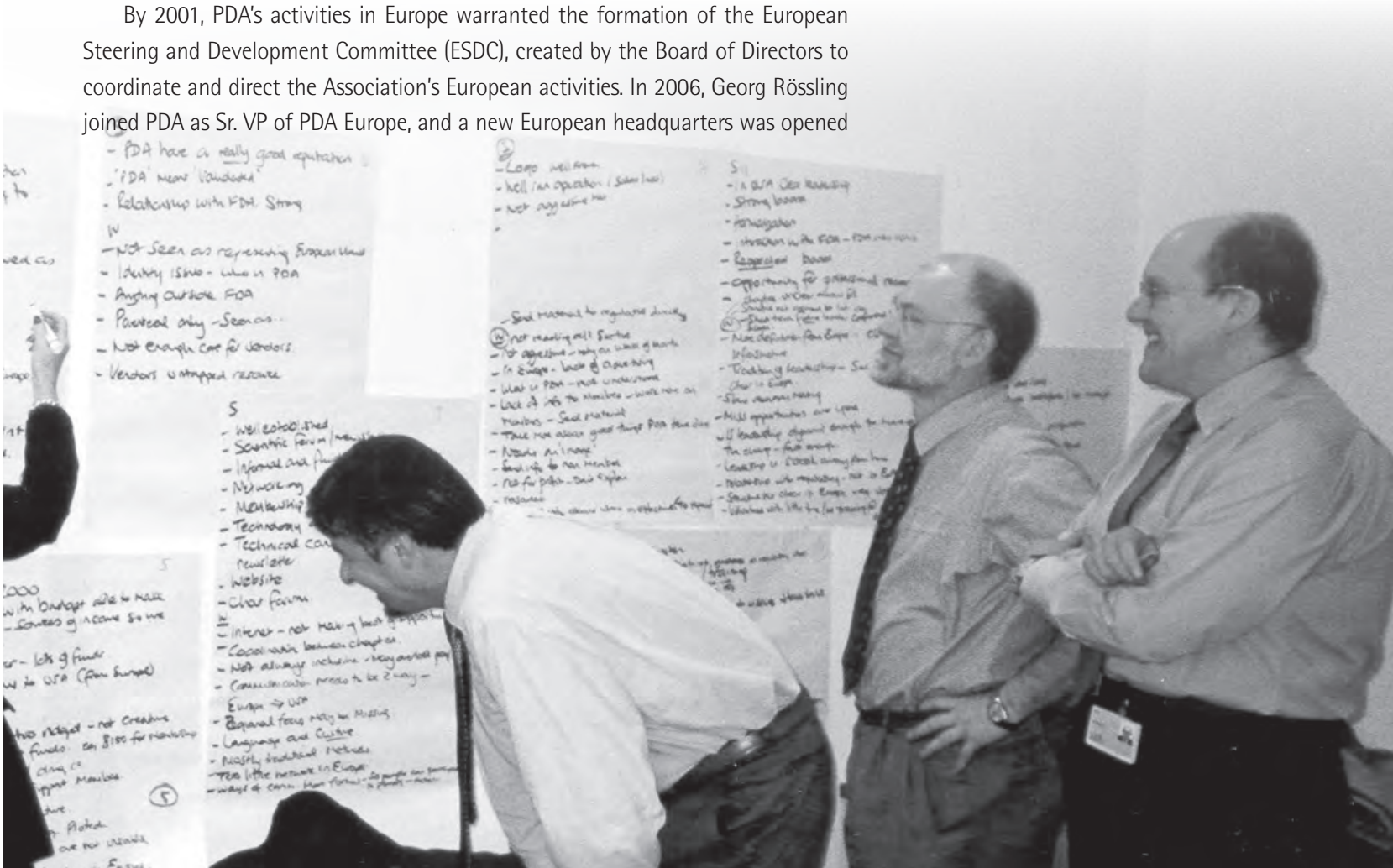


Globalization of the pharmaceutical industry presented PDA with its biggest opportunities and challenges leading up to its 65th Anniversary. By the beginning of 1997, PDA was well to its way of matching the industry's global reach, with 16 Chapters flourishing worldwide. By 2011, PDA supported more Chapters outside of the United States—Australia, Canada, China, France, Ireland, Israel, Italy, Japan, Korea, Puerto Rico, Taiwan, and the United Kingdom—than inside (10 U.S. Chapters) for a total of 22 Chapters.

In 1998, PDA ramped up the work done over the previous decade to grow overseas membership with the appointment of its first full-time staff person in Europe. Jim Lyda accepted the assignment as PDA's first VP for External and Regulatory Affairs. Soon after, the "European Report" was introduced in the *PDA Letter*. PDA's first technical conference in Italy was held in Pisa in June of 1999, with further conferences held in Verona, Taormina and Rome. In a very short period of time, new chapters were formed in Europe to represent and serve a growing membership: Italy, Central Europe, United Kingdom and Ireland.

By 2001, PDA's activities in Europe warranted the formation of the European Steering and Development Committee (ESDC), created by the Board of Directors to coordinate and direct the Association's European activities. In 2006, Georg Rössling joined PDA as Sr. VP of PDA Europe, and a new European headquarters was opened

1. A growing city, Shanghai, and a growing PDA membership
2. PDA leaders work with PDA volunteers at GlaxoSmithKline in London to plot ways to better serve members (2001): (l-r) Jim Lyda, Joyce Aydlett, Marco Budini, Georg Rössling and Colin Booth
3. PDA leadership with representatives of China's SIFDS after signing an agreement to form the SIFDS/PDA Joint Development Center (SHJDC)

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in the "green" building in Gleinicke, Germany, a suburb of Berlin. Today PDA Europe maintains its own website and manages all membership activity in Europe. Working closely with the Interest Groups, PDA Europe hosts over 25 conferences, workshops and training courses each year.

PDA Europe attained perhaps its most important milestone in October 2006, when it joined with the European Medicines Agency to host the first PDA/EMA Joint Conference in London. Planning for the Joint Conference started in 2005 with the formation of the planning committee, which selected the theme of the inaugural conference, "Understanding the European Environment." The potential for this conference: to grow into a European corollary to the PDA/FDA Joint Regulatory Conference (begun in 1990) was obvious to all following the success of the 2006 meeting, which drew over 400 attendees.


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As reported in the Nov/Dec 2006 *PDA Letter,* planning committee member and EMA official David Cockburn said in his opening remarks to the 2006 PDA/EMA Joint Conference, "The high number of attendees at this first event demonstrates the high level of interest that there is within the GMP community in the topics under discussion on the agenda. One of the primary aims of the conference is to create better understanding of the European pharmaceutical framework

in the GMP area, which can be considered fairly complex."

The next PDA/EMA Joint Conference took place in February 2008 in Budapest, Hungary and featured an "open meeting" on behalf of the EMA Inspections Sector to foster consultation on draft Annex 2 of the European GMP. The third PDA/EMA meeting was held in October of 2009 in downtown Berlin. In 2011, the PDA/EMA Joint Conference returned to the Agency's home city, London.

The growth and success of the PDA/EMA Joint Conference is a testament to the hard work, and dedication support of PDA's members in Europe, including those in the regulatory agencies. Their efforts helped PDA become a contributor at the EMA's annual Interested Parties Meetings conducted by the Agency's Inspections office and the GMP Inspectors Working Group, which coordinates and advises on the inspections activities in Europe. PDA has been represented at this meeting by staff and/or member volunteers consistently for the past 5 years. In 2007, a PDA delegation was invited to participate in the EMA/Biologics Working Party (BWP) to discuss PDA commentary on the draft viral safety guidance for IMPs. The next year, PDA's invitation to the BWP scientific discussions on monoclonal antibodies resulted in the establishment of a PDA Monoclonal Antibodies Workshop, now offered for the fourth time in 2011.

4. PDA's Leslie Zeck (standing left) and Russell Madsen (staning right) with the planning committee for the 2002 PDA International Congress

5. PDA teamed up with IABS to host a conference on process validation in Berlin in 2001: (l-r) John O'Conner, Genentech; Christopher Joneckis, FDA; Anthony Ridgeway, Health Canada; John Purves, EMEA; Vincent Anicetti, Genentech

6. Jim Agalloco, Russell Madsen, Stephen Bellis, Gordon Farquharson

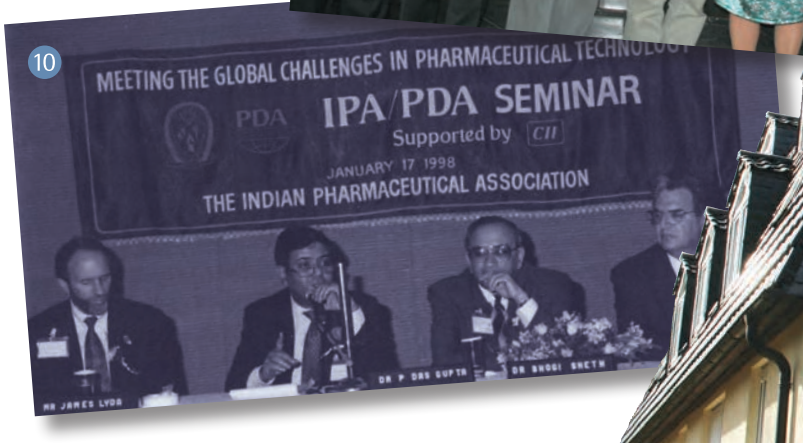
7. PDA and PDA Italy Chapter Conference on Global Pharmaceutical Manufacturing and Quality Strategies

8. PDA Italy Chapter presented highlights of the 2001 PDA/FDA Joint Regulatory Conference with Jim Lyda, Vincenzo Baselli, Claudia Nardini, Gabriele Gori

9. Attendees at the R³Nordic Annual Conference in Oslo

10. 1998 IPA/PDA Seminar with (l-r) James Lyda, Dr. P. Das Gupta, Bhogi Sheth and Ira Berry

11. PDA's "Green Building" outside of Berlin



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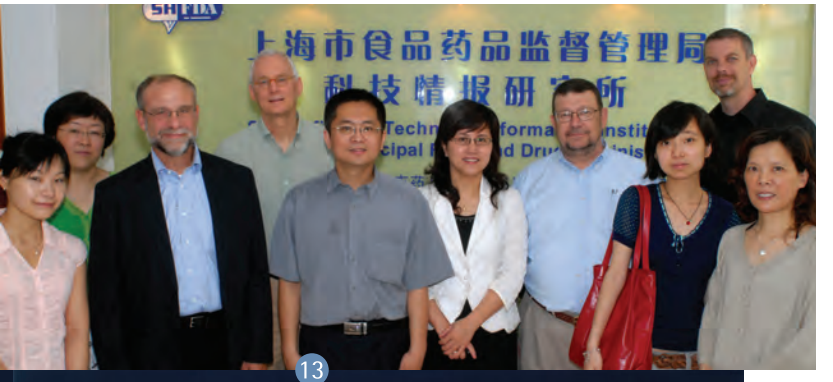
In parallel to these efforts to serve industry professionals in Europe, PDA has had an eye towards serving their counterparts in Asia. PDA's efforts to work with Taiwan Pharmaceutical Manufacturers Association culminated in the formation of the PDA Taiwan Chapter in 1997. The Korea Chapter was chartered in 1998.

The Japan Chapter—PDA's first outside of the United States has evolved into one of the largest and most self-sufficient Chapter. Today, it boasts over 700 active members and in 2011 will host its 18th Annual Meeting. The event has grown so popular that the Chapter's 2010 Annual Meeting, themed "Moving from Quality Assurance to Quality Management," drew over 600 attendees.



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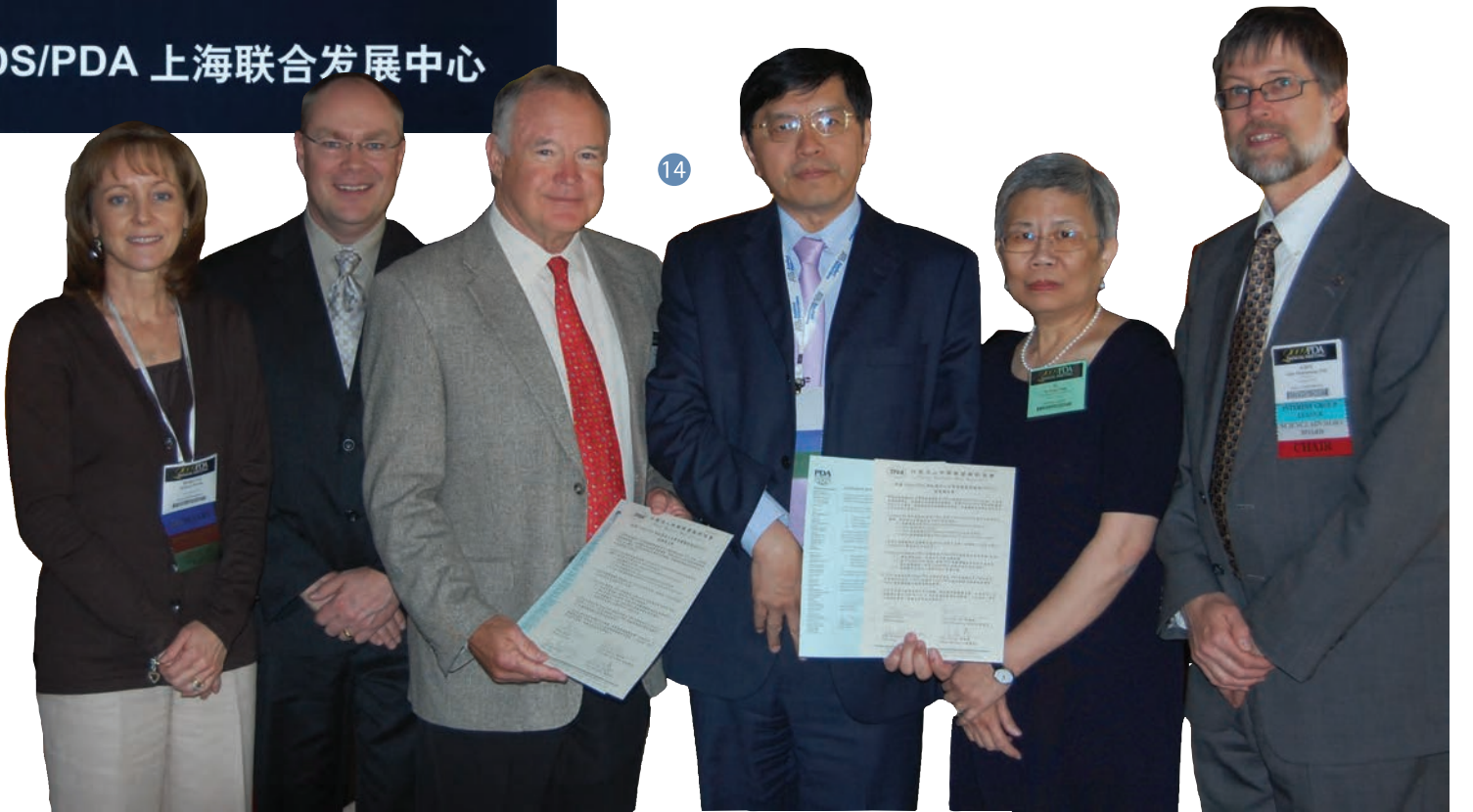
From the Japan Chapter's early days in the 1990's, one of its members has sat on the PDA Board of Directors: Dr. Kunio Kawamura (served on BoD from 1994-1997), Dr. Toshiaki Nishihata (1998), Taiichi Mizuta (2000-2002), Yoshihito Hashimoto (2003-2008), and Junko Sasaki (2008-present).

PDA's expanding membership in Asia was demonstrated by the PDA Pacific Rim Congress in Singapore in 2004 and again in 2006 with meetings in India (PDA/USP Joint Symposium) and Japan (2006 PDA Asia Pacific Congress).



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In 2008, PDA began working in earnest to help manufacturers secure supplies from China, both by focusing on growing its membership there and by holding its PDA/FDA Quality Systems conference in Beijing and in Shanghai. That same year, PDA signed a Memorandum of Understanding with the Shanghai Institute for Food and Drug Safety (SIFDS), a part of the Shanghai FDA, to create the SIFDS/PDA Joint Development Center. The next year, the PDA/FDA Asia Pacific Pharmaceutical Ingredient Supply Chain Conference and TRI courses were held in Shanghai.

In 2010, PDA hosted an intern from the Korea Food & Drug Administration, as part of the Korean government's Long-Term Fellowship Program for Overseas Study. Hee-Young "Hailey" Park worked at PDA for twelve months, meeting weekly with Richard Levy, Sr. VP of Scientific and Regulatory Affairs, to discuss various aspects of biologics manufacture and the regulatory requirements. On top of filing routine reports with her Agency, Hailey contributed to the *PDA Letter* a series of articles about the Korean regulatory system.

12. 2008 PDA/FDA Quality Systems Conference in Shanghai
13. SIFDS/PDA Shanghai Joint Development Center
14. PDA and SIFDS officials form the SIFDS/PDA Joint Development Center (SHJDC)
15. 2009 PDA/FDA Asia Pacific Pharmaceutical Ingredient Supply Chain Conference
16. PDA President Neal Koller (standing right) accepts a gift from Woo-Hyun Paik of the PDA Korea Chapter
17. Korean regulator Hee-Young "Hailey" Park at the end of her international internship with PDA
18. The Puerto Rico Inaugural Event in 2007

CHAPTER 7

the CONFERENCES

1

2

PDA's first event, the Annual Meeting is the place for PDA's members to learn about the latest industry scientific trends, technological developments, and PDA activities. This event also allows PDA's volunteers to congregate to manage the business of PDA and advance technical projects. The Annual Meeting features the largest exhibit hall of any PDA event.

For many years, the Annual Meeting was PDA's biggest fall event, held in Philadelphia and then Washington. Since 2002, PDA has moved the meeting to different regions of the United States. PDA also began holding the Annual Meeting in the spring in 2004. What follows is a collection of photo montages from each Annual Meeting, 1997-2011, organized by year and location.

1. When the attendees go marching in...from the plenary session at the Ritz Carlton to exhibit hall at the New Orleans Marriott during the 2002 Annual Meeting
2. A marching band again rallies attendees to the exhibition at the 2010 Annual Meeting

Philadelphia, PA

1997, 2000

Washington, DC

1998, 1999, 2001

New Orleans, LA
2002

Atlanta, GA
2003

Orlando, FL

2004, 2010

Chicago, IL

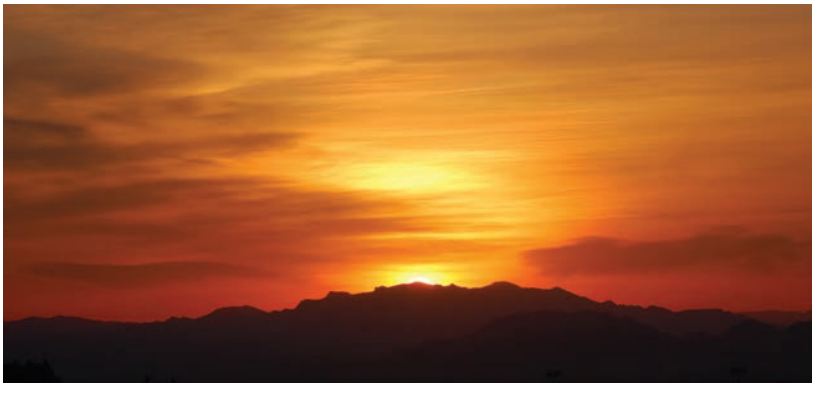
2005

Anaheim, CA

2006

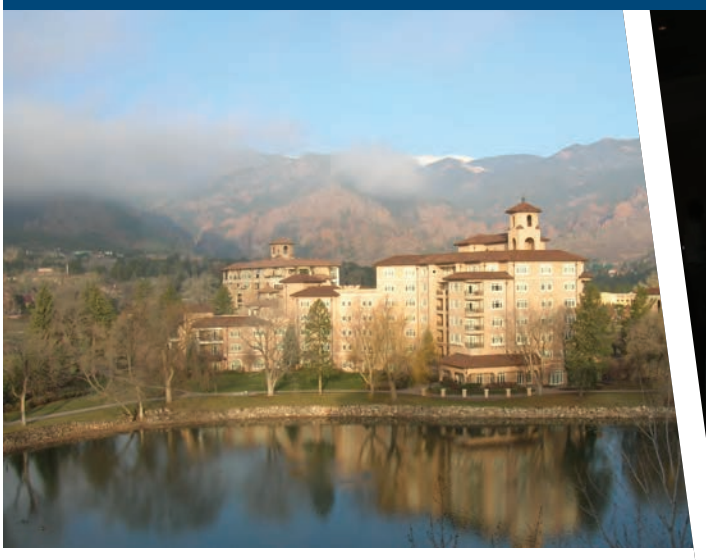
Las Vegas, NV

2007, 2009



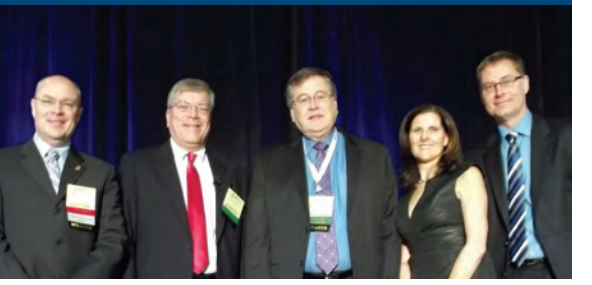
Colorado Springs, CO

2008



San Antonio, TX

2011

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Co-Sponsored Meetings with Regulatory Agencies

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An evolutionary step in PDA's involvement in the regulatory process with the U.S. FDA was the development of the PDA/FDA Joint Regulatory Conference. This meeting established a new opportunity for professional collaboration with the U.S. FDA, and has grown in scope and attendance. The conference is now entering its third decade and is going strong, as it is usually the most highly attended event each year.

The value of collaborating face-to-face became obvious to the U.S. FDA officials and PDA members, so additional cosponsored meetings have been developed over the last 15 years on important regulatory and scientific topics like supply chain management, viral clearance, quality systems, ICH guidelines, adventitious viruses/cell substrates, glass quality.

As PDA became more active in Europe over the last 15 years (see Chapter 6), opportunities to collaborate with EU and member state health authorities also grew. The European Medicines Agency (EMA) and PDA teamed up first in 2003 to cosponsor a conference on Virus Safety. Two years later, the first PDA/EMA Joint Conference was held. Like the PDA/FDA conference, the PDA/EMA Joint Conference is a large event that covers multiple relevant and important regulatory topics. It has been held every other year since 2005.


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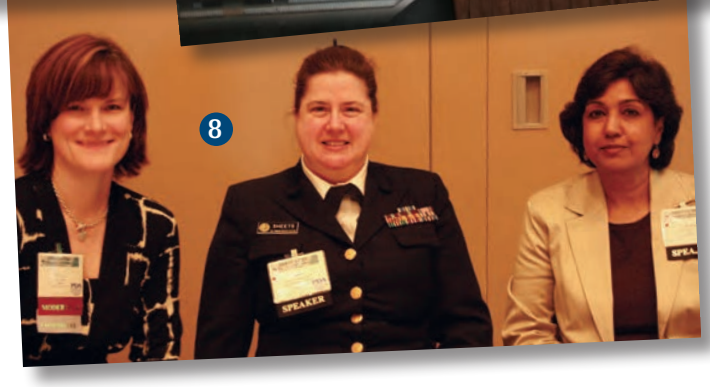
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3. Attendees at the 2000 PDA/FDA Joint Regulatory Conference
4. PDA/FDA lighting gel
5. Networking at the 2000 PDA/FDA Joint Regulatory Conference
6. PDA's Jim Lyda (right) gets ready to present the Berlin Bear to Riccardo Luigetti of the EMA (left) and Lothar Hartmann, F. Hoffmann-La Roche, as Georg Rössling announces the gift
7. The PDA/FDA Joint Regulatory Conference has become a "must attend" event over the last 20 years
8. Speakers at the 2010 PDA/FDA Vaccine Conference
9. Panelists at the 1998 Joint Regulatory Conference
10. Panelists at the1997 PDA/FDA Joint Regulatory Conference
11. Networking at the 2010 PDA/FDA Joint Regulatory Conference Gala
12. Georg Rössling (left) and Jim Lyda (right) thank 2009 PDA/EMEA Joint Conference planning committee chairs Veronique Davoust, Pfizer and Katrin Nodop, EMEA
13. Richard Johnson speaks with FDA's Deborah Autor at the 2010 PDA/FDA Pharmaceutical Supply Chain Workshop

When Tragedy and Mother Nature Strike

In 2001, PDA's annual Joint Regulatory Conference with the U.S. FDA had to be cancelled during the second day due to the tragic terrorist attacks in New York City and at the Pentagon, just miles from the hotel in which the meeting was held. Speakers, attendees and staff alike were shocked by the news as it unfolded live on the televisions in the hotel lobby. People were stuck in Washington as the city's transportation was halted and air traffic was grounded. Ed Fry wrote in the *PDA Letter* the following month: "My hat is off to the speakers, panelists and audience who remained calm and did the best they could under the most horrible of circumstances. I am also very proud of the PDA staff, who stayed on the job to make sure the attendees were cared for and organized arrangements with the hotel for all the out-of-towners. Following 9/11, PDA staff pooled their contributions to the American Red Cross Disaster Relief Fund, which were matched by PDA.

Tragedy struck the United States again in 2005, just weeks before the PDA/FDA Joint Regulatory Conference. Only this time, it was Mother Nature's wrath in the form Hurricane Katrina, the sixth strongest Atlantic hurricane ever recorded. The destruction left in the wake of the hurricane still impacts New Orleans and other Gulf cities to this day. PDA teamed up with Novatek International and EMD Chemicals to raise money for relief work. Over $7,000 was raised and used to buy pharmaceuticals for Bayouclinic Inc, a not-for-profit clinic in Bayou La Batre, Alabama.

14

While not as devastating or deadly, the spring of 2010 eruption of Eyjafjallajokull in Iceland resulted in an ash cloud so large that travel throughout Europe was interrupted. Some reports say the volcano caused the worst travel disruption in Europe since the Second World War. Needless to say, PDA Europe's events during that timeframe were not very well attended.

15

PDA members responded again to another natural disaster in 2011. The earthquake and ensuing Tsunami in Japan has had devastating effects on that country. PDA responded by matching employee contributions to the Red Cross Japan Disaster Relief fund. PDA also provided a link on its website encouraging members to contribute, as well. Over $4,000 was raised by the end of March from members and over $5,000 from the employee/PDA match contributions totaling in $9,493 in relief funds.


16

1997

PDA/FDA Joint Regulatory Conference
Washington, DC

FDA/PDA Open Conference on Post-Approval Changes for Sterile Aqueous Solutions (PAC-SAS)
Washington, DC

2000

PDA/FDA Joint Regulatory Conference
Washington, DC

PDA/FDA Public Conference on Technical Implementation of Part 11 (21 CFR Part 11, Electronic Records; Electronic Signatures)

PDA/FDA Conference on the Validation of Manufacturing Processes for Biologics

PDA/FDA Conference on Team Biologics

PDA/FDA Joint Regulatory Conference
Washington, DC

2001

System Based Inspections Workshops
New Brunswick, New Jersey; Los Angeles, California; San Juan, Puerto Rico

ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (with PhRMA and GPhA)
Chicago, Illinois; Princeton, New Jersey

PDA/FDA Viral Clearance Forum
Bethesda, Maryland

2002

PDA/FDA Joint Regulatory Conference
Washington, DC

ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (with PhRMA and GPhA)
Newport Beach, California; San Juan, Puerto Rico; Dublin, Ireland; Milan, Italy; Frankfurt, Germany

2003

PDA/FDA Joint Regulatory Conference
Washington, DC

ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients
Tokyo, Japan; San Francisco, California

PDA/EMEA European Virus Safety Forum
Langen, Germany

2006

PDA/FDA Joint Regulatory Conference
Washington, DC

PDA/EMEA Joint Conference
London, England

2007

PDA/FDA Joint Regulatory Conference
Washington, DC

PDA/FDA Co-Sponsored Conference Series on Quality Systems
Bethesda, Maryland and Dublin, Ireland

2008

PDA/FDA Joint Regulatory Conference
Washington, DC

PDA/EMEA Joint Conference
Budapest, Hungary

PDA/FDA Quality Systems
Shanghai and Beijing, China

PDA/FDA Pharmaceutical Ingredient Supply Chain Conference
Washington, DC

PDA Compendial Forum: Future Directions of the Pharmacopoeias, co-Sponsored with USP/EP/JP
Frankfurt, Germany

PDA/PICS/ISPE Quality Risk Management Conference
Geneva, Switzerland

2009

PDA/FDA Joint Regulatory Conference
Washington, DC

PDA/FDA Asia Pacific Pharmaceutical Ingredient Supply Chain Conference
Shanghai, China

PDA/EMEA Joint Conference
Berlin, Germany

2010

PDA/FDA Joint Regulatory Conference
Washington, DC

PDA/FDA Pharmaceutical Supply Chain Workshop
Bethesda, Maryland

PDA/FDA Vaccine Conference
Bethesda, Maryland

PDA/FDA Adventitious Viruses in Biologics: Detection and Mitigation Strategies Workshop
Bethesda, Maryland

14. The Katrina Relief Fund raised thousands of dollars at the 2005 PDA/FDA Conference, including a sizable contribution from FSK, presented by President Frank Kohn (right) to PDA's Nahid Kiani and Novatek International President Parsa Famili.

15. PDA launched a website to raise funds to help the Red Cross Japanese relief efforts in 2011

16. Sarah Graham of Allergan wins a digital camera at the 2008 PDA/EMEA Joint Conference in Budapest, Hungary

17. Attendees always come armed with questions to conferences cosponsored with the regulatory agencies; here, a question at the 2011 PDA/FDA Pharmaceutical Glass Conference

2011

PDA/FDA Joint Regulatory Conference
Washington, DC

PDA/FDA Pharmaceutical Supply Chain Conference and TRI Courses
Bethesda, Maryland

2011 PDA FDA Glass Quality Conference
Arlington, Virginia

PDA/EMA Joint Conference
London, England

PDA/Finish Medicines Agency, ATMPS -- Next Generations of Medicines
Helsinki, Finland

PDA/FDA Adventitious Virus and Novel Cell Substrates Conference
Rockville, Maryland

18

Other Meetings

Over the last 15 years, PDA has offered a number of additional meetings annually to address a growing number of technical and regulatory challenges. These events are driven by member volunteers, who approach PDA with a need and an idea, which becomes an opportunity then the event. Some of these events are so important, they've been offered biannually or annually. Others have received such strong support from the membership that they include exhibits and TRI courses.

19

18. PDA lighting gels
19. Networking with exhibitors at the 2010 Pharmaceutical Cold Chain Management Conference
20. 2007 Global PAT Conference
21. Posters are popular attractions at PDA conferences
22. 2004 Universe of Pre-filled Syringes

1997

PDA International Congress Osaka, Global Pharmaceutical Manufacturing in the 21st Century
Osaka, Japan

Viral Clearance Forum
Rockville, Maryland

PDA/AAPS Joint Workshop on Clinical Supplies, Issues Related to Formulation, Testing, Production, Packaging and Compliance
Arlington, Virginia

SUPAC-MR Training
Crystal City, Virginia

PDA Spring Conference, Directions for Parenteral Products: Current Issues in Technology and Regulation
Sand Diego, California

2nd PDA/AFM Pan American Conference on Pharmaceutical Manufacturing
Morelos, Mexico

PDA Special Scientific Symposium on Sterilizing Filtration of Liquids
Bethesda, Maryland

PDA Special Scientific Forum on Sterile Filtration Validation
Basel, Switzerland

1998

International Congress, Courses and Exhibition, Advances in Pharmaceutical Manufacturing – Technology for Tomorrow
Basel, Switzerland

Spring Conference, Courses and Exhibition, Preparing for a Successful Future in Biopharmaceuticals
San Francisco, California

Technical Update, Impact of ISO Technical Committee 209, Cleanroom Standards on Manufacturers of Medical Devices and Injectable Products
Bethesda, Maryland

PDA/AEFI Joint European Regulatory Conference, Courses and Exhibition, Drugs and Biologics Quality – Regulatory Initiatives and Technical Aspects
Barcelona, Spain

Training Conference, Courses and Exhibition, Training in Transition – Tools for the 21st Century
Baltimore, Maryland

1999

International Congress Courses and Exhibition: Bridging the Centuries through Innovation and Technology
Tokyo, Japan

Computer Supplier Auditing and Qualification
Bethesda, Maryland

Contract Manufacturing
Indianapolis, Indiana

Environmental Monitoring
Bethesda, Maryland

Investigating Out-of-Specification Test Results for Pharmaceutical Production
Frankfurt, Germany

Microbiology
Washington, DC

PDA European Forum, Steam Sterilization and Parametric Release – Science and Regulation
Basel, Switzerland

Plasma Fractionation
Bethesda, Maryland and San Francisco, California

Spring Conference Courses and Exhibition: Myths and Realities of Pharmaceutical Science
San Francisco, California

Steam Sterilization
New Brunswick, New Jersey

Sterile Bulk Pharmaceuticals
Bethesda, Maryland

Validation and Risk Analysis in the Manufacture of Sterile Products
Pisa, Italy

2000

PDA International Congress and Courses, Regulatory and Technological Challenges for One World
Basel, Switzerland

A Day with FDA
Verona, Italy and London, England

The Future of Validation: Evolving Requirements for Pharmaceutical Development and Manufacturing
Milan, Italy

PDA Conference on Isolation Technology, Course & Tabletop Exhibit

PDA European Forum 2000 and Course, Environmental Monitoring for Aseptic Processing of Medicinal Products
Basel, Switzerland

PDA Spring Conference, Courses & Tabletop Exhibit
Prescription for Successful Contracting: Your Product from Concept to Commercialization

PDA Special Scientific Forum on Visual Inspection

PDA Training Conference, Courses & Exhibition and Exhibition, New Century, New Challenges, New Solutions
Baltimore, Maryland

2001

PDA and PDA Italy Chapter Conference on Global Pharmaceutical Manufacturing and Quality Strategies
Taormina, Italy

PDA/IABs Conference on Process Validation for the Manufacturing of Biologics and Biotechnology Products
Berlin, Germany

PDA Japan Congress, Courses & Exhibition, Bridging the Healthcare and Pharmaceutical World in the New Millennium
Kyoto, Japan

PDA Spring Conference, Courses & Tabletop Exhibit, Modern Pharmaceutical Microbiology – Advancing the Science
Las Vegas, Nevada

PDA Conference on Good Electronic Records Management
Tampa, Florida

The Extractables Puzzle: Putting the Pieces Together – Resolving Analytical, Material, Regulatory and Toxicology Issues to Find Solutions
Rockville, Maryland

2002

PDA International Congress, Courses and Exhibition, Adding Value to the Pharmaceutical Industry-Leveraging the Future
Basel, Switzerland

PDA Spring Conference, Courses and Tabletop Exhibition, Current Practices in Aseptic Processing: Reaching a Common Understanding of the Regulatory and Technical Requirements
Orlando, Florida

PDA Isolation Technology: User Issues Conference, Courses and Tabletop Exhibition
East Brunswick, New Jersey

PDA/USP Joint Conference on Sterile Product Manufacturing
Fort Myers, Florida

PDA/AAPS Workshop, The Paperless Laboratory – Finally a Reality: Defining the Criteria for a Quality System
Arlington, Virginia

PDA 2002 Training Conference, Courses and Exhibition, Charting a Course for Success
Tampa, Florida

PDA and PDA Italy Chapter: Technology Transfer in Pharmaceutical Environments--Regulatory, Chemistry, Manufacturing, Controls and Engineering Aspects
Milan, Italy

2003

PDA International Congress, Courses and Exhibition, Back to the Future – Ahead to the Past
Prague, Czech Republic

PDA Spring Conference, Courses and Tabletop Exhibition, Bridging the Gap between Science and Compliance
San Diego, California

Taormina Conference and Exhibition, Managing for Quality in a Cost-Focused Environment
Taormina, Italy

2004

PDA International Congress, Courses and Exhibition
Basel, Switzerland

PDA Biennial Training Conference, Courses and Vendor Exhibit
Puerto Rico, Mexico

PDA Pacific Rim Congress
Singapore

PDA Visual Inspections Meeting
Berlin, Germany

PDA/R³ Nordic: Science, Industrial, and Regulatory Aspects of Clean Products and Devices
Stockholm, Sweden

Aseptic Processing: The New Guidance
Washington, DC and Frankfurt, Germany

PDA Universe of Pre-Filled Syringes
Hanover, Germany

2005

Aseptic Processing Training Workshop
San Francisco, California; Philadelphia, Pennsylvania; London, England and Las Vegas, Nevada

PDA International Congress, Courses and Exhibition
Rome, Italy

PDA Viral & TSE Safety Conference
Bethesda, Maryland

PDA Extractables/Leachables Forum
Bethesda, Maryland

PDA Visual Inspection Forum
Bethesda, Maryland

The Universe of Pre-filled Syringes
Munich, Germany

Nano-Pharmaceutical Conference
London, England

23. FDA's Rick Friedman at one of his many PDA podium appearances

24. PDA European Forum, Steam Sterilization and Parametric Release – Science and Regulation

25. Biennial Training 2002

26. Stanley Prusiner, 1997 Nobel Prize winner for medicine, spoke at the 2005 PDA Viral & TSE Safety Conference

2006

PDA/USP Joint Symposium
Hyderabad, India

PDA Pharmaceutical Anti-Counterfeiting Forum
Bethesda, Maryland

PDA Pharmaceutical Cold Chain Management Conference
Bethesda, Maryland

Workshop on Biotech Process Validation
Anaheim, California

PDA Biennial Training Conference
Philadelphia, Pennsylvania

Process Understanding and the Future of Validation
Barcelona, Spain

Status of Moist Heat Sterilization: Revisions to PDA Technical Report No. 1
Cork, Ireland; London England; Pavia, Italy; and Washington, DC

PDA Training Workshop 2006: FDA's Aseptic Processing Final Guidance
Prague, Czech Republic and Washington, DC

Meeting the Aseptic Processing cGMPs in the United States and European Union
Washington, DC

PDA Visual Inspection Forum
Berlin, Germany

PDA European Pharmaceutical Cold Chain Management Conference: A Global Approach to Harmonization
Berlin, Germany

PQRI Workshop on Excipient Testing and Control Strategies
Bethesda, Maryland

The Universe of Pre-filled Syringes and Injection Devices
Bethesda, Maryland

PDA's 1st Annual Global Conference on Pharmaceutical Microbiology
Bethesda, Md. USA

PDA Asia-Pacific Congress
Tokyo, Japan

Process Validation of Protein API Manufacturing
Berlin, Germany

ISPE/PDA Joint Workshop: Challenges of Implementing ICH Q8 and Q9 – Practical Applications
Washington, DC

Application of New Techniques of Sterilization for the Pharmaceutical Industry and Contaminant Removal
Paris, France


27

29

28

2007

PDA Emerging Manufacturing and Quality Control Technologies Global Conference
San Diego, California

Designing a Cleaning and Disinfection Programme for a GMP Environment
Vienna, Austria

Rapid Microbiology Methods: Make Them Work, Get Them Approved
Verona, Italy

Anti-Counterfeiting
Berlin, Germany

Continuous Improvement in the Pharmaceutical Industry & Impact of ICH Q10
Verona, Italy

Good Practices for Investigational Medicinal Products
Lyon, France

Best Practices in Aseptic Manufacturing
Milan, Italy

Quality by Design for Biopharmaceuticals: Concepts and Implementation – A PDA Workshop
Bethesda, Maryland

PDA Global PAT Conference
Bethesda, Maryland

PDA Pharmaceutical Cold Chain Management Conference
Bethesda, Maryland

PDA/EBE Conference on Biopharmaceutical Development and Manufacturing
Berlin, Germany

PDA Technical Report No. 1, 2007 Revision, Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control
Chicago, Illinois

Pharmaceutical Freeze Drying and Spray Drying
Cologne, Germany

Technology Transfer Today
Basel, Switzerland

Cleanrooms/RABS/Isolators
Berlin, Germany

Workshop on ICH Q10 (Draft): Pharmaceutical Quality System – Impact and Challenges
Milan, Italy and Berlin, Germany

2007 PDA Visual Inspection Forum
Bethesda, Maryland

Pharmaceutical Cold Chain Management
Berlin, Germany

Supplier Quality and Global cGMPs
Rome, Italy

Lonza Executive Awareness Seminar
Leesburg, Virginia

PDA's 2nd Annual Global Conference on Pharmaceutical Microbiology
Bethesda, Maryland

PDA Technical Reports – A Sneak Peek
Thousand Oaks, California

PDA Extractables/Leachables Forum
Bethesda, Maryland

Workshop Series on *PDA Technical Report No.1, Revised 2007, Validation of Moist Heat Sterilization Processes*
Södertälje-Stockholm, Sweden; London, United Kingdom; and Milan, Italy

PDA/R3 Nordic Conference on Modern Aseptic Production
Södertälje-Stockholm, Sweden

The Universe of Pre-filled Syringes and Injection Devices
Berlin, Germany

Pharmaceutical Industry and Contaminant Removal
Paris, France

2008

PDA Biennial Training Conference, Focus on Performance: Partnering for Business Success
New Orleans, Louisiana

PDA Conference on the Development and Regulation of Clinical Trial Supplies
Boston, Massachusetts

PDA Pharmaceutical Cold Chain Management Conference and Training Course: Global Regulations and Standards
Bethesda, Maryland

PDA Technical Report No 1, Revised 2007
Montreal, Canada

The Universe of Pre-Filled Syringes and Injection Devices
San Diego, California

PDA Technical Reports — A Fresh Look
San Francisco, California

PDA's 3rd Annual Global Conference on Pharmaceutical Microbiology
Chicago, Illinois

PDA Risk Management and Aseptic Processing Conference and Training Course
Bethesda, Maryland

PDA/AEFI Annex 1 Forum
Berlin, Germany; Hameln, Germany; Madrid, Spain; Milano, Italy; and Södertälje, Sweden

PDA Pharmaceutical Cold Chain

Management Conference: Current Good Distribution Practices
Berlin, Germany

Pharmaceutical Freeze Drying Technology
Berlin, Germany

Investigational Medicinal Products
Paris, France

PDA/EBE BioPharmaceutical Development and Manufacturing
Dublin, Ireland

Monoclonal Antibodies
Berlin, Germany

PDA Visual Inspection Forum
Berlin, Germany

Sterilisation Technologies in Development and Manufacturing of Parenterals
Milano, Italy

PDA Virus & TSE Safety Forum
Berlin, Germany

PDA Global QbD Conference
Frankfurt, Germany

Quality Requirements for Phase 0/1 Pharmaceutical Development Workshop
Colorado Springs, Colorado

27. FDA's Patricia Love at the 2006 Pre-filled Syringes Forum

28. Checking in with exhibitors at the 2011 PDA Cold Chain Conference

29. 2009 Global Supply Chain Conference

2009

Sterilization Technology Today and Tomorrow
San Francisco, California; New Brunswick, New Jersey; and San Juan, Puerto Rico

PDA Pharmaceutical Cold Chain Management Conference
Bethesda, Maryland

PDA Workshop: Cleanrooms Technology and Contamination Control
Las Vegas, Nevada

Workshop on FDA's New Guidance on Process Validation
San Francisco, California; Chicago, Illinois; Bethesda, Maryland; San Juan, Puerto, Rico; Munich, Germany

Cell Substrate Workshop
Bethesda, Maryland

Assessing Risks of Changing Sterile Drug Manufacturing Sites Workshop
Washington, DC

Combination Products Workshop
Washington, DC

PDA's 4th Annual Global Conference on Pharmaceutical Microbiology
Bethesda, Maryland

Visual Inspections Conference
Bethesda, Maryland

PDA Workshop on Annex 1 EU GMP Guide/Media Fills
Lyon, France

Global Challenges for IMPs
Rome, Italy

Rapid Microbiology Methods: Successful Implementation Strategies
Berlin, Germany

Workshop on Disposables
Munich, Germany

PDA Europe Update on Pharmaceutical Ingredients Supply Chain
Munich, Germany

2009 PDA Europe Conference on Endotoxins
Paris, France

3rd Workshop on Mycoplasmas
Berlin, Germany

Workshop on Container/Closure Systems
Berlin, Germany

Biopharmaceutical Development and Manufacturing Advanced Therapies and Vaccines
Munich, Germany

2nd Workshop on Monoclonal Antibodies QbD: Science to Submission Approaches
Munich, Germany

PDA Discussion Forum: Implementing Rapid Microbiology Methods
Frankfurt, Germany

QBD by Design – Putting Principles into Practice
Frankfurt, Germany

Pharmaceutical Freeze Drying Technology
Frankfurt, Germany

Pharmaceutical Cold Chain Management
Berlin, Germany

Workshop: The Future of Glass as Parenteral Primary Packaging
Venice, Italy

2009 The Universe of Pre-filled Syringes & Injection Devices
Venice, Italy

Sterilization Technologies for Pharmaceuticals
Milan, Italy

Validation of Aseptic Processes
Milan, Italy

2009 PDA France Chapter Workshop: Annex 1 to EU GMP Guide Impact on Fill and Finish Practices
Bordeaux, France

2010

Lean Manufacturing Workshop
Orlando, Florida

Pharmaceutical Cold Chain Management Conference
2010, Bethesda, Maryland

PDA Pre-Filled Syringe IG Workshop
Carlsbad, California

PDA Extractables and Leachables Workshop
Washington, DC

ICH Quality Implementation Working Group Integrated Implementation Training Workshops for ICH Q8, Q9 and Q10
Tallinn, Estonia; Tokyo, Japan; Washington, DC

PDA Biennial Training Conference
Baltimore, Maryland

Universe of Pre-filled Syringe and Injection Devices
Las Vegas, Nevada

PDA's 5th Annual Global Conference on Pharmaceutical Microbiology
Washington, DC

PDA Workshop on Aseptic Processing: Issues and Approaches
Bethesda, Maryland

PDA 2010 Pharmaceutical Freeze Drying Workshop
San Diego, California

2010 PDA Technical Report Workshop: Moist Heat Sterilizer Systems
Chicago, Illinois

Investigational Medicinal Products
Paris, France

Small Batch Production
Berlin, Germany

Technical Report – Media Fills
Berlin, Germany

Microbiology Methods
Berlin, Germany

Endotoxins
Milan, Italy

Stoppers & Elastomers
Cologne, Germany

Siliconisation
Cologne, Germany

Filtration
Berlin, Germany

Bio-Films
Frankfurt, Germany

Container Closure Systems + Annex 1
Berlin, Germany

Flexible Immediate Containers
Berlin, Germany

Cleanrooms/RABS/Isolators
Basel, Switzerland

Aseptic Technologies
Basel, Switzerland

Advanced Therapies
Berlin, Germany

Vaccines
Berlin, Germany

Monoclonal Antibodies
Berlin, Germany

Lean Manufacturing
Dublin, Ireland

Freeze Drying
Vienna, Austria

Cold Chain
Berlin, Germany

Visual Inspection
Berlin, Germany

Parenteral Conference
Berlin, Germany

Analytic Method Validation
Vienna, Austria

Modern Biopharmaceutical Manufacturing Contract Manufacturing
Amsterdam, Netherlands

2011

Pharmaceutical Cold Chain Management Conference
Bethesda, Maryland

PDA Atypical Actives Workshop
Bethesda, Maryland

PDA Pharmaceutical Ingredient Supply Workshop
Bethesda, Maryland

PDA Analytical Methods Development & Validation Workshop
Bethesda, Maryland

Single Use Systems Workshop
Bethesda, Maryland

Visual Inspection Forum
Bethesda, Maryland

Q10 Training Conference
Washington, DC

PDA's 6th Annual Global Conference on Pharmaceutical Microbiology
Bethesda, Maryland

IG Freeze Drying Technology
Brussels, Belgium

Stoppers + Elastomers
Rennes, France

IG Visual Inspection
Berlin, Germany

An Introduction to Visual Inspection
Berlin, Germany

Advanced Therapy Medicinal Products (ATMPs)
Helsinki, Finland

4th Monoclonal Antibodies Workshop
Basel, Switzerland

Virus/TSE Safety Forum
Barcelona, Spain

Pharmaceutical Cold Chain Management & Good Distribution Practice
Berlin, Germany

Freeze Drying Technology
Barcelona, Spain

The Universe of Pre-filled Syringes and Injection Devices
Basel, Switzerland

Green Pharmaceutical Production
Copenhagen Denmark

30. 2009 Cell Substrate Workshop

31. 2011 PDA Atypical Actives Workshop

APPENDIX 1

P D A

A FORUM FOR
SCIENTIFIC
EXCELLENCE

This publication is dedicated to the thousands of PDA members, past and present, without whose efforts the Association would not exist. Through their collective work, PDA members have made significant contributions to advance the science and technology of sterile drug products. The success of PDA and the industry to which it is committed is a tribute to their talent, expertise, and cooperation.

Raymond Shaw, Jr.
PDA Chairman

PDA
A Forum For
Scientific Excellence

Acknowledgments

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A debt of gratitude must be paid to the staff at PDA headquarters. Their assistance facilitated the project at all stages. Finally, a special thanks goes out to the PDA 50th Anniversary Publication Committee: Kenneth Avis, Frederick Carleton, Jack Cole, Edmund M. Fry, Russell E. Madsen, and Margaret A. Wanca. The Committee's input and interest helped bring the publication to fruition and is greatly appreciated.

Joseph Bedford
Ilana Drucker
October 1996

Introduction

Fifty years have passed since the formation of the Parenteral Drug Association (PDA) in 1946. In that half century, PDA has undergone dramatic change. Yet, certain themes in the story of the Association remain unchanged, linking five decades of members, leaders, and industry representatives in a common mission and experience.

For fifty years, the driving force at PDA has been the voluntary contributions of its members. PDA's members have shaped the Association, giving generously of their time, knowledge, and expertise. In recent times, the efforts of the members have been complemented by the work of the headquarters staff. Together, members and staff have elevated PDA to higher levels of excellence.

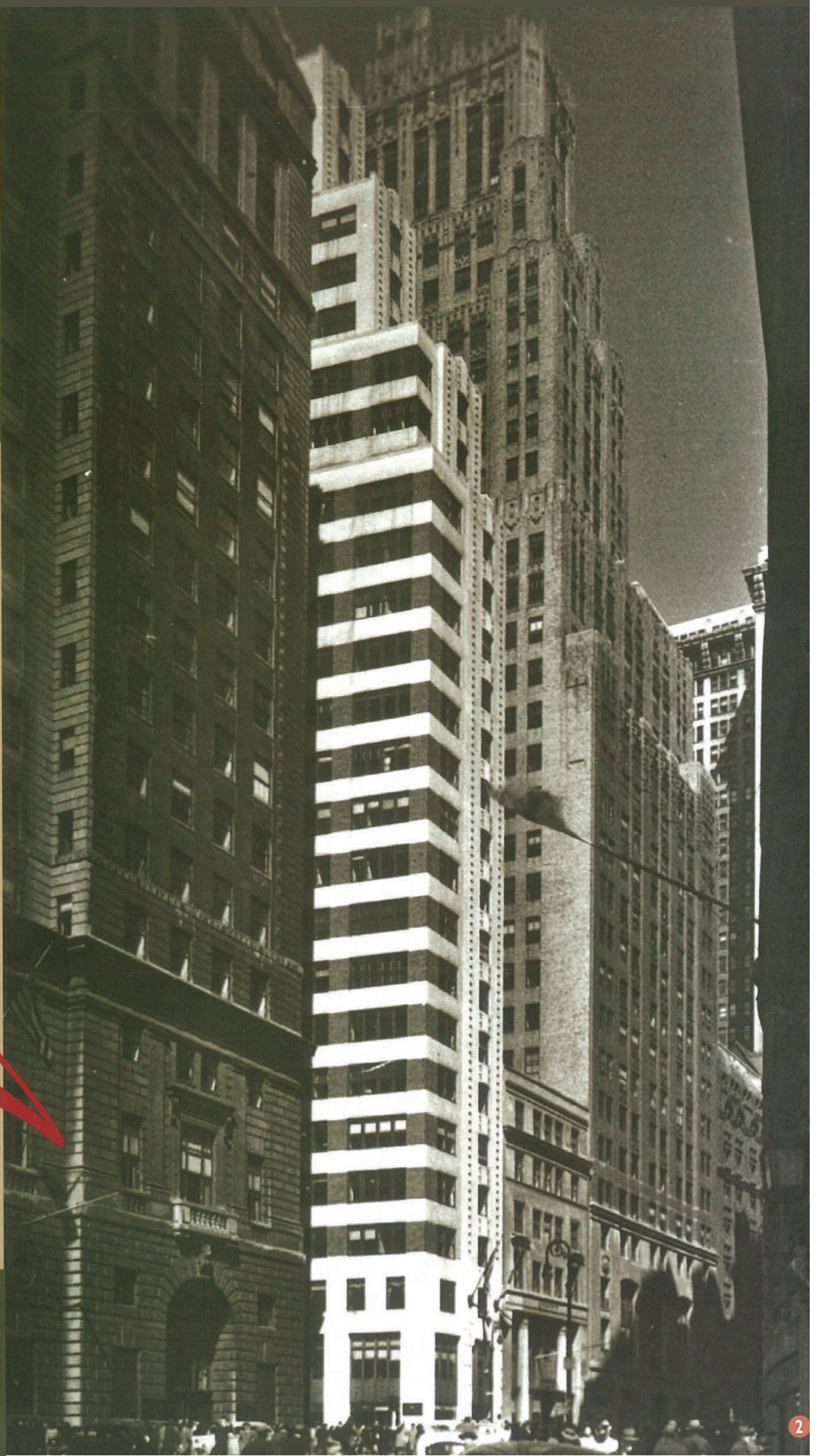
It would have been impossible to reach such levels without foresighted leadership. From the banding of a small cadre of men in 1946, PDA leaders have carried on the tradition of looking ahead. This visionary quality has made it possible for PDA to meet the needs of its members and stay on the cutting edge of a rapidly advancing industry.

As the industry evolved, PDA has grown in tandem. The Association has consistently expanded its services to educate and inform its members. PDA has also cultivated cooperative working relationships with the Food and Drug Administration as well as the United States Pharmacopeial Convention, serving as a vital resource on regulatory actions impacting the industry.

Today, PDA is an internationally recognized and respected pharmaceutical association. On this 50th anniversary occasion, the Association and its members can take pride in their accomplishments. Through the forum provided by PDA, the quality and standards of sterile drug products have significantly improved. And through its fifty-year commitment to the advancement of pharmaceutical science and technology, PDA has helped safeguard and promote the public health.

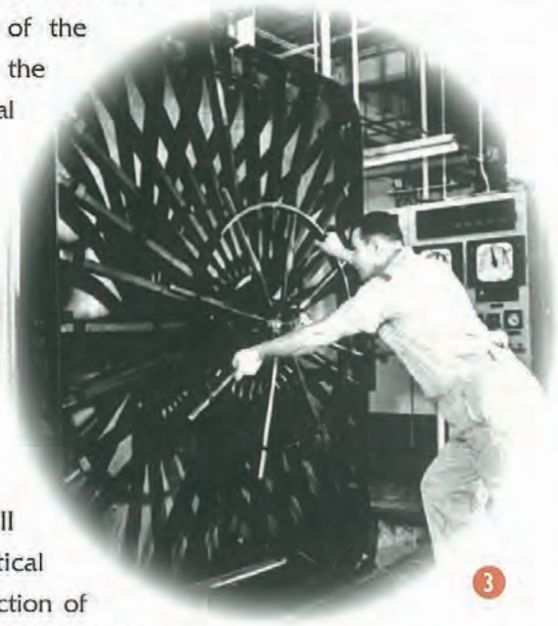
CHAPTER 1

The Founding VISION



The inspiration for one of today's most respected international pharmaceutical associations came from the founding vision of six individuals. Yet, the formation of the Parenteral Drug Association (PDA) in November of 1946 was a relatively quiet event. There were no photos taken or speeches scripted to mark the occasion. There were no banner-sized headlines or large press conferences. There was, however, a profound need for PDA.

It was no accident of history that PDA was organized in 1946. In fact, several major events set the stage for the new association. The 1925 issue of the *National Formulary* provided the first specifications for parenteral drugs in a U.S. compendium. Then in 1938, Congress passed the Federal Food, Drug, and Cosmetic Act, establishing new guidelines and procedures that pharmaceutical manufacturers were mandated to follow. Finally, the widespread use of penicillin during World War II catapulted the pharmaceutical industry into high scale production of parenteral products. Once peace was negotiated in 1945, manufacturers began in earnest to market parenteral drugs for civilian use. In this context, producing products free of contamination, maintaining sterility, and practicing aseptic techniques became increasingly important. PDA's timely founding helped its members meet these industrial and regulatory challenges of the postwar era.



Who were PDA's founders and what were their common concerns? The original incorporators included Rudolph N. Price of Metropolitan Labs; A. Lincoln Konwiser of C.F. Kirk Company; Max Gold of Gold Leaf Pharmacal Company, Inc.; Harold H. London of Estro Company; Arthur D. Herrick, an attorney; and Abraham P. Wagner. Most were owners of small businesses interested in advancing the science and technology of parenteral and sterile drug products.

Joseph Ushkow, President of Endo Laboratories Inc., also played a major role in forming PDA. Although not an incorporator, Ushkow was one of the prime organizers of PDA, and reportedly helped finance some of its early initiatives. His firm was one of PDA's first corporate members and contributed several leaders to its board of directors in ensuing decades.

The founding members had a vision for PDA. They laid out that vision in PDA's Articles of Incorporation, filed with the Secretary of State of New York on November 18, 1946. But as with all objectives, it is one thing to espouse them

"The manufacture of parenteral products and equipment more and more calls for the highest technical skills and abilities. In order to guarantee stability, uniformity, clarity, and sterility of solutions, new methods have [to be] constantly... developed and new control procedures devised. In recognition of these compelling facts a number of manufacturers joined hands several years ago and founded the Parenteral Drug Association, Inc."

Paul deHaen, 1951

1. **Signatures of PDA's founders on incorporation papers, 1946.**
2. **The bustling scene outside PDA's headquarters (third building, right), 39 Broadway, New York City, c. 1940s.** *Courtesy of the New York Public Library.*
3. **Lab worker opens door of sterilizer, c. 1940s.** *Courtesy of the American Institute of the History of Pharmacy.*
4. **Joseph Ushkow.**

The Founders' Mission

"(1) To foster and advance, in the interest of public health, the art and science of parenteral therapy... (2) to provide and disseminate information relating to parenteral drugs and parenteral therapy... (3) to foster and encourage a spirit of friendly cooperation among its members, and promote favorable relations between its members and the medical and pharmaceutical professions... (4) to cultivate and maintain cooperative relations with governmental departments and agencies... (5) to collect and disseminate... business and scientific information... (6) to sponsor research projects into matters of scientific and technical interest... (7) to promote higher standards in the production of parenteral drugs...."

and another to carry them out. The legacy of PDA's founders resides in the fact that they also put in place the programs and personnel to achieve their lofty vision.

To do so was not easy. PDA's early members were small businessmen, not employees or officers of the large ethical drug companies. Funding was tight and potential conflicts abounded. By creating its own organization, PDA placed itself in competition with some of the larger associations, such as the Pharmaceutical Manufacturers Association and the American Pharmaceutical Association. This made recruitment difficult for PDA leaders.

5

Still, they persevered, knowing there was a real purpose for the Association. They held informal meetings, mainly in Arthur Herrick's New York City law office at 39 Broadway, sometimes at local hotels, and other times in rented rooms at the New York Academy of Sciences. Out of these meetings came plans to carve a niche for PDA.

The first few issues of the *Bulletin of the Parenteral Drug Association* reflected this scrappy start. The journal was published by Arthur Herrick on loose sheets of mimeographed paper. But it was a beginning, and it covered interests of concern to PDA's members. First and foremost, it kept them abreast of regulatory matters, especially Food and Drug Administration (FDA) regulations. Early readers could find out how to handle FDA inspections, get information on the Federal Food, Drug, and Cosmetic Act of 1938, or meet *United States Pharmacopeia (USP)* standards. The *Bulletin* also served as a forum to discuss the pressing technical problems of the late 1940s, such as the clarity of solutions and multiple dose limitations.

5. **Sterile filling and packaging line for penicillin, c. 1940s.** *Courtesy of Merck & Co., Inc.*
6. **Program for PDA Annual Meeting, 1952.**
7. **First official PDA newsletter, 1949.**

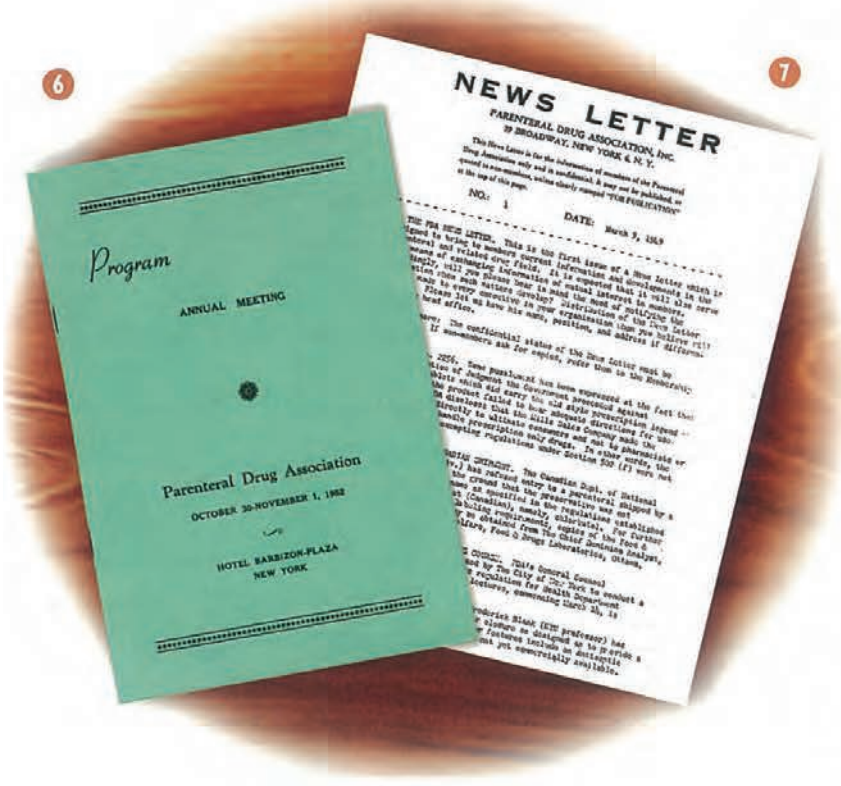
"I must not fail to acknowledge the debt of gratitude owed by the USP Committee of Revision to the pharmaceutical industry of which this Association {PDA} is playing an increasingly important role. We hope to conserve always the friendly cooperation which has characterized our relationships."

Lloyd C. Miller
Director of Revision, USP, 1957

Early members also took the step of publishing PDA's first newsletter. The premier issue appeared on March 9, 1949. The publication focused on industry news and regulatory affairs. Consequently, it freed up space in the *Bulletin* for more scientific and technical material.

It was not long, however, until these early initiatives were institutionalized. Informal gatherings gave way to PDA's first recorded annual meeting in 1951. That same year, under the direction of President Paul deHaen (Ames Company, Inc.), membership was opened to individuals, academics, and suppliers. The inclusion of suppliers proved to be a turning point in PDA history. They contributed much to the organization by financing the banquets, recruiting new members, and supplying vital information relating to the latest equipment and technologies.

In the context of burgeoning regulatory demands, gaining access to technological and scientific information through suppliers, vendors, and compendial officials became increasingly important. Accordingly, during Ushkow's term as president, the Association



Milestones in Compendial & Regulatory History

1820 USP is founded on New Year's Day in Washington, D.C.

1848 Drug Importation Act passed by Congress allows U.S. Customs agents to deny entry of adulterated drugs.

1852 American Pharmaceutical Association is founded (APhA).

1888 The *National Formulary (NF)* is established by APhA.

1898 Pure Food Congress, predecessor to FDA, focuses attention on movement to pass federal laws against misbranding and adulteration of food and drugs.

1902 Congress passes the Biologics Control Act in an effort to insure purity of serums, vaccines, and similar products used to prevent human diseases.

1906 The original Food and Drugs Act is passed by Congress prohibiting interstate commerce in misbranded and adulterated food, drinks, and drugs. The Act recognizes *USP* and *NF* standards of strength, quality and purity, and mandates the federal government to enforce them.

1925 *NF V* provides first specifications for parenteral drug products in a U.S. compendia.

1927 The Food, Drug, and Insecticide Administration is formed as a special law enforcement agency. In 1930, it changes its name to the Food and Drug Administration (FDA).

1936 *NF VI* produces definition of clarity, providing first standard for clarity in ampul solutions.

1937 An elixir of Sulfanilamide containing a poisonous solvent kills 107 persons, mostly children, and speeds passage of pending legislation.

1938 Congress passes the Federal Food, Drug and Cosmetic Act of 1938. It requires new drugs to be proven safe prior to marketing and authorizes factory inspections. It also reaffirms *USP* and *NF* standards for strength, quality, and purity, and adds *USP* standards for packaging and labeling.

1940 *USP* expands its scope to include injectable dosage forms.

1941 Insulin Amendment requires FDA to test and certify purity and potency of insulin.

1942 First standards for containers and first pyrogen test included in *USP XII*.

1945 Penicillin Amendment requires FDA to test and certify safety and effectiveness of all penicillins.

1953 Factory Inspection Amendment requires FDA to give manufacturers an analysis of samples and written reports of conditions observed during inspection.

8. **Kenneth Avis of Philadelphia College of Pharmacy and Science demonstrates new ampul rinser to visitors at laboratory, 1956.**
Courtesy of the American Institute of the History of Pharmacy.

9. **John Henderson, c. 1950s.**

10. **FDA inspector and drug manufacturing plant superintendent review control records to ensure against violations of Federal Food, Drug, and Cosmetic Act, 1956.**
Courtesy of FDA Archives.

reached out to the United States Pharmacopeial Convention, Inc. (USP). At PDA's 1953 Annual Meeting, USP Director of Revision Lloyd C. Miller addressed the conference on the use of methods to control the pain of injections. Two days later, USP Board Chairman Robert Swain was the featured speaker at the banquet, delivering a paper entitled "You Can't Win by Getting Sore." This was the first of many PDA meetings attended by high-ranking USP officials, and heralded the budding relationship between PDA and the nation's most influential compendial organization.

PDA's founding members also sought out areas of common interest with the FDA. In 1947, FDA Deputy Commissioner George P. Larrick appeared at a PDA meeting to deliver a paper on enforcement of the Federal Food, Drug, and Cosmetic Act. In 1951, FDA Associate Commissioner John L. Harvey spoke at a PDA meeting on the same topic. And in the mid 1950s, FDA's Earl L. Meyers began a cooperative relationship with PDA that lasted for over two decades.

PDA's founding generation also reached out to the international community. The first available membership roster, published in the January-February 1953 issue of the *Bulletin*, revealed that PDA had mem-bers in Israel, South Africa, New Zealand, Canada, and Puerto Rico. The seeds of PDA's later global expansion had already been planted.

At the same time, an international flavor was added to PDA's annual banquets. In 1955, John Henderson (Chase Equipment Corporation), a British native, was appointed chairman of the Arrangements Committee. Henderson became legendary for his work on the banquet, transforming it from a strict meat-and-potatoes meal into a full-scale gourmet event. Henderson, a gourmet cook in his own right, spent innumerable hours meeting with hotel staff to plan the affair. He made it common practice to introduce the chef after each banquet, much to the delight of the attendees. Former President Nathan C. Kirsch (Schering Corporation) recalls that "PDA's banquets became the talk of the industry — literally."

While almost everyone enjoyed the fine cuisine, members came mainly for the opportunity to exchange information with other professionals in the industry. Elliot Bartner of E.R. Squibb recalls his exact reason for joining PDA around 1950: "They were the experts, and I wanted to join them." Harold Newmark of Vitarine Company was attracted to PDA because it provided "a place

In the Shadow of Dinosaurs

Quality information was sometimes exchanged in the strangest places at PDA meetings during the late 1940s and early 1950s. One year following sessions at the New York Academy of Sciences, an evening cocktail party was held in the dinosaur section of the Museum of Natural History. Elliot Bartner, an early member, recalls that "a huge bowl of martinis and manhattans was laid out... in the dinosaur room of all places... So there we were... talking about scientific matters with dinosaurs all around us and this nice spread of food and drinks at our disposal."

to meet, a place to talk, a place to listen to science. PDA's utility was the exchange of information, the presentation of new data, and the opportunity to learn new approaches to manufacturing, standardization, and quality assurance."

The legacy of the founders is clear. Working with little resources, without the support of large companies, and distributing information in modest ways, the early members marched in stride to achieve their objectives. They wished to promote the public health by advancing the science and technology of parenteral and sterile drug products. They were also practical businessmen who realized it was necessary to band together in order to meet the regulatory and industrial challenges of their day. The founders had an intuitive sense of PDA's worth. And it inspired them to lay the foundation upon which future generations would build. ■

11

11. A news clip from *Glass Packer* featuring a photo of PDA board members, 1954. L/r: Arthur Herrick, Harold Blumberg, Floyd Hallet, David Ashkenaz, L. James Graham, and F.C. Ninger, 1954.

12. Syrette assembly line at E.R. Squibb & Sons, Brooklyn, New York, c. 1940s.
Courtesy of Bristol-Myers Squibb Company Archives.

PDA Presidents 1947-56

1947	Rudolph N. Price Metropolitan Laboratories, Inc.
1948	Paul A. Naef Sandoz Chemical Works
1951	Paul deHaen Ames Company, Inc.
1953	Joseph Ushkow Endo Laboratories, Inc.
1954	David M. Ashkenaz Wyeth Laboratories
1956	L. James Graham Burroughs Wellcome & Co.

12

CHAPTER 2

Putting Science First

The late 1950s was an era of major transition for PDA. Faced with a slowly growing membership, financial difficulties, and lack of recognition by the ethical drug industry, a new generation of volunteer leaders stepped forward to transform PDA from a trade association into a highly technical and scientific professional organization.

An early phase of this transition occurred in 1957, when David M. Ashkenaz (Wyeth Laboratories) was appointed editor of the *Bulletin of the Parenteral Drug Association*. Whereas previous editor Arthur Herrick relied on legalistic approaches to address regulatory issues, Ashkenaz was more apt to apply technology and science in this regard. Ashkenaz and his successor, Robert E. King (Philadelphia College of Pharmacy and Science), were part of a generation of PDA members who sought scientific solutions to regulatory challenges, and as a general rule, put science first when planning for PDA's future.

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2

The next phase of this transition was more dramatic: a shake-up of management. In 1958, PDA moved from New York City to Philadelphia, Pennsylvania. Herrick's position of executive director was abolished and power was transferred to the board of directors. President William S. Bucke (Lafayette Pharmacal, Inc.) led this development and guided the assumption of leadership by the board.

PDA's plans to put science first were reflected in the programs at the Association's meetings. Harold Blumberg of Endo Laboratories took the leading role in this process. Under his extended term as Program Chairman (1955-63), the quality of the speakers and papers presented at PDA meetings increased dramatically. And this was very important, since the programs reflected the thrust of PDA and the *Bulletin* mainly published papers, speeches, and audience commentary delivered at PDA meetings. Blumberg recently commented on his role in this transition. "If I am remembered for anything in PDA history, I hope it is that under my term as Program Chair, PDA changed from a group concerned basically with trade and regulatory issues into one concerned with technical and scientific matters. I'd like to believe that I had a lot to do with that change."

3

As part of its effort to promote parenteral science and technology, PDA established the "PDA Award" in 1965. It was granted annually to a college student who submitted the best paper on parenteral drugs and technology. The significance of this new award cannot be overstated. It raised the professional stature of PDA, encouraged college students to pursue studies in the parenteral sciences, and strengthened the Association's status as a nonprofit organization.

PDA's new focus on scientific and technical matters attracted members

4

from the ethical drug companies. So, too, did PDA's first membership drive. William A. Thawley of S.B. Penick & Company led the effort. As a long-time board member, head of both the Membership and Publicity Committees, and organizer of the annual meeting cocktail party, Thawley was a natural candidate to recruit new members. Due mainly to his work, PDA membership grew from 237 individual and forty-three corporate members in 1959 to 361 individual and fifty-nine corporate members by 1965.

Thawley's membership drive was part of a larger plan to place the Association on solid financial ground. William Bucke and Joseph W. Kouten (Smith, Miller, and Patch, Inc.) played leading roles in managing PDA's money.

As treasurer, Kouten diligently administered the Association's finances from the late 1950s through 1964. Meanwhile, Bucke urged PDA to raise its spending on programs and services in order to attract more members and increase revenues. Kouten's fiscal conservatism and Bucke's investment strategy paid off. PDA's financial assets grew from $10,652 in 1959 to $32,350 in 1965.

With membership and revenues multiplying, it became apparent that PDA needed to expand the operations of its headquarters. In response, PDA President Harold Dembo (Chicago Pharmacal Company) hired an agency to provide additional administrative services. He also spearheaded the 1961 effort to move PDA's headquarters office from 1420 Snyder Avenue to the Western Saving Fund Society building in Philadelphia, Pennsylvania.

While PDA was physically located in Philadelphia, it was obvious that the organization's focus was on matters taking place in Washington, D.C. During the early 1960s, the federal government increased its regulatory activities in regard to the pharmaceutical industry. Its efforts were prodded by Senator

1. **Robert King.**
2. **PDA's first logo appeared in 1960.**
3. **Billie Wickliffe (right) receives PDA Award for excellence in research from President Harold Blumberg, 1967.**
4. **PDA's Headquarters, located in Western Saving Fund Society Building, c. 1962.** *Copyright Courtland V. Hubbard, Courtesy of Temple University.*
5. **Joseph Kouten (left) receives Honorary Membership Award from President Kenneth Avis, 1968.**
6. **Liquid filling line, c. 1950s.** *Courtesy of SmithKline Beecham.*

Milestones in Compendial & Regulatory History

1961 AMA/USP Nomenclature Committee formed to coin generic names for all drugs. It is later joined by FDA and renamed the United States Adopted Names Council (USAN).

1962 Kefauver-Harris Drug Amendments passed to ensure greater drug safety. Drug manufacturers mandated to prove the effectiveness of their products prior to marketing them.

1963 FDA issues GMPs for human drugs.

1966 FDA contracts the National Academy of Sciences/National Research Council to evaluate the effectiveness of 4,000 drugs approved on the basis of safety alone between 1938 and 1962.

Fair Packaging and Labeling Act passed. It requires all consumer products in interstate commerce to be honestly and informatively labeled. FDA chosen to enforce provisions on foods, drugs, cosmetics, and medical devices.

1970 *In Upjohn v. Finch* the Court of Appeals upholds enforcement of the 1962 drug effectiveness provisions of the Kefauver-Harris Amendments. Court rules that commercial success alone does not constitute substantial evidence of drug safety and efficacy.

Educators, not just Vendors

A rather unique quality of PDA's annual meeting during the 1960s was the scheduling of a program session for exhibitors to demonstrate their products, provide information, and answer questions. This session allowed members to get first-hand information on developments in technology. Nathan Kirsch assesses the importance of vendors in PDA history: "I think the vendors played a very important role in PDA's evolution, both from a scientific standpoint and from a financial standpoint… I can tell you that much of what the industry learned about rubber closures, glass containers, and so on from a technical sense came from the vendors' research laboratories…."


ANNUAL BANQUET
PARENTERAL DRUG ASSOCIATION IN
HOTEL STATLER HILTON, NEW YORK
OCTOBER 11, 1962.

7. **PDA and USP officials share a table at 1970 Annual Meeting Banquet. Extreme left, clockwise: Bradshaw Mintener, PDA; Lloyd Miller, USP; Frederick Kronenwett, USP; Gordon Personeus, PDA; Mrs. Personeus; Mrs. Schaufus; Charles Schaufus, PDA; Thomas Macek, USP; Mrs. Mintener; Hubert Boyden, PDA.**

Estes Kefauver, who from 1958-1962, held a series of Senate hearings that stirred consumer skepticism of the pharmaceutical industry.

Then in 1960, an incident occurred that brought widespread public scrutiny on the industry. Thalidomide, a sedative widely distributed in Europe, was found to cause birth defects and other complications in thousands of pregnant women.

Spurred to action by Kefauver's crusade and the thalidomide catastrophe, in 1962 Congress passed the Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act. These amendments forced manufacturers to prove the efficacy of their drugs through well-controlled trials prior to marketing. This new legislation also gave FDA the authority to set standards for Good Manufacturing Practices (GMPs) and to monitor pharmaceutical advertising and promotion.

To fulfill the legislative mandate, FDA issued the first GMPs for human drugs in June 1963. They positioned FDA to assume a larger role in evaluating the manufacturing, efficacy, and proper packaging and labeling of drugs.

Former PDA President Nathan Kirsch (Schering Corporation) describes the impact of the first GMPs on PDA and the industry: "The whole tenor of the meetings shifted to provide a great deal of emphasis on compliance with the GMPs and overall improvement of quality [in drug manufacturing]."

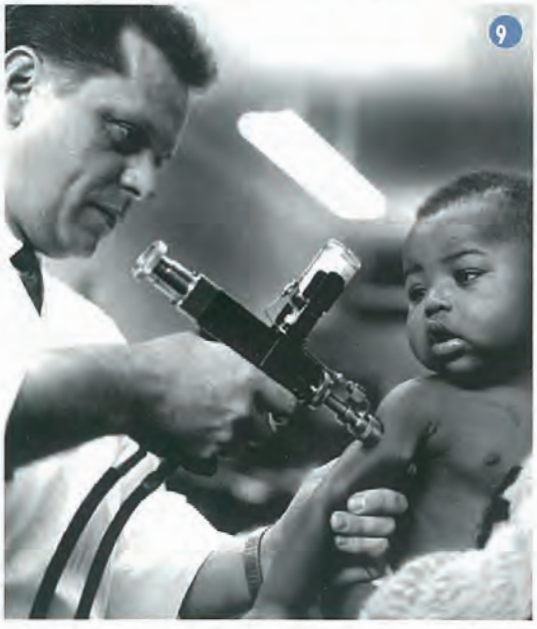
PDA responded to this new regulatory activity with great vigor. Given the growing importance of compendial and regulatory agencies during this period, PDA strengthened its relationship with USP and FDA. After Blumberg stepped down as program chairman in 1963, Nathan Kirsch, Kenneth E. Avis (University of Tennessee), William J. Artz (Smith, Kline & French Laboratories), and Gordon R. Personeus (Lederle Laboratories) planned and implemented annual meetings that featured a steady stream of officials from these organizations.

In order to keep its members informed of developments in Washington, PDA

PDA Makes The Washington Scene

Nearly 300 representatives of national drug concerns met at the "FDA Special Symposium on the Safety of Large Volume Parenterals" to study several issues of importance to manufacturers, regulators, and compendial organizations. Held in Washington, D.C., July 28-29, 1966, this meeting brought together members of industry, government, and professional associations. PDA was widely represented through its individual members: Leon Lachman, Kenneth Avis, Nathan Kirsch, and Hubert Boyden.

also established the "Washington Letter" in 1963, a bi-weekly newsletter that focused on regulatory and industry news. Editor Carlson Frailey covered major stories coming out of FDA, the National Institutes of Health, Congress, the White House, and other agencies of the federal government. As an added feature, the newsletter published stories on path-breaking research as well as drug product news. The "Washington Letter" proved to be a big hit with PDA's membership.



Following the establishment of GMPs in 1963, parenteral drug manufacturers became even more concerned about the menace of particulate matter and contamination. Dissatisfied with the quality of visual inspections, parenteral manufacturers urged the development of machines designed to detect particulate matter and contamination. Enter PDA and the Emhart project.

The Emhart Project was one of the first initiatives of PDA's newly formed Research Committee. Chaired by Leon Lachman (Endo Laboratories, Inc.) the Committee assisted in the development of an automatic inspection machine, named "Autoskan," to detect particulate matter. Initiated in 1967, the project called for a joint effort between PDA and the Emhart Corporation (Bloomfield, Connecticut) to develop and test this new machine. While Autoskan did not enjoy widespread commercial success, it was a forerunner of things to come. More importantly, it symbolized PDA's efforts to apply technical knowledge to pressing public health concerns and industry problems.

With PDA's active role in research, publishing, and regulatory affairs growing more important year by year, it became obvious that the organization would have to finally act on Harold Dembo's advice to obtain a full-time administrative secretary. Fortunately for PDA, it was not necessary to search outside the Association to fill the position. Long-time board member, Hubert E. Boyden had recently retired from his job at William H. Rorer Inc. and was encouraged to accept the position.

8. **PDA and FDA officials take a break at FDA Symposium on Large Volume Parenterals. L/r: Earl Meyers, FDA; Harold Blumberg, PDA; Fred J. Delmore, FDA; Hubert Boyden, PDA; Nathan Kirsch, PDA; Leon Lachman, PDA; Kenneth Avis, PDA, 1966.**

9. **Physician inoculates child using a jet injector, c. 1960s.** *Courtesy of United States Public Health Service, Program Support Center.*

PDA Presidents 1958-71

1958	William S. Bucke Lafayette Pharmacal, Inc.
1960	John Henderson Chase Equipment Corp.
1961	Harold Dembo Chicago Pharmacal Company
1963	Hubert E. Boyden William H. Rorer, Inc.
1965	Nathan C. Kirsch Schering Corporation
1967	Harold Blumberg Endo Laboratories, Inc.
1968	Kenneth E. Avis University of Tennessee
1970	Charles P. Schaufus Millipore Corporation

from Detroit to Canada, Vietnam and back

In order to encourage participation from members of the Pharmaceutical Manufacturers Association of Canada, PDA held its 1968 spring meeting in Detroit, Michigan. Two years later, PDA held its first meeting outside the United States. U.S. members descended upon Montreal, Canada, on April 10, 1970, to meet with Canadian colleagues. To the delight of many, Bradshaw Mintener, PDA's legal counsel, treated the attendees to a speech that went beyond parenteral sciences. The "PDA Letter" of May 1970 summarized Mintener's comments: "A highlight of the meeting was a forceful luncheon address delivered by Brad Mintener... He minced no words in pointing out the weaknesses of today's society, many of which are brought about by the reluctance of the public to become involved. He discussed the Food and Drug Administration, the Vietnam War, and inflation, with constructive commentary. The luncheon provided food for the mind as well as food for the body."

10. Operator adjusts machine that automatically fills and heat seals ampuls, 1957. *Courtesy of the American Institute of the History of Pharmacy.*

Hats Off to Nina

Nina L. DeMuth of DeMuth Development Corporation opened the door to future generations of PDA women. She was the first female to deliver a paper at a PDA conference and to serve as annual meeting program chair. In 1979, she co-founded the PDA Foundation for Pharmaceutical Sciences. While known for her record of accomplishment in PDA and as a female pioneer, Nina is also well remembered for her style: she wore the most fashionable hats ever to appear at PDA conferences. Kenneth Avis recalls: "Each year the members at the conference would talk about Nina's hats. She didn't wear ordinary hats, she wore custom-made hats." Conference attendees during the 1960s and 1970s had no problem spotting Nina. She was the woman with the hat.

Boyden served as administrative secretary for ten years. During that period, he transformed the "Washington Letter," renaming it the "PDA Letter," and changed its focus from events in Washington to happenings inside PDA. More importantly, Boyden coordinated the efforts of PDA volunteers. Together, they increased membership and revenues, expanded the committee structure, improved services, and established PDA as the leading professional association in parenteral and sterile products technologies.

PDA's 25th anniversary in 1971 provided an opportunity to recognize these achievements. The Association had come a long way since 1946, and it was time to do something special to celebrate. After much debate, the board of directors decided that PDA's anniversary convention would be held at Caesars Palace in Las Vegas, Nevada. This was a major departure from the tradition of holding the annual meeting in New York. William Bucke served as Anniversary Convention Chairman. With the assistance of Nathan Kirsch, William Artz, Fred Carleton (Pfizer Inc.), Sol Motola (Schering Corporation) and others, Bucke orga-

nized one of PDA's most memorable conventions.

Twenty-five years had been put in the books. A new generation of leaders had taken charge and charted PDA through difficult waters. They had established the Association financially, scientifically, and professionally. Through their voluntary work, PDA had gained a reputation as an authority on parenteral drugs, products, and devices. Yet, there was still much to be done. And the Association's members and leaders began planning for challenges ahead. ■

A President and a Scholar

Something different happened in 1968. For the first time in its history, PDA elected an academician as its president. Kenneth Avis, Professor of Pharmacy at the University of Tennessee, however, was no stranger to PDA. He joined the organization in 1956 and served on the board of directors for several years before becoming president. During his presidency, PDA published its first membership directory and volume one of a series of bibliographies on parenteral drug literature. A gentleman and a scholar? Sure, but in Avis' case, a president and a scholar is far more descriptive.

11. Caesars Palace welcomes PDA's 25th anniversary convention, 1971.

12. PDA Board of Directors, 1967. Seated, l/r: Kenneth Hewitt, Hubert Boyden, Dale Steiner, William Artz, Harold Blumberg, Glen Sperandio, Norman Hobbs, G. Willard Webster. Standing, l/r: John Henderson, William Bucke, Nathan Kirsch, Gordon Personeus, Roger Varney, Kenneth Avis, Charles Schaufus, W.R. Brownell. Not pictured: Leon Lachman.

CHAPTER 3

Selling

A Growing Need

Developments in regulation and technology presented the parenteral drug industry with fresh challenges between 1972-88. It was an age of computerization, automation, and mass communications. It was also an age of significant progress in pharmaceutical science and technology. Against this backdrop of change, PDA stepped up to fill its members' growing needs by launching initiatives in training, technical guidance, education, international programming, and regulatory affairs.

Parenteral drug manufacturing gained heightened attention in the early 1970s. In May 1972, FDA and USP jointly formed the National Coordinating Committee on Large Volume Parenterals (NCCLVP) to investigate problems associated with the production of large volume parenterals (LVPs). PDA appointed Patrick P. DeLuca (University of Kentucky) representative to the Committee while several PDA members served on committee task groups. NCCLVP findings crystallized the need for information and training in the preparation of sterile drug products.

PDA was quick to respond. At the 1972 annual convention, the Association debuted its inaugural training film, "Sterile Products and You." Produced under the direction of Thomas Riggs (Abbott Laboratories) and the PDA Film Subcommittee, it visually demonstrated the nature of working with sterile products. "Sterile Products and You" was the first of many PDA slide presentations developed to train personnel in the operations of parenteral drug manufacturing.

The manufacture of parenteral drugs reached a turning point in 1976 when FDA published a formal proposal to establish requirements for validation in the GMP regulations. "It was the single most comprehensive, new requirement and the most profound and expensive change in the history of GMPs," asserts Edmund M. Fry, PDA's current president. The new requirements mandated that the pharmaceutical industry follow certain validation processes and procedures. Faced with a dearth of information, the

1. Filter validation service in action, c. 1987.
Courtesy of Millipore Corporation.

Milestones in Compendial & Regulatory History

1972 NCCLVP jointly formed by USP and FDA.

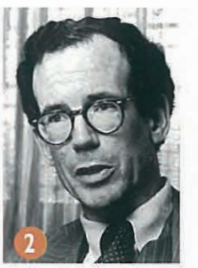
1974 FDA introduces concept of validation of processes used to manufacture parenteral products.

1975 USP acquires *National Formulary* from APhA.

1980 First *USP DI* released by USP.

1987 FDA publishes "Guidelines on Sterile Products Produced by Aseptic Processing" to educate industry about acceptable FDA procedures.

industry turned to PDA for direction. As a result, membership in the Association and attendance at its events grew markedly throughout the 1970s and 1980s.



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With validation as the galvanizing issue, PDA assumed a clearly proactive approach to regulatory matters. On October 26, 1976, PDA submitted its first formal response to an FDA guideline: comments on the proposed GMP regulations on LVP products and their applicability to small volume parenterals (SVPs). After reviewing FDA drafts and generating input from SVP manufacturers at a special meeting organized by George H. Hopkins (The West Company), Sol Motola (Schering Corporation), and James Boylan (Eli Lilly and Co.), the Association issued its comments. In its sixteen-page submission, PDA concluded that "Good Manufacturing Practices for SVPs [should] not be proposed until the as yet unresolved problems for LVPs are addressed in finalized regulations."

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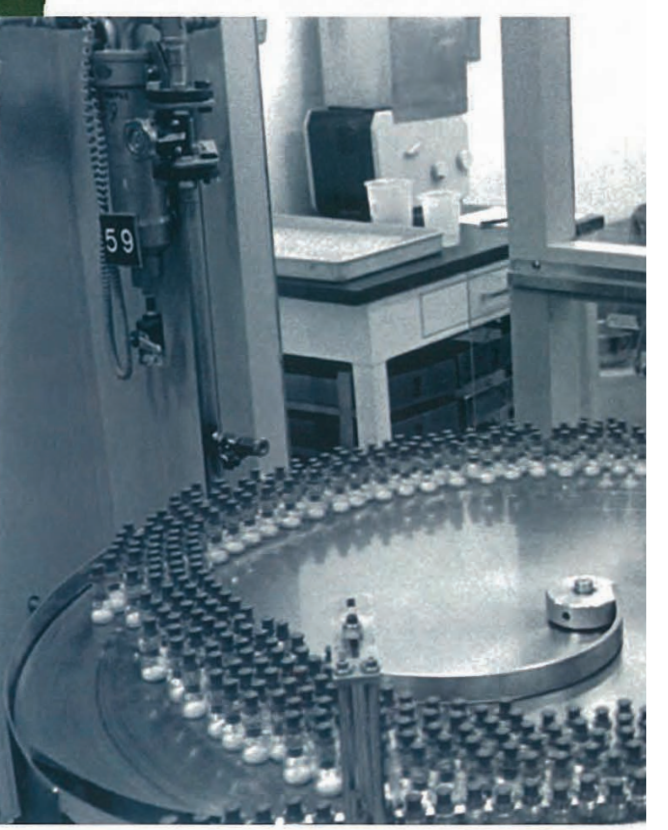

PDA's response regarding LVPs and SVPs was a harbinger of future PDA regulatory activity. Under the aegis of its newly established Regulatory Affairs Committee, PDA responded to FDA's proposed limits on the use of Ethylene Oxide as a sterilizing agent in 1978. Then in the early 1980s, the Association prepared comments on FDA guidelines and USP proposed particulate standards for SVPs. Based upon feedback from PDA's Regulatory Affairs and Research Committees, as well as from other industry groups, implementation of particulate standards for SVPs was delayed pending further study. Meanwhile, PDA furnished technical guidance to FDA and USP on other pressing topics during this period, including closures, containers, visual inspection techniques, particulate matter, the Limulus Amebocyte Lysate (LAL) test, DNA

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2. **Donald Kennedy was the first FDA commissioner to deliver an address at a PDA convention, 1979.**

3. **Sol Motola presents Distinguished Service Award to Gordon Personeus, 1985.**

4. **Joseph Robinson, PDA journal editor, 1978-87.**

Sleeping Through the Smoke

It was 4:20 a.m. PDA members, in attendance for the 1973 Mid West Meeting, were roused from sleep to the sound of fire alarms. The night club at Chicago O'Hare's Regency Hyatt House had caught fire and was filling the newly built hotel with smoke. Wearing pajamas, bathrobes, blankets, (or in the case of Gordon Personeus, a full suit and tie), all guests evacuated the smoking hotel. Well, not all of the guests: Hubert Boyden, who had already removed his hearing aid, managed to sleep right through the smoke and commotion, providing PDA with one of its most memorable anecdotes.

recombinant technology, terminal sterilization, and aseptic processing.

PDA also provided its members with technical guidance in the form of monographs, information bulletins, and methods bulletins. Led by Chairman Michael R. Enzinger (The Upjohn Company), the Research Committee published PDA's first technical monograph, "Validation of Steam Sterilization Cycles" in 1978. Within the next ten years, PDA completed a total of fourteen such documents. They proved a valuable resource for members, industry representatives, and government personnel alike.

Still, this dynamic age demanded more than technical guidelines. Practitioners in the parenteral and sterile products industry needed continuing education but found that few formal institutions or facilities offered this type of training. PDA met the challenge, formalizing its educational program with the creation of workshops and short courses.

Irving J. Pflug (University of Minnesota), a noted authority on sterilization, taught the first workshops in microbiology and engineering processes at the Chicago regional meeting in 1977. This event marked the start of PDA's now enviable reputation as a provider of continuing education. The American Council on Continuing Education soon recognized the Association's educational qualifications, granting PDA accreditation in 1979.

That same year, the Association advanced its commitment to education by creating the PDA Foundation for Pharmaceutical Sciences, Inc. Fred Carleton (Pfizer Inc.), along with Nina Demuth (Demuth Development Corporation), Jack Cole (Pall Corporation), Nathan Kirsch (Schering Corporation), Leon Lachman (Endo Laboratories), and others, established the Foundation to support research and education in parenteral sciences and technology. "I felt ... that we could get the general public to contribute to scientific research," Demuth explained in a recent interview. And

PDA Presidents 1972-87

1972	Gordon R. Personeus Lederle Laboratories
1974	William J. Artz Smith, Kline & French Laboratories
1976	George H. Hopkins The West Company
1978	Frederick J. Carleton Pfizer Inc.
1980	Jack Cole Pall Corporation
1982	Leon Lachman Lachman Consulting Services, Inc.
1984	Sol Motola Lypho Med, Inc.
1986	Robert G. Kieffer Sterling International Group

5. The Mix-O-Vial, a device that mechanically mixes two separate sterile components of a drug product, 1983.
Courtesy of the Upjohn Company.

6. In honor of her late husband William, Edith Bucke presents PDA Research Foundation Vice President Nathan Kirsch with a grant of $10,000 to support parenteral nutrition research.

Joining The USP Ranks

At its 1980 Quinquennial Meeting, USP admitted PDA as an eligible member organization with voting privileges, a testament to the Association's heightened influence in the regulatory arena. PDA appointed Frederick Carleton its first delegate to the USP Convention.

7. **Irving Pflug.**
8. **Jack Cole.**
9. **PDA's inaugural technical report, "Validation of Steam Sterilization Cycles," published in 1978.**
10. **"Inspect and Measure," a PDA training aid, 1980.**
11. **The first annual report to membership, 1976.**

The Hearty PDAers

PDA was at the right place at the wrong time. The Association held its 1976 GMP-LVP meeting at Philadelphia's Bellevue Stratford Hotel only days after the American Legion Convention. Many of the attendees at the American Legion Convention contracted what became known as "Legionnaires Disease;" twenty-seven died and over 150 were hospitalized. But the stalwart PDA members were not deterred. "I must say that I and most of the members stayed at the hotel and that we also ate very heartily," insists Sol Pflag.

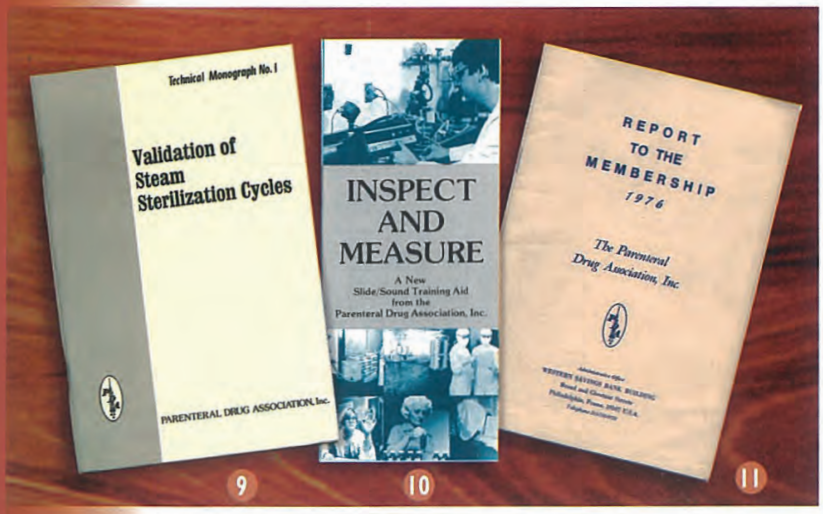
get them to contribute she did; Demuth played a primary role in the genesis, administration, and growth of the Foundation. Since 1979, the Foundation has awarded $1.2 million in grant money to scholars in the pharmaceutical sciences.

The growth of PDA's educational programming was swift and dramatic. Courses were overbooked and demand grew daily. In response, PDA organized the Education Committee to develop short courses on advancing technologies. By the close of 1987, PDA had presented 155 continuing education courses, covering topics from sterilization to lyophilization, bioengineering to computer systems validation, and chromatography to metrology.

While filling a void at home, PDA's educational offerings also brought the Association closer to its international colleagues. Throughout the late 1970s and 1980s, PDA took its courses to overseas destinations including the United Kingdom, Puerto Rico, and Switzerland. With its educational programming providing the stimulus, the Association began developing relationships with professional organizations outside the U.S. In 1978, PDA formed the Internationalization Committee to formally fulfill that objective. Its chairman, Jack Cole, set the committee in action by visiting several Latin American countries and stimulating interest in PDA activities.

One of the Committee's first accomplishments was co-sponsoring a meeting with the Asociación Farmacéutica Mexicana in Mexico City from March 27-28, 1980. This collaborative effort fostered the exchange of technical, scientific, and cultural information between the U.S. and the Mexican pharmaceutical communities.

The International Conference on Liquid Borne Particle Inspection and Metrology, held in May 1987, represented another milestone in PDA's growing international program. The gathering converged experts from around the world to examine the issue of particulate matter. "This was a precedent setting meeting," explains Regina C. McCairns of SmithKline Beecham. "It provided a focal point for all people, manufacturers, regulators, vendors, quality assurance personnel, and the USP, to talk about [the subject of] particles."



PDA's journal reflected and responded to many of the organizational changes adopted during these years. Robert King (Philadelphia College of Pharmacy and Science), who assumed the editorship in 1964, oriented the journal more deeply toward issues of science and technology. His 1978 successor, Joseph R. Robinson of the University of Wisconsin, enlarged the journal's size and scope and changed its name to the *PDA Journal of Parenteral Science and Technology.* At the end of Robinson's term in 1988, the journal had clearly matured from a technical bulletin into a scientific publication of international repute.

Information Pipeline

Joyce H. Aydlett, current PDA Chair-Elect, joined the Association in 1985. Aydlett explains how PDA's informational services initially attracted her to the Association. "I was so impressed with the overall exchange of information, the openness of the members and the willingness to share technical information which I felt was so vital, not only to me but also to my company."

Who led PDA through this dramatic period of expansion? In the words of 1982 President Leon Lachman, it was PDA's volunteers. "The PDA lifeblood is its active members who participate in the various committees, task forces, and management of the Association's affairs. It is only through these collective efforts that the PDA has been able to provide the many services to membership as a whole, academia, and government."

The staff at headquarters guided these collective efforts. Hubert Boyden infused PDA with his strong managerial talents and high ethical standards. Upon Boyden's retirement in 1976, administrative leadership was turned over to retired Captain Solomon C. Pflag who applied his business skills practiced in the Navy to the affairs of PDA. As James P. Agalloco of Agalloco and Associates recently recalled, "Sol ran a tight ship... He also gave PDA its dignified style and tone."

From 1972-87, PDA addressed the growing needs of its members, honed its commitment to scientific excellence, and adopted a global perspective. But when the calendar reached 1988, the Association stood at the threshold of a new era. PDA had just completed a strategic plan and appointed a new executive director. With Frederick Carleton at the helm and a comprehensive strategy for change in hand, PDA was prepared to redefine its course for the future. ■

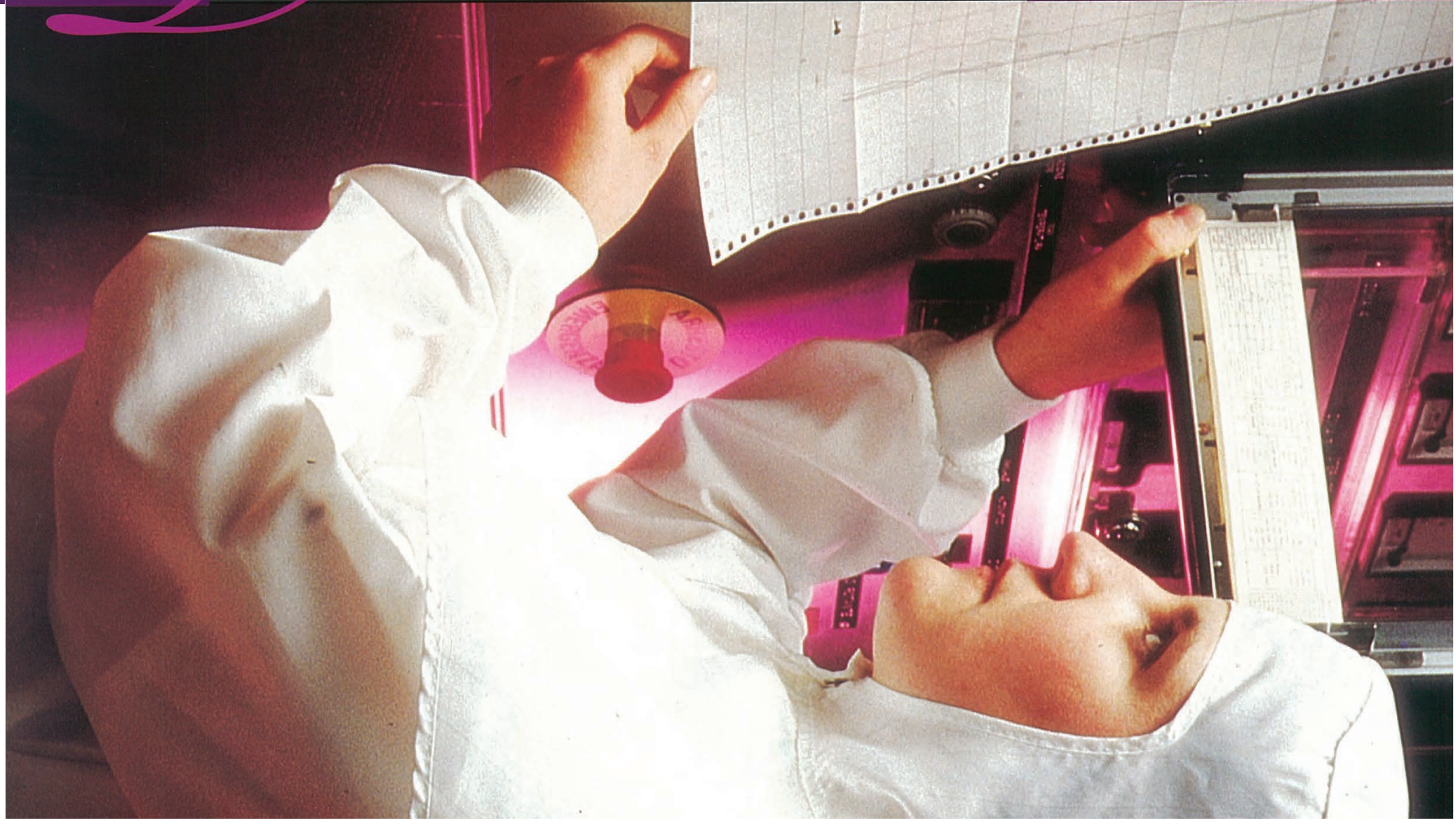
12. PDA members visit one of more than 150 exhibits at the 1984 annual meeting in Philadelphia.

13. PDA Board of Directors, 1975. Seated, l/r: Gerald Hecht, George Hopkins, William Artz, Leland Blazey, G. Willard Webster. Standing, l/r: Hubert Boyden, Frederick Simon, Walter McKenzie, Kenneth Avis, Roger Varney, Frederick Carleton, Henry Carlson, Paul Kiritsy, Joseph McIntyre, Gordon Personeus, W.R. Ashford, Patrick DeLuca. Not pictured: Carl Woodward, Jr.

14. Leon Lachman.

CHAPTER 4

Adding New DIMENSIONS



In the short period from 1988 through 1996, PDA grew at a rate unparalleled in the Association's history. To serve its members amidst rapidly changing climates in science, health care, and world trade, PDA added new dimensions to almost every facet of its identity.

PDA's transformation began with a strategic plan. Initiated during the presidency of Robert G. Kieffer (Sterling Drug, Inc.), board members and volunteers helped bring the plan to fruition. Its completion coincided with the appointment of Frederick Carleton to executive director in 1988. Using the strategic plan as a blueprint, Carleton and his 1991 successor, Edmund Fry, led PDA through this eventful era.

The strategic plan recommended that PDA integrate the field of biotechnology into its activities. And so the Association organized educational courses, featured biotechnology at its meetings, and established a task force to explore the nascent science. PDA also created the West Coast and New England chapters to address biotechnology-related issues.

Formation of these two regional chapters was part of PDA's chapter building campaign, a second major element of the strategic plan. The campaign flourished during the presidential terms of James Agalloco (E.R. Squibb and Sons, Inc.), Michael S. Korczynski (Abbott Laboratories), and Clarence A. Kemper (Kemper-Masterson, Inc.). Between 1989-96, PDA established the following domestic and international chapters: Canada, Midwest, New England, Puerto Rico, West Coast, Delaware Valley, Japan, Metro, Capital Area, Mountain States, Southern California, and European.

In creating chapters abroad, PDA fulfilled perhaps the most significant component of its growth strategy: international expansion. The collapse of communism, the opening of trade barriers, and the formation of the European Economic Community (EEC) radically changed the international marketplace. "[PDA] can no longer afford the luxury of thinking domestically," claimed

1. **(Opposite page) Operator reviews data from computer monitoring system of vial washing and sterilization tunnel, Merck's NeoPharmed facility, Milan, Italy, c. 1990.**
   Courtesy of Merck and Co., Inc.

2. **Robert Kieffer.**

3. **Signing of Memorandum of Understanding between PDA, A^{3}P, R^3-Nordic, and the Parenteral Society. L/r: Berit Reinmulter, R^3-Nordic; Bernard Kronenberg, PDA; Francois Maes, A^{3}P; Trevor Deeks, Parenteral Society; Frank Talbot, Parenteral Society; Bengt Ljungqvist, R^3-Nordic; James Akers, PDA; and James Lyda, PDA.**

Milestones in Compendial & Regulatory History

1990 Safe Medical Devices Act passed, expanding FDA's authority to regulate interstate movement of medical devices.

1991 FDA proposes requirement that manufacturers use terminal sterilization process when preparing sterile drug products unless the process adversely affects the product.

1993 *U.S. v. Barr Laboratories* decision raises industry-wide questions regarding development of pharmaceutical standards.

CARLETON: The Consummate Ambassador

In the eyes of many, Frederick Carleton was PDA's consummate ambassador. He had an uncanny ability for enlisting strong members to the Association and mentoring future leaders. "In terms of recruiting people into PDA, there probably was no better," asserts current Chairman Raymond Shaw, Jr. James Agalloco similarly comments on Carleton's role as a PDA mentor. "He had a vision about what PDA could become. He brought in 'movers and shakers' and helped them to push the Association forward."

Origins of PDA's Japan Chapter

The founding of the Japan Chapter in December 1991 was spurred by a successful educational program PDA sponsored earlier in the year, as well as by the devoted efforts of Frederick Carleton, Timothy Leahy (Millipore Corporation), Masayoshi Nishiyama (Millipore Ltd.), and Kunio Kawamura (Takeda Chemical Industries). Under the leadership of its first president, Toshinobu Aoyama (Kyusyu University), the Japan Chapter added 450 new members to PDA after only one year of operation.

Michael Korczynski, a primary proponent of PDA's increased global role. For PDA, this meant forging closer relations with pharmaceutical communities in Europe and Asia.

On February 17-19, 1992, PDA conducted its first major European meeting in Basel, Switzerland with The Parenteral Society (UK) and France's Association Pour Les Produits Parénteraux et Stériles (A^3P). Focusing on the technology of aseptic and terminal sterilization, the Basel Congress heralded a commitment to global affairs that proclaimed PDA as an international association.

At the Basel Congress the following year, PDA's burgeoning relationships in Europe were formalized. PDA, The Parenteral Society, A^3P, and the Nordic Association for Contamination Control (R^3-Nordic) signed a "Memorandum of Understanding" promising to promote communication and the mutual exchange of technical information in sterile health care products.

While creating alliances in Europe, PDA also pursued partnerships in Asia. From November 14-16, 1994, PDA's Japan Chapter hosted the Asian Symposium. It was an historic occasion, marking the first international meeting on GMPs, validation, and related pharmaceutical science and technology ever held in Asia. Ties with Asian countries were further strengthened when PDA established Statements of Common Interest with the Thai Pharmaceutical Manufacturers Association, the Pharmaceutical Society of Singapore, and the Indonesian Pharmacist Association in October 1995.

Alliances were only one aspect of PDA's international program during this period. With its members increasingly affected by globalization and new trade rules, PDA joined the movement to harmonize international standards. "PDA must serve our members in the U.S. and throughout the world by actively participating in efforts to harmonize manufacturing standards," explained James E. Akers (Akers Kennedy & Associates). "Perhaps even more importantly, we must provide our membership with the best possible information on all significant issues facing our segment of the industry."

PDA thus followed the activities of the International Conference on Harmonization (ICH), reviewing regulatory guidelines and reporting developments to members. The Association also supported the International Organization for Standardization (ISO) Technical Committees on sterilization for health care products as well as on clean rooms and controlled environments. PDA's James C. Lyda, Michael Korczynski, and other members attended working group meetings, ensuring that technical issues and industry needs were understood in the context of setting standards. And in late 1995, a PDA

5

4. **PDA Asian Symposium, 1994.**

5. **PDA's chairman Clarence Kemper and Thai Pharmaceutical Manufacturers Association (TPMA) Chairman S.S. Tsai sign information-sharing agreement on November 24, 1994.**

6. **H. Kyogoku (Nihon Pall) of the Japan Chapter presents Ōgi (Japanese fan) to Edmund Fry at PDA headquarters, September 20, 1994.**

Task Force, co-chaired by Doris L. Conrad (SmithKline Beecham) and Colin Booth (Glaxo Group Research), prepared comments and participated in international meetings to revise the European Union GMP Annex for Sterile Medicinal Products.

PDA also enhanced its liaisons on the home front. The traditionally cooperative relationship between PDA and FDA reached higher levels of productivity and interaction from 1988 to 1996. Through the efforts of its volunteer task groups, PDA issued comments on regulatory issues including aseptic processing, terminal sterilization, validation of bulk chemical pharmaceuticals, the filing of New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs), sterile filtration, computer validation, electronic signatures, and biologics licensing.

It was the inception of the PDA/FDA Joint Conference on September 5-6, 1990, however, that established a new opportunity for professional collaboration between the two groups. Over the years, the Conference grew in scope and attendance; and so too did FDA's recognition of PDA as a valuable techni-

PDA Presidents

1988-96

1988	James P. Agalloco E.R. Squibb & Sons, Inc.
1990	Michael S. Korczynski Abbott Laboratories, Inc.
1992	James E. Akers Akers Kennedy & Associates
1994	Clarence A. Kemper* Kemper-Masterson, Inc.
1996	Raymond Shaw, Jr. Wyeth-Ayerst Labs, Inc.

* (Title changed to Chairman)

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7. **Sharon Smith Holston awards FDA Commissioner's Special Citation to PDA.**

8. **Technological advances, international harmonization, NAFTA, and GATT were among the topics featured at the Pan American Conference, jointly sponsored by PDA and the Asociación Farmacéutica Mexicana (AFM), June 7-9, 1995.**

9. **Program from the PDA/FDA Joint Conference, September 19-21, 1994.**

10. **From August 26-29, 1990, PDA and the Pharmaceutical Manufacturers Association (PMA) co-hosted the highly successful international conference, "Sterilization in the 1990s."**

11. **Program for PDA Spring Meeting and courses, 1994.**

12. **A overview of PDA's current headquarters (center building), located in the busy Washington metropolitan area.**

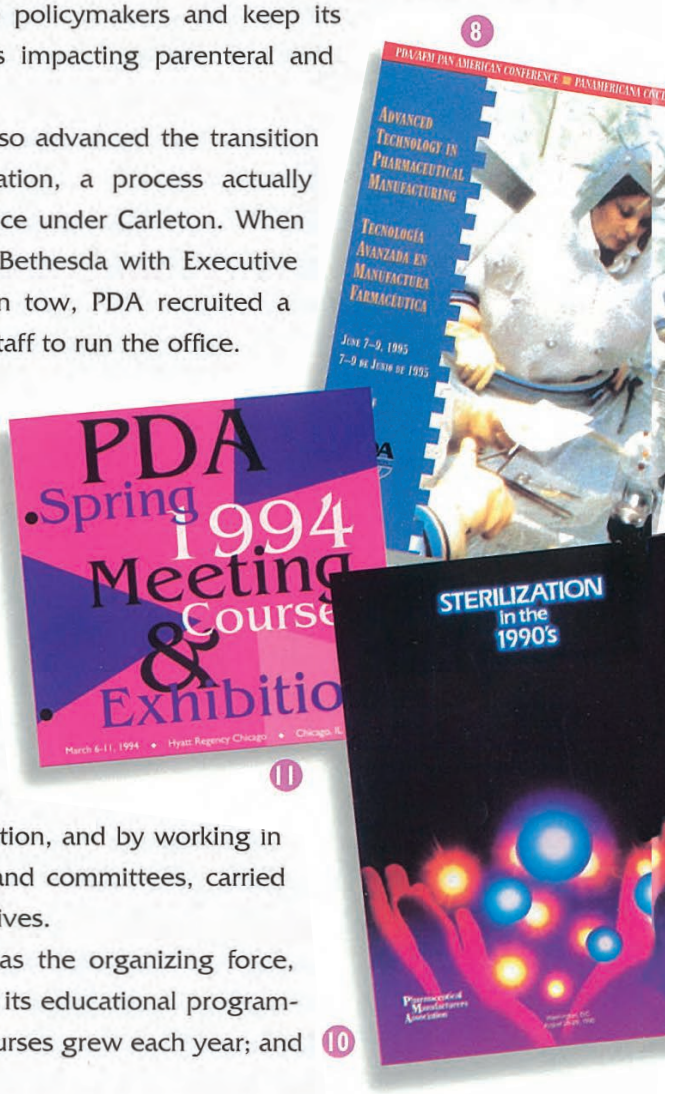
cal resource. At the conclusion of the 1995 event, Sharon Smith Holston (FDA) awarded the FDA Commissioner's Special Citation to the Association. "PDA and its board members have time and again made themselves available and assisted FDA in reaching out to the regulated industry," acknowledged Holston. "Your organization makes our communications easy, and our joint programs are, for us at FDA, a source of pride."

PDA's relocation to Bethesda, Maryland in April 1992 elevated the Association's influence and visibility in the regulatory arena. The new Washington-area headquarters facilitated contact with FDA, USP, and other health care agencies. It helped PDA communicate industry concerns more effectively to policymakers and keep its members abreast of changes impacting parenteral and sterile drug products.

The move to Bethesda also advanced the transition to a staff-managed organization, a process actually begun in the Philadelphia office under Carleton. When the Association relocated to Bethesda with Executive Vice President Edmund Fry in tow, PDA recruited a comprehensive professional staff to run the office.

Under Fry's strong leadership, PDA met the needs of a membership that was rapidly growing and diversifying. Fry enhanced PDA's rapport with industry, government, and international organizations, while coordinating the efforts of PDA members and staff. The staff took over the day-to-day operations of the Association, and by working in concert with PDA members and committees, carried out additional strategic objectives.

With headquarters' staff as the organizing force, PDA increased the breadth of its educational programming. The number of short courses grew each year; and

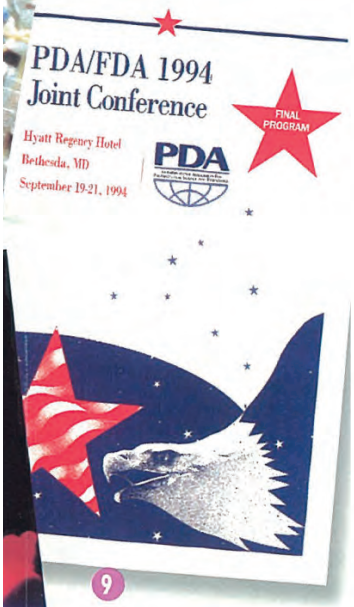


13. PDA 1996 Board of Directors. L/r: Clarence Kemper, Ray Gabler, Kunio Kawamura, James Akers, Martin Henley, Joyce DeYoung, Raymond Shaw, Jr., Joyce Aydlett, R. Michael Enzinger, Jennie Allewell, Terry Munson, and Floyd Benjamin. Not pictured: Peter Bigelow, John Geigert, Henry Kwan, Robert Morrissey, and Robert Myers.

14. Newsletter Award presented to the members of the PDA staff in 1994 by the board of directors. Top row, l/r: Edmund Fry, Russell Madsen, Jr., Suzanne Stone, Margaret Wanca. Bottom row, l/r: Patricia Rafferty, James Lyda, and Blake Stenning.

by 1996, PDA offered over 100 courses. Production of training aides also continued with the release of new presentations, films, and, in 1992, PDA's first video, "Keep it Clean." Then in 1996, PDA announced plans to create a one-of-a-kind training institute featuring hands-on instruction in laboratory and classroom settings.

PDA also improved the utility of its publications. Between 1988 and 1996, the Association published a record number of technical reports. "Fundamentals of a Microbiological Environmental Monitoring Program" (1990), "Common Practices in the Validation of Aseptic Processing" (1992), and "Validation of Computer-Related Systems" (1994), reports directed by James Wilson (Abbott Laboratories), James Agalloco and James Akers, and Clarence Kemper respectively, proved especially practical against unfolding regulatory and technological conditions. And, in 1996, PDA unveiled its first book, *Cleaning and Cleaning Validation: A Biotechnology Perspective*, written by Jon R. Voss (Biopure Corporation) and colleagues.



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PDA staff, meanwhile, updated the newsletter, and Joseph B. Schwartz of the Philadelphia College of Pharmacy and Science revamped the journal. Appointed editor in 1988, Schwartz introduced a number of innovations to the publication. He also directed the plan to bring the journal in line with the broadened scope of the Association by retitling it the *PDA Journal of Pharmaceutical Science and Technology*.

Throughout this period in history, PDA's interests transcended beyond parenterals to embrace wider

15. PDA/FDA 1992 Conference Committee, l/r: Donald Baker, Doris Conrad, Theodore Meltzer, Frederick Gustafson, Committee Chair, Robert Haggerty, and Suzanne Stone.

disciplines and technologies in pharmaceutical science. These included biotechnology, solid dosage forms, isolation technology, blow-fill-seal technology, computer integration, and genetic engineering. Therefore, to remain the "Parenteral Drug Association" was no longer accurate. In 1994, the Association adopted "PDA" as its official name and "An International Association for Pharmaceutical Science and Technology" positioned atop a stylized globe as its service mark.

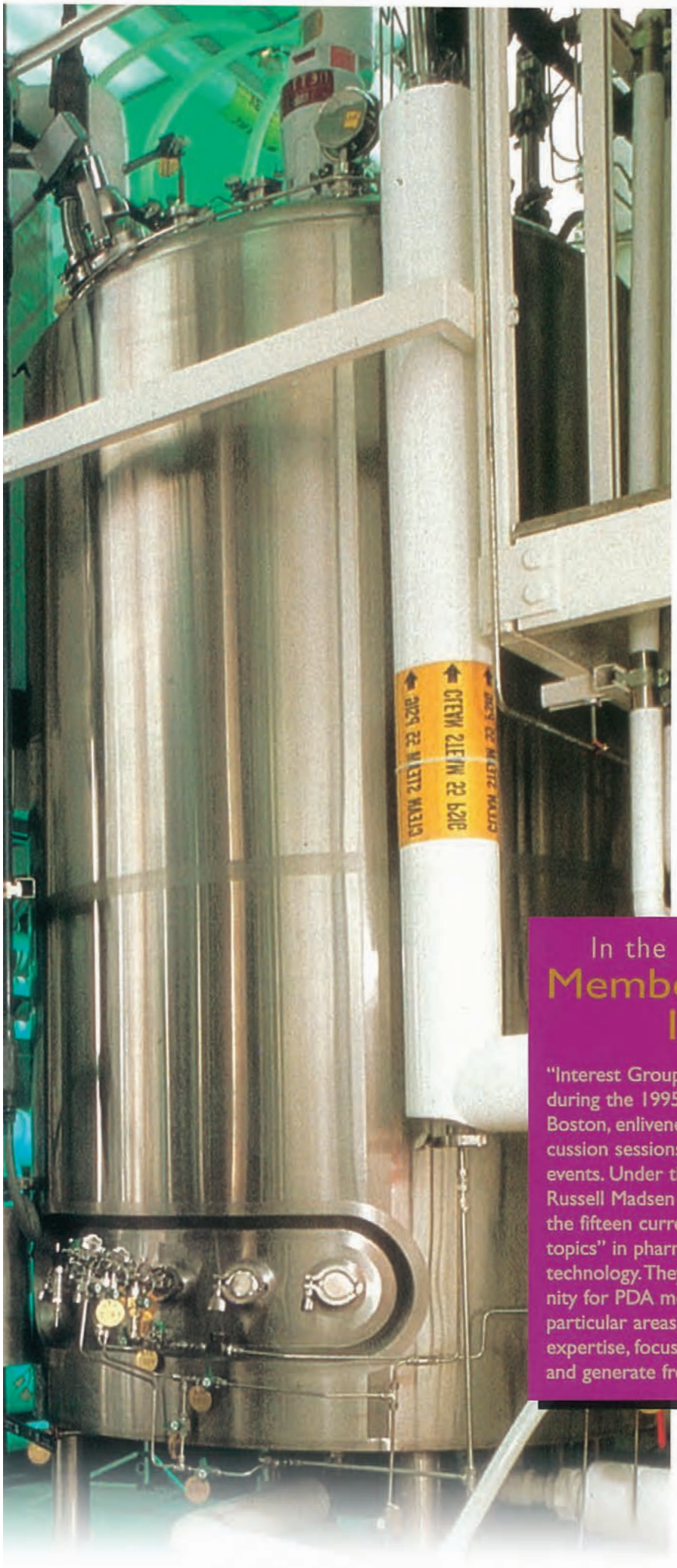
By the occasion of its 50th anniversary, PDA had evolved from a small, commercial organization for parenteral drug interests into an internationally recognized, scientific and technical association for the pharmaceutical industry. Over a fifty year period, PDA's membership increased from twenty individuals to more than 7,500; the

Setting An Example

Frederick D. Simon was an exemplary member of PDA. As a volunteer, Simon served on almost every committee in the organization. Upon his retirement from a forty-year career at Merck, he joined the PDA staff and became Director of Scientific and Regulatory Affairs. Simon's dedication inspired many PDA members, and following his death in 1992, a wooden clock honoring his memory was presented for permanent display at PDA headquarters.

Partnership For Progress

It was a groundbreaking event. PDA and the International Society for Pharmaceutical Engineering (ISPE) jointly sponsored the Advanced Barrier Technology Conference from January 17-18, 1995. The Conference brought the two groups together to explore developing technologies of common interest, and spawned a partnership between PDA and ISPE that will likely progress into the future. Robert P. Best, ISPE's director, agrees. "I think it is a very valuable relationship to maintain as we move into the 21st century and certainly from ISPE's perspective, we welcome that."



number of exhibitors at its annual meeting from five to over 150; its financial status from paltry to prosperous. And since the inception of its first workshops and courses in 1977, PDA has become the authoritative source for educating professionals in the sterile drug products industry.

While adding all of these new dimensions, PDA maintained essential qualities that have withstood the test of time and contributed to its fifty-year record of success. Since 1946, the efforts of PDA's dedicated members, foresighted leaders, and committed staff have shaped a vibrant organization. PDA's responsiveness to change and an unwavering commitment to provide a forum for scientific excellence have sustained the Association through five decades of innovation. Continuing to honor these essential traditions will guide PDA into the 21st century. ■

In the Members' Interest

"Interest Groups," officially launched during the 1995 Annual Meeting in Boston, enlivened the tradition of discussion sessions so popular at PDA events. Under the supervision of Russell Madsen at PDA headquarters, the fifteen current groups target "hot topics" in pharmaceutical science and technology. They provide the opportunity for PDA members to interact in particular areas of their interest or expertise, focus on mutual concerns, and generate fresh ideas.

16. Pall Corporation filters in use at the Genetics Engineering Institute in Massachusetts, c. 1990s.
Courtesy of Pall Corporation.

Appendices

PDA Honorary Members

Arthur D. Herrick, 1958
Joseph F. Greene, 1961
Hugo Schaefer, 1961
Joseph W. Kouten, 1968
William S. Bucke, 1973
Hubert E. Boyden, 1975
Harold Blumberg, 1976
George H. Hopkins, 1983
Robert E. King, 1985
Joseph Ushkow, 1985
Nathan C. Kirsch, 1987
Bradshaw Mintener, 1987
Solomon C. Pflag, 1987
Kenneth E. Avis, 1988
Gordon R. Personeus, 1990
Frederick J. Carleton, 1991
Frederick D. Simon, 1991
Leon Lachman, 1995
Jack Cole, 1996
Robert G. Kieffer, 1996
Theodore H. Meltzer, 1996

PDA Timeline

1946 PDA incorporates as not-for profit organization in New York State on November 18.

1947 First issue *Bulletin of the Parenteral Drug Association* issued early in year.

1949 PDA "News Letter" introduced.

1951 PDA extends membership from corporate firms to individual vendors and suppliers.

1952 First of a series of roundtable discussions held in mid-January.

1957 David Ashkenaz replaces Arthur Herrick as journal editor.

1958 Membership drive initiated under leadership of William Thawley.

PDA moves administrative office from New York to Philadelphia.

Herrick designated as PDA's first Honorary Life Member.

1963 PDA "Washington Letter" first issued on July 29.

1964 PDA establishes Parenteral Drug Association Award to promote student interest and study in parenteral research.

Robert King becomes editor of journal.

1967 Hubert Boyden appointed administrative secretary.

Research and Planning Committees formed.

1968 PDA enters into contract with Emhart Corporation to assist in development of in-line particle inspection device.

Kenneth Avis becomes first academician to serve as PDA president.

PDA's spring meeting held in Detroit to encourage Canadian participation.

1969 *PDA Directory of Membership* published as separate entity.

1970 First PDA meeting outside of the U.S. held in Montreal, Canada.

1971 PDA celebrates its 25th anniversary at Caesars Palace in Las Vegas, November 10-12.

1972 PDA's first training film "Sterile Products and You" premiered.

1973 PDA meetings formalized to three: one-day meetings in March and June and three-day annual meeting in the fall.

1974 PDA's spring meeting held in Puerto Rico.

1975 Patrick DeLuca receives first Schaufus Memorial Award.

1976 PDA prepares formal response to FDA request for comment on proposed "Good Manufacturing Practices for Large Volume Parenterals."

Solomon Pflag replaces Hubert Boyden as administrative secretary.

PDA issues first "Report to the Membership."

1977 Membership classes grow with addition of "student" and "retiree."

PDA launches educational workshops and seminars on microbiology and engineering processes.

1978 The *Bulletin of the Parenteral Drug Association* changed to the *Journal of the Parenteral Drug Association.*

PDA forms Internationalization Committee.

Joseph Robinson appointed new journal editor.

FDA Commissioner Donald Kennedy delivers address at PDA's annual convention.

1979 The American Council on Pharmaceutical

Education approves PDA as provider of continuing education.

PDA Foundation for Pharmaceutical Sciences, Inc. established.

1980 USP admits PDA as an eligible member organization.

PDA holds first meeting in Mexico City in March.

The Parenteral Drug Association Foundation for Pharmaceutical Sciences, Inc. founded.

1981 Thirteen new task groups added to Research Committee.

Journal name changed to *Journal of Parenteral Science and Technology.*

1982 First PDA journal award presented to Lowell Tensmeyer and co-authors at annual meeting.

Table top exhibits first featured at Chicago meeting, April 2.

1983 First PDA Distinguished Service Award presented to Nathan Kirsch.

1984 PDA launches PDA Scholars Program to support two graduate students.

1985 In joint venture with American Society of Hospital Pharmacists, PDA publishes *Abstracts on Sterile Products, 1975-84.*

1987 PDA and IES co-sponsor "International Conference on Liquid Borne Particle Inspection and Metrology," May 11-13.

1988 Frederick Carleton succeeds Solomon Pflag as Executive Director.

Joseph Schwartz becomes new journal editor.

1989 Charters approved for PDA Canadian Chapter and PDA West Coast Chapter on March 8, 1989.

1990 PDA hosts first joint PDA/FDA Conference, September 5-6.

PDA and PMA co-sponsor conference "Sterilization in the 1990s" from August 26-29 in Washington, D.C.

1991 Edmund Fry succeeds Carleton as Executive Director, August 1.

Japan Chapter, PDA's first overseas international chapter, chartered.

1992 PDA opens new headquarters in Bethesda, Maryland on April 15.

The first PDA Computer Integrated Manufacturing (CIM) meeting is held October 13-14 in New Brunswick, NJ.

PDA sponsors first International Conference in Basel, Switzerland, February 17-19.

1993 PDA signs a "Memorandum of Understanding" with the Association Pour Les Produits Parenteraux et Steriles (A^3P), the Parenteral Society, and R^3-Nordic on February 21.

1994 Journal name changed to *Journal of Pharmaceutical Science and Technology.*

"PDA" adopted as official name and "An International Association for Pharmaceutical Science and Technology" as official tagline.

Tim Leahy Memorial Speakers Endowment established.

PDA's first Asian Symposium held November 14-16, 1994 at Schoen Bach Sabour Center, in Tokyo, Japan.

PDA reincorporates in Washington, D.C. and rewrites bylaws.

PDA signs Statement of Common Interest with Taiwan Pharmaceutical Manufacturers Association, November 24.

1995 Groundbreaking conference held January 17-18 between PDA and ISPE on Advanced Barrier Technology.

PDA signs Statements of Common Interest with Thai Pharmaceutical Manufacturers Association, Pharmaceutical Society of Singapore, and Indonesian Pharmacist Association, October 11-16.

1996 PDA finalizes plans to establish its own state-of-the-art training institute.

Epilogue

With the passing of its 50th anniversary, PDA looks to the future with anticipation and a solid record of accomplishment. Yet, this is no time to rest on our laurels. PDA faces a rapidly changing world with nuances that our founders could never have imagined. As we approach the 21st century, PDA members and officials will have to deal with an increasingly competitive pharmaceutical industry. The globalization of the industry combined with rapid advancements in technology and science offer PDA its greatest challenge: Can the Association thrive in this new and exciting era?

The eager and dedicated way that our members approach PDA business indicates that the Association will build on its past successes. During the past year we have made great strides to position PDA for the future. Aware that education and training will become even more essential to its members and the industry, PDA has finalized plans to open its own training institute. The first of its kind, the institute will include modern laboratory facilities that will make it possible for PDA to take its educational program to another level.

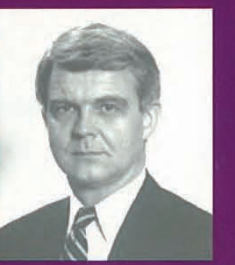
To keep pace with the dramatic developments in technology, science, and healthcare, PDA has widened its forum for information sharing among industry members. In 1995 the Association launched the first "Interest Group" sessions at its annual meeting in Boston. These sessions allow professionals involved with specialized technologies to discuss issues of common concern. As PDA continues to broaden its scope beyond parenteral and sterile products, Interest Groups will serve an increasingly vital role for exchanging information on emerging technologies and scientific matters.

Just as important, in the face of current advances in barrier isolation, advanced aseptic processing, and related technologies, PDA has also pledged to build upon its already cooperative relationships with the Food and Drug Administration, the United States Pharmacopeial Convention, and fellow health care associations. PDA has never taken regulatory matters lightly, and this tradition will continue as we enter our next half century.

Still, PDA would not fulfill its mission if it ignored the globalization of the pharmaceutical industry. During the past decade the Association has made great strides to recruit overseas members and establish relationships with pharmaceutical associations abroad. Today, nearly 30% of PDA's members reside outside the United States, and a group of PDA members in Europe have recently formed a new PDA European Chapter to complement the existing international chapters in Japan and Canada. PDA intends to build upon that growth by reaching out to new members and associations around the world.

PDA has much to celebrate as it enters its second century. My instincts tell me that nothing can stand in the way of the Association's progress. While we certainly will experience some setbacks on the road to achieving our goals, we will continue to move ahead. If I have learned anything during my term as President of this valuable organization, it is that PDA's members are resilient, resourceful, and foresighted. These three qualities will drive the organization to even greater levels of success.

If our founders could see us today, they would surely admire what PDA has accomplished. Today, it is our responsibility to carry on the tradition of past PDA loyalists and make future members proud. That will be PDA's greatest challenge as it embarks upon its next fifty years.



Edmund M. Fry
President

APPENDIX 2

Parenteral Drug Association
The First Fifty Years
1946–1995

by
Kenneth E. Avis, D.Sc.
Frederick J. Carleton

Forward

by
Edmund M. Fry
PDA President

We are greatly indebted to Kenneth E. Avis, D.Sc. and Frederick J. Carleton for writing the story of PDA's first 50 years. These distinguished long-time active Honorary PDA members volunteered their services in 1994 as we were beginning preparations for our 50th Anniversary celebration, and the PDA Board enthusiastically agreed to support this project. PDA has had a tremendously positive impact on pharmaceutical product quality around the world, and writing its chronicles was an important job. I could not imagine a that better team could have been found to do it.

Ken Avis published his first paper in the PDA Bulletin in 1957. He served as PDA President in 1968-1969. Among his publications are 54 papers and 28 books and book chapters, including some of the most authoritative books on preparation of parenteral products. His research, consulting, and teaching over the past four decades have greatly shaped manufacturing practices in our industry, and helped make better and safer products to the benefit of all. At the time of this writing he is Emeritus Professor, College of Pharmacy, University of Tennessee in Memphis.

Fred Carleton has been a PDA member for over 30 years, and his name appeared first as an author in the PDA Bulletin in 1967. He has served on committees too numerous to count, and served as association President in 1978-1979. He also served as Executive Director from 1988-1991, and as recounted below, was instrumental in introducing me to PDA. Fred has provided an incredibly positive influence on PDA over the decades.

As readers might imagine, Ken's and Fred's jobs were not easy. The archives of PDA, a volunteer organization that has occupied a variety of homes over its 50-year history, were not neatly arranged. The authors spent a substantial amount of their time here at PDA's headquarters reading minutes of meetings of the Board of Directors, old program brochures, committee reports and much other printed material. Fortunately, both of the authors have invested a good amount of their own personal and professional lives in PDA and thus were able to draw upon recollections, interviews and personal perspectives to help fill in the blanks. This work was invaluable in providing the raw material for PDA's outstanding fiftieth anniversary publication, "A Forum for Excellence" that was sent to all members in 1996. Their work will also assure that knowledge of many details of PDA's past will not be lost in the decades to come.

The authors deserve all the credit for relating the details of a fascinating period in the history of modern pharmaceutical science; the inevitable editing mistakes are solely my own responsibility. I also want to acknowledge the support of the PDA staff, especially Margaret A. Wanca, Director of Marketing and Member Services who compiled research materials, helped with editing and made the arrangements needed to bring this project to fruition.

The Beginning - 1946

As the Parenteral Drug Association, Inc. approaches its fiftieth anniversary it is appropriate, perhaps even mandatory, to turn back the pages of history to its beginning and then progressively review events through the intervening years. Such retrospection not only will be interesting but may reveal philosophies, events or anecdotes that will help guide the Association in the years ahead. Thus, a review of where it has been may help to point the way ahead as we pursue our historical journey. In any event, the Association and the professional environment in which it operates is dramatically different today than it was at the beginning.

The beginnings of most organizations are small and often inconspicuous. Typically, one or a few individuals will recognize a need for sharing ideas or experiences or uniting for some type of action. Similarly, the Parenteral Drug Association began in a small way. Arthur D. Herrick, a New York City attorney specializing in drug-related affairs, recognized that the budding specialty field of injectable (parenteral) dosage forms of drugs needed the development of a unique and distinctive technology for the manufacture and quality control of these dosage forms. Further, he was concerned about the increasing involvement of the Food and Drug Administration (FDA) in the affairs of the pharmaceutical industry. Therefore, he proposed to a few of his pharmaceutical company clients the formation of a specialty organization to share ideas and experiences, an approach not widely accepted among drug manufacturers at that time.

Nevertheless, the idea became a reality and the Parenteral Drug Association, Inc. came into being in 1946. By-laws of the Association were drafted, directors were chosen, and a certificate of incorporation was presented to the State of New York. This certificate was approved on November 18, 1946, identifying the Association as a not-for-profit organization. The incorporating directors who had the foresight to recognize the need for such an organization but could not have foreseen the changes that fifty years have brought were Harold H. London, Estro Company; Rudolph N. Price, Metropolitan Labs; A. Lincoln Konwiser, C. F. Kirk Company; Max Gold, Gold Leaf Pharmacal Company, Inc.; Arthur D. Herrick, attorney; and Abraham P. Wagner, all of the New York area.

The purposes identified for the formation of the Parenteral Drug Association (soon familiarly identified as the PDA) are detailed in Section 2 of the Certificate of Incorporation (See Table 1). Briefly, the purposes were to foster and advance the art and science of parenteral dosage forms of drugs, disseminate information of both a scientific and business nature, promote friendly cooperation among its members and cooperative relations with governmental and other agencies and organizations, promote research in the field, enhance compliance and understanding of labeling and related regulations and in general to promote higher standards in the production of parenteral drugs. These purposes formed the framework for the activities of the PDA during its early history, although the focus of interest during the early years seemed to be in developing a response to the FDA as this governmental agency became more and more involved in regulation of the pharmaceutical industry.

Relevant Circumstantial Events

Prior to the publication of the National Formulary V in 1925, there had been no specifications for parenteral drug products in the United States. These were essentially new dosage forms. But, in NF V, there were specifications for six injectable solutions under the designation of "Ampuls". Prior to their listing there was a two-page general discussion on ampuls, including a glass durability test and directions for cleaning, filling and sterilizing the filled ampuls. Elsewhere in the NF, six methods of sterilization were described and, amazingly by today's standards, directions for achieving "approximate sterilization." No tests for sterility were given for ampuls and no assays were described. It is apparent, in retrospect, that the specifications were quite inadequate, by today's standards.

Within the Committee on National Formulary, work progressed slowly until 1940 on improving the specifications and increasing the number of injectable products listed. However, following the

1940 United States Pharmacopeia Convention, the USP expanded its scope to include injectable dosage forms and the NF relinquished its jurisdiction. Although the USP built upon the work previously done, progress on preparing improved specifications for parenteral dosage forms was slow. However, the high rate of usage of large volume parenterals during World War II focused attention on the quality of these products. Consequently, the Surgeon General's Office and the FDA developed quality standards for government procured parenteral products. Nevertheless, even by 1946, compendia standards for these dosage forms were still in their infancy.

Meanwhile, Congress enacted the Federal Food, Drug and Cosmetic Act in 1938, which - among other things - continued to recognize the USP and NF as official compendia and strengthened their roles in formulating specifications for the strength, quality and purity of official drugs. The Act also strengthened the role of the FDA to ensure that drug products in interstate commerce met the standards of the USP and NF. Specifically, the Act prohibited the introduction into interstate commerce of adulterated or misbranded drugs and new drugs in violation of the requirements of the new drug section. By 1946, the FDA had become more aggressive in pursuing its responsibilities under the 1938 Act.

Within these circumstances PDA was born and began to develop.

The First Decennium - 1946 - 1955

Records of the early history of the PDA are incomplete, but some information is available. At the first organizational meeting, Rudolph N. Price, President of Metropolitan Laboratories, Inc., was elected President and served for one year. Arthur D. Herrick was named the legal counsel. Joseph Ushkow, President of Endo Products, Inc., is reported to have financed the organizational expenses. The administrative affairs of the Association were initially handled by the officers out of Herrick's office at 39 Broadway, New York 6, NY.

The activities involving the membership apparently focused particularly on evening dinner meetings, held at New York hotels, at which speakers presented various topics of interest to the membership. Speakers identified among the earliest records included:

> John H. Brewer, Director of Biological Research for Hynson, Westcott & Dunning, Inc., Baltimore, MD. Dr. Brewer spoke at the Hotel New Yorker on the topic, "Some Problems in the Preparation of Sterile Ampul Products," on October 15, 1948. The charge per plate for members was $5.75 and for non-members $7.75.
>
> Walter Wolman, Director, AMA Chemical Laboratory, and Abraham Taub, Professor, Pharmaceutical Chemistry, Columbia University, spoke on April 22, 1949 in New York.

Initial Publications

A publication, The Bulletin of the Parenteral Drug Association, was started in 1947, shortly after PDA was formed, and published in multigraph style. Copies of the earliest issues are not available, but the earliest issue on file, Vol. 2, No. 6, September-October, 1948, initiated a new format, a 6x9 inch, staple bound, printed publication with a light blue cover, intended to be a "forum for the parenteral technologist." Arthur D. Herrick served as editor and the Publication Committee consisted of John J. Miskel, Paul deHaen, Harold Erdreich and Julian R. Reasenberg. It was published bimonthly, contained advertisements and accepted subscriptions from non-members and institutions. Interestingly, annual subscriptions for member firms were only $1.00 and for non-members or organizations $10.00. The table of contents for this issue was:

Editorials:
- "The New Bulletin"
- "Another Forum"
- "The Consultant and the Manufacturer"
- "The Doctor's Lot is not a Happy One"

"Cost Accounting for Parenteral Products", Bradley O. Potter
"Sterile Filtering, Filling and Sealing", Adolph E. Tiesler
"Evaluation of Parenteral Equipment: The Chase 'Auto-Ampak'"
Association News:
- The October Dinner
- New Members
- Endo Scientist Address A.C.S. Meeting

Book Review by Jerome Trichter: *Drug Research and Development*, edited by Austin Smith and Arthur D. Herrick
Industry News

Thus it can be seen that early editions consisted largely of news and commentary. The November-December 1948 issue announced a New York dinner meeting for January 21, 1949, at the Hotel New Yorker. The same issue also announced developing plans for the formation of a mid-west section to meet at Chicago and a proposal for the formation of a Pacific section.

An external event that had a significant impact on the entire parenteral industry was the "Bristol Case." The January-February 1949 issue of the Bulletin carried the entire ruling by Thomas W. Brennan, United States District Judge along with editorial comments by Mr. Herrick. In his comments Mr. Herrick stated, "The injunction suit instituted by the Government against the Bristol Laboratories, Inc., to bar the channels of interstate commerce to parenterals violating the official standards for clarity of solutions, has been dismissed after seven days of trial on the ground of insufficient evidence and the indefiniteness of the pharmacopeia requirement." The outcome of the case revealed to the USP the need to more clearly identify a standard for clarity of parenteral solutions. For the industry a period of confusion followed for several years while debate continued over how best to resolve the issues. The FDA

announced that it expected parenteral solutions to be "substantially free" from particulate matter, yet the USP had no enforceable standard to which the industry could relate. The ongoing debate surfaced several times in subsequent issues of the Bulletin as PDA sought to aid in bringing the matter to a conclusion. To the disappointment of many, the matter was brought to a temporary conclusion by the decision of the USP Revision Committee not to include a clarity standard in its 14th revision of the compendium.

Paul A. Naef, Sandoz Chemical Works, Inc., was elected and served as PDA president from 1948 through 1950. The officers of the Association during the first ten years are listed in Table 2.

The desirability and advisability of separating news items from technical articles led to the publication of a News Letter, "designed to bring members current information and developments in the parenteral and related drug field." The first issue, in mimeographed format, was published on March 9, 1949. Interestingly, it was stated "This News Letter is for the information of members of the Parenteral Drug Association only and is confidential. It may not be published or quoted to non-members, unless clearly stamped 'FOR PUBLICATION' at the top of this page." Reviewing the contents of the first few issues available one wonders what was "confidential" about the items for the exclusive benefit of PDA members, and even more, how restrictions on quoting to non-members was significant and enforceable. To illustrate, among the items in the first two issues were:

"New Multiple Dose Closure"
"Chlorobutanol in Canadian Shipment"
"Herrick to Conduct Inspectors Course"
"F&DA Corrects Anti-anemia Board Announcement"
"Chloromycetin Synthesis Announced"
"Estrone Patent Violations Protested"
"Penicillin Vehicle Case Defeated"

The News Letter was published at irregular intervals, sometimes as short as one day, apparently to coincide with news that was considered to be important.

The use of the Bulletin as a forum for addressing issues of the day is illustrated in the February-March 1950 issue of the Bulletin. Editor Herrick comments on an issue of apparently common practice, that of "private brand" products being manufactured by various contractors without the actual manufacturer being identified on the label and the varying quality that may be encountered. Similarly, he comments on the practice of bulk drug suppliers not identifying the actual manufacturer. Mr. Herrick states forcefully the right of the physician, in the first instance, and the pharmaceutical manufacturer in the latter instance, to know who makes the product that is being used.

Organizational Changes

In the Bulletin, Vol. 5, No. 1, January-February 1951, then President Paul DeHaen wrote of changes in the organization. Membership of firms was continued with an annual fee of $100 but, for the first time, individual membership was offered at a fee of $25 for those actively involved in the manufacture of parenteral drugs and their control. Firms were given the privilege to identify four persons eligible to attend meetings and to vote on Association matters. Individual membership was also broadened to include persons from firms offering equipment and supplies needed for the production of parenterals and to individuals in the teaching profession. The change to permit membership of suppliers proved to be a critical step for they gradually became enthusiastic supporters and contributors to the activities and goals of PDA. Mr. DeHaen also announced that, in addition to the evening dinner meetings, all-day conferences on parenteral problems would be planned on an annual or semi-annual basis.

The May-June 1951 Bulletin lists eighty individuals as PDA members (Table 3), the earliest listing available. In the Fall of 1951 the first one-day annual meeting and dinner began at 1:30 p.m. on Friday afternoon, October 26th, in the New York Academy of Sciences. Four presentations were given prior to dinner and two afterward, concluding at about 10:00 p.m. The meeting reconvened on Saturday morning with three symposia, and ended at about 1:00 p.m. An equipment exhibit was also listed as part of the program, an innovation that soon became a learning opportunity for members and an effective promotional and inter-

active opportunity for suppliers. This first program is shown as Figure 1.

1952 - Under the continuing leadership of President Paul DeHaen, 1952 began with an evening meeting featuring a new format, that of round table discussions, at the New York Academy of Sciences on January 16. Five topics were identified for discussion. They were then edited and published in the Bulletin, and consisted of the following:

1. Cleaning of Finished Containers before Inspection and Labeling.
2. Identification Tickets During Cleaning and Sterilization Operations.
3. Volume Checking and Maintenance During Filling.
4. Filling Techniques for Aqueous Suspensions Within Allowable Tolerances.
5. Method of Cleaning and Testing Selas Candles.

The round table topics were planned by a committee chaired by Harold Blumberg and, as can be seen by the above titles, were very practical in nature. This format also reflected an increasing willingness of the membership to share their knowledge and experiences. Two other round table meetings were held that year, one again in New York at the Academy of Sciences on April 3 and another at the Edgewater Beach Hotel in Chicago on May 9. The proceedings of both these discussions also were published in the Bulletin. Interestingly, the chairman for the Chicago round table was Austin Smith, M.D., the long-time, highly respected editor of the Journal of the American Medical Association.

The Bulletin of March-April 1952 carried a listing of the membership, showing an increase to 108 by that date.

The Annual Meeting of the Association, now expanded to two and one-half days was held at the Hotel Barbizon-Plaza in New York City on October 30-November 1. Speakers and panel discussions were scheduled all day on Thursday and Friday and through noon on Saturday. New equipment and supplies were again exhibited. A reception and dinner was planned for Friday evening with E. Emerson Leuallen, Dean, Columbia University College of Pharmacy as the speaker. The registration fee of $15 covered admission to all meetings, the exhibits, and the reception and dinner.

1953 - Joseph Ushkow became president of an organization that had grown to 158 members at the beginning of 1953. The list of members, published in the January-February issue of the Bulletin, included one member each from Israel, New Zealand and South Africa, three from Canada and two from Puerto Rico. Thus, PDA was already becoming international in scope.

Three full days of addresses and round table discussions, along with supplier's exhibits, comprised the format for the Annual Meeting at the Hotel Barbizon Plaza in New York City on October 28-30. At the reception and dinner on Friday evening, Robert L. Swain, Chairman of the Board of Trustees of the United States Pharmacopeia Convention was the featured speaker.

1954 - At the beginning of 1954 David Ashkenaz became the president, a man who was to have a prominent role in moving the PDA into an increasingly respected leadership role as the preeminent association in parenteral science and technology. Harold Blumberg became Eastern Vice President this year and continued his long-time role in developing PDA programs to project the planned scope and high caliber objectives of the Association through the papers presented. The nature of the meeting programs is seen in the contents of the Bulletin, for most of the articles printed were from presentations given at meetings. Without reservation it can be said that PDA meetings contributed to a steady improvement in the quality of parenteral products and served as the foremost educational forum for the industry.

1955 - Dr. Ashkenaz was returned to office for 1955, as was Dr. Blumberg. Dr. Blumberg also became chairman of the Program Committee for the Annual Meeting, held October 25-27. The meeting was moved to the Hotel New Yorker to provide greater convenience for commuters and to provide more spacious accommodations for the growing number of attendees and exhibitors. Further, John Henderson became chairman of the Arrangements Committee and began using a unique personal ability to arrange an outstanding

and elegant dinner. These exceptional dinners became a tradition and a special feature of PDA annual meetings. The honored guest and speaker for the dinner was Austin Smith, renowned editor of The Journal of the American Medical Association, speaking on "Trends in Drug Evaluation".

The Second Decennium - 1956 - 1965

1956 - L. James Graham became PDA president at the beginning of the second decennium and served with distinction with the other officers (See Table 4). Mr. Graham presided over three regional meetings, one in New York City, one in Philadelphia, and the third in Chicago (See Table 5). The dinner address at the Annual Meeting in New York City was given by Lloyd C. Miller, Director of Revision, The United States Pharmacopeia, a frequent participant in PDA programs. He spoke on "A Quarter Century of Success - and Failure - In Standardizing Parenterals."

1957 - The technical and scientific nature of the programs at the three regional one-day meetings and the one annual three-day convention had grown in significance and recognition. Consequently, there was a growing demand for publication of more of these presentations, as well as other worthwhile manuscripts. This precipitated the need for a more aggressive pursuit of papers but, also, for their critical evaluation prior to publication. As a consequence, a change in the editorial program of the Bulletin was instituted with the first issue in 1957. David Ashkenaz was engaged to be the editor and an Editorial Board was appointed, consisting of Dr. Ashkenaz as chairman with Kenneth Avis, Vivian Mankey, Fred Ninger and Fred L. Tompkins as members. Under their leadership the Bulletin increased its publication from five to six issues a year, and increased the number of pages per issue. Most published papers had been presented orally at PDA meetings, and were followed by an oral discussion. As an innovation, its discussion was transcribed and became a printed addendum to the paper. This feature soon became very popular. Numerous comments suggested that these transcripts were often the most valuable and useful feature of the publication.

To gain a general flavor for the nature of articles published in the Bulletin during 1957, a survey indicated the following classification of the 29 articles published: five each related to processing technology, applied research, quality control matters or clinical use/evaluations, four to regulatory matters, three to inventory control and two to formulation. Thus, it is evident that a variety of topics had been presented at meetings to cover the technical and regulatory interests of the members. Increasingly, a primary factor in attracting membership in the PDA was the quality, variety and relevancy of the papers presented at meetings and their subsequent publication in the Bulletin.

1958 - Major changes in the organizational structure and professional emphasis of PDA began during 1958. One of the situations that had been recognized as problematic was the on-going struggle to establish the organization on a financially sound foundation. At the end of January 1958 the cash balance on hand was only $4,751.89. As a partial remedy, the annual membership fee for corporations was increased from $100 to $125 and for individuals from $25 to $35. Fees for meetings were increased as were the charges for exhibitor space at the annual meeting. At this time William S. Bucke had become president and had begun contributing his astute business acumen and his optimistic view of the PDA's future to the affairs of the Association. One of his theses was the necessity for a successful organization to spend sufficient money to provide the services needed to advance the affairs and goals of the Association. Therefore, he set about to begin a more liberal perspective of Board policy relative to this thesis.

By the end of the year William Thawley, chairman of the Membership committee, had initiated an energetic plan for increasing membership. Also, the Administrative Office had been moved to Philadelphia and a part-time administrative secretary, Mrs. Rosemary Marino, had been hired at the handsome salary of $500 per year, to provide needed secretarial support. Further, Dr. Ashkenaz was given $1,500 per year for his services as Editor of the Bulletin, essentially as expense money.

With the growth of PDA and changes in orientation, it was decided that Mr. Herrick's services as Executive Director should be terminated at the end of the year. In appreciation for his vision in starting the PDA and his many contributions in leading it through the beginning years, he was designated as the first Honorary Life Member.

The above changes introduced an increased emphasis on making PDA, in fact, a premier professional organization dedicated to promoting higher technical and scientific practices and standards in the development, manufacture and distribution of parenteral medications. Thus, the year 1958, in retrospect, was one of the most significant years in the development of PDA.

1959 - William S. Bucke continued as president for 1959 and, along with the other reelected officers, provided a continuum of leadership as the administrative functions of the organization became the responsibility of the officers and committees. By-Law changes were enacted to place the property and administrative affairs in the hands of the Board Of Directors. In addition to the Administrative Office, an Editorial Office for the Bulletin was also established in the Philadelphia area.

PDA continued a steady growth in number of members and in professional and technical stature. Table 6 summarizes some of the facts signaling this growth during the period 1959 through 1965, although, unfortunately, all of the data is not available. A list of the corporate and individual members was published in the May-June 1959 issue of the Bulletin. Among the 237 members listed, which included corporate representatives and individual members, 18 were from overseas. Of these there were four members each from Canada and England, two from Australia, and one each from Denmark, France, India, Israel, Italy, Nicaragua, South Africa and Turkey. The international interest in the PDA was growing stronger.

At the Annual Convention held at the Hotel Statler in New York City, a tradition of PDA was perfected by the imaginative gourmet, John Henderson, whose sensational banquets of culinary art became a highlight of PDA conventions for many years to come. Rumors circulated that the annual ceremonial introduction of the chef assured the elegance of the banquet. Surprisingly, even with the entertainment provided by a musical trio the cost was only $20 per person.

1960 - The activities for 1960 began with the New York dinner meeting on February 5 at the Hotel Statler, under the presidency of John Henderson. Mr. Henderson introduced the administrative committee type of organizational structure to the functions of the Board of Directors, an attempt to render more efficient the activities of the Board. A logo had been designed (See Figure 2) and was placed in service during 1960.

A change in the By-Laws was approved by the membership at the Annual Meeting, changing the composition of the Board of Directors to the five officers, the three immediate past-presidents, the Editor of the Bulletin, and eight at-large members. The elected directors were to serve for two-year terms.

1961 - Harold Dembo became President at the beginning of 1961. The distinguished membership category of Honorary Member was activated again when the Board selected two additional men to honor, namely, Joseph F. Greene, Kimble Glass Division, Owens-Illinois Glass Co., and Hugo H. Schaefer, Dean, Brooklyn College of Pharmacy, for their professional leadership and their many contributions to the development of PDA.

Even though some of the data is unavailable, there is enough shown in Table 6 to indicate that membership, attendance at meetings, and financial assets had continued to increase. By the May-June 1961 issue of the Bulletin, total membership had grown to 273 and the international members to 23. As a consequence of this growth, the Board of Directors decided that the time had come to establish a national headquarters and administrative office in central Philadelphia. Therefore, office space was leased in the Western Saving Fund Society Building at Broad and Chestnut Streets, and a contract for clerical and related services was let with Professional Services, Inc. This giant step provided administrative identity for the PDA and increased the capability of providing needed services for the membership.

The papers presented at PDA meetings reflected the increasing interest in the science and technology of parenteral dosage forms of drugs and the regulations affecting their production and distribution. To convey something of the interests at this time, the titles of papers published in the July-August and November-December 1961 issues of the Bulletin are listed:

Freeze-Drying - Application and Equipment.

Practical Aspects of Ethylene Oxide Sterilization.

A Comparative Study of Some of the Effects of Filter Media on Atropine Sulfate and Vitamin B12 Solutions.

Evaluation of Criteria and Methods for Parenteral Drug Standards.

New Parenteral Drugs in 1961.

Experience Under the Revised Drug Regulations.

Experiences in Gas Sterilization.

New Data on Ethylene Oxide Sterilization.

1962 - The establishment of an administrative office in central Philadelphia, the increase in financial assets, and the growth in membership (See Table 6) verified significant maturing of PDA. These very events, however, led to discussions at Board of Director's meetings of the increasing difficulty for officers and directors to give the time and effort required for Association activities. Such discussions naturally led to various considerations but, particularly, to the possible need for at least a part-time executive secretary. Under the leadership of President Harold Dembo, these discussions continued through most of 1962.

Further evidences of the developing stature of the PDA and growing interest in implementing other of its objectives was reflected in new considerations by the Board of Directors. A proposal for a grant to study rubber closures was submitted by Kenneth Avis from the University of Tennessee. This proposal was considered but tabled, in part because it was considered to be too expensive but, probably, also because it was a little ahead of its time in the thinking of the Board. Considerations of the possible need of legal counsel surfaced and, at a special meeting of the Board in October, a motion was made and approved to retain Carson Frailey, of Washington, D.C., as Legal Counsel.

At the August Board meeting a decision was made to award plaques to past presidents as a token of appreciation for the many contributions each had made to PDA. It also was decided that they were to be guests at the banquet when the plaques were presented.

1963 - At the beginning of 1963 Hubert E. Boyden assumed the presidency. At the New York City meeting on February 8, a special engraved Sterling Revere Bowl was presented to Harold Blumberg in recognition of his leadership in developing the outstanding stature of the programs of the PDA during his eight-year service as chairman of the Program Committee.

At the meeting of the Board on February 8, Dr. Ashkenaz, editor of the Bulletin, announced a new and expanded Editorial Board to replace the former Publications Committee. Also, at this meeting Kenneth Avis submitted a proposal for the preparation and publication of an annotated bibliography of literature published in the technical and scientific areas of parenterals. The funds provided would support a graduate student at the University of Tennessee who would prepare the bibliography under Dr. Avis' supervision. Dr. Avis suggested that support of this proposal would contribute a needed literature resource for our membership and would enhance the professional image of PDA in a new dimension complimentary to its objectives.

President Boyden requested that consideration be given at a later meeting on the new concept of the PDA funding projects, and that other proposals, in addition to the one from Dr. Avis, be submitted. Consequently, at a special Board meeting held on June 28, a vote was taken among three proposals submitted: 1) the annotated bibliography, 2) a PDA-sponsored lectureship, and 3) a semi-monthly news letter publication to be edited by Mr. Frailey. The Board chose the latter proposal and the PDA Washington Letter was launched on July 29, 1963.

It was to include news about governmental regulation, NIH developments, new equipment in the parenteral field, scientific and technical developments of interest, and news about PDA and its members. A distinctive masthead, using the PDA logo (See Figure 2), and printed in a reddish-brown color was chosen. The Letter immediately became a "hit" with the membership.

1964 - President Boyden was re-elected to serve again in 1964. He continued the standing committee structure of the Board, consisting of, Membership, Research, Program, Arrangements, Exhibits and Publications, but stated that the time was at hand to consider greater activity on the part of some of the committees, particularly, Research

and Publications. He emphasized the value of the committee structure in lightening the work load of members of the Board and in increasing the involvement of more members of the organization.

On February 27, 1964 the PDA membership was saddened by the sudden death of beloved associate, David M. Ashkenaz. Dr. Ashkenaz had served the Association as director, past-president and editor of the Bulletin. He had promoted strongly the focusing of the Association on the technical and scientific aspects of parenteral dosage forms of drugs, and was a major influence in the development of this focus. He had served as editor of the Bulletin since 1957 and was instrumental in developing its professional stature. His passing was a great loss to the PDA and the pharmaceutical industry.

The widow of Dr. Ashkenaz, Eleanor Ashkenaz, served as interim editor of the Bulletin until August 31, 1964. At the June 19 meeting of the Board, Robert E. King, professor at the Philadelphia College of Pharmacy and Science, was selected as editor at an annual remuneration of $1800. Also at that meeting, a motion was made to propose to the membership a change in the By-Laws to increase the number of elected directors from eight to nine and to delete the requirement that the editor of the Bulletin be a director. This proposal was approved at the Annual Convention.

At the October 13 meeting of the Board another new initiative was approved, that of sponsoring an award of $1,000 to promote interest in research in the parenteral field by students in colleges of pharmacy in the United States, Canada or the possessions of the U.S. The Parenteral Drug Association Award, as it was named, was to be offered annually beginning in 1965 for the best paper submitted.

1965 - At the February 5 meeting of the Board, presided over by President Nathan C. Kirsch, special acknowledgment was made of the many years of dedicated service and devotion by Joseph Kouten as treasurer, upon his retirement from that office.

At the October 19 meeting of the Board it was reported that the efforts of our legal counsel, Carson Frailey, had been successful in that our application for I.R.S. tax exemption status had been approved. Also, at that meeting, it was announced that a special recruiting effort was being made among hospital pharmacists to show them the value of becoming members of the PDA.

The Third Decennium - 1966 - 1975

1966 - The new PDA Letter was introduced on February 1, under the editorship of Norma Reno Miller, of Washington, D.C. To assist her with the gathering of news items, twelve regional reporters were appointed. This new publication was to be a four-page, monthly news letter with current newsworthy items of interest to PDA members.

Nathan Kirsch was re-elected President for 1966. At the February 4, 1966 meeting of the Board of Directors, Bradshaw Mintener was approved as the new legal counsel.

Because of relatively few competitors for the PDA Award, the Board broadened the eligibility beyond pharmacy majors to include students from other accredited colleges and universities, to be effective for the 1967 Award. Victor A. Yanchick, at the University of Iowa, was the recipient of the 1966 Award, with the manuscript "Urinary Excretion of Low Molecular Weight Dextran in Endotoxin Shock."

At the Board meeting of June 23, after considerable further discussion about the need for an executive secretary, a committee was appointed to prepare a job description.

A decennial index of the Bulletin for 1957-1966 was prepared by Dr. King and published as a separate entity. It contained approximately 1000 entries and included both authors and subjects of the articles published.

The exhibits at the Annual Convention had become of increasing importance and interest to the members attending. Further, under the chairmanship of Robert Boyden, exhibits had increased in number until 28 booths were used at the 1966 Convention. Accommodating the exhibitors in terms of space, facilities and drayage had become a very critical and, sometimes, difficult operation. Hotel space and accommodations were becoming more and more important in planning as the attendance grew. Also, a recurring question was how to plan the meetings in a way which would encourage registrants to spend quality time visiting the exhibits.

1967 - At the February 3 meeting of the Board of Directors, under the presidency of Harold Blumberg (See Table 7) a very significant step was taken, the appointment of Hubert E. Boyden as Administrative Secretary. The need for a full-time administrative secretary had been discussed for some time and a committee to research the possibilities had been appointed. Mr. Boyden's pending retirement from William H. Roher as Vice President - Production, his intimate knowledge of PDA through serving on the Board of Directors and as secretary and president of the Association, and his intense belief in the future growth and professional stature of PDA combined to make him an ideal candidate for the position. His appointment was effective immediately.

In recognition of the need for PDA to contribute directly to new developments in parenteral technology, the Board activated a Research Committee with Leon Lachman as chairman. Its first project was a study of particulate matter in parenteral solutions. A Planning Committee was also activated, under the chairmanship of Nathan Kirsch, to anticipate and propose plans for future needs and activities of the Association.

The Board also initiated action to have all future issues of the Bulletin copyrighted, beginning with the September-October, 1967 issue. As an example of the type of articles being published at that time in the Bulletin, those appearing in the September-October and November-December issues were:

"A Look at Generic and Trade Name Injections", by Glen J. Sperandio
"An Evaluation of Membrane Filters for Sterile Processing", by Robert A. Nash, Bruce E. Haeger, Joseph T. Powers and Gordon R. Personeus
"Parenteral Water-in-Oil Emulsions as Adjuvants", by Jack Lazarus and Leon Lachman
"Parenteral Incompatibilities-Past, Present and Future" by E.A. Parker, R.J. Boomer and S.C. Bell
"Microbiological Data: Laminar Flow Room Versus Non-Laminar Flow", by Remy Hazinski

"Parenteral Nutrition", by Robert P. Geyer
"Intravenous Fat Emulsions - An Enigma", by John F. Mueller.

A special plaque was designed and presented to William Thawley at the Annual Banquet for his many contributions to the work of PDA over several years, including, serving as chairman of such committees as Membership, Cocktail Party and Publicity.

Because of increasing costs, registration fees for meetings for 1968 were increased to $25 for members and $30 for non-members for one day meetings and $50 to $60, respectively, for the Annual Meeting. Student fees for scientific meetings only remained at $3 per day. Annual corporate membership fees were increased to $150.

The winner of the 1967 PDA Award was Billie W. Wickliffe, Assistant Professor of the University of Georgia School of Pharmacy. The research reported in her paper was performed under the direction of Donald Cadwallader and Howard Ansel. The award-winning paper entitled, "Radioisotope Analysis of In Vivo Hemolysis Following Intravenous Injections," was presented at the Annual Meeting.

1968 - Kenneth E. Avis, the first academician so honored, became President of PDA. Another "first" that had been discussed for some time came to pass with the scheduling of the Spring Meeting in Detroit. This attempt to encourage Canadian participation resulted in several guests from the Pharmaceutical Manufacturer's Association of Canada attending. An opportunity was thereby afforded to explore the feasibility of holding a PDA meeting in Canada at some future time. However, Canadian participation was reduced somewhat because the program had to be curtailed to comply with the curfew imposed by the City of Detroit because of the unrest occurring as a result of the assassination of Martin Luther King, Jr.

One of the duties planned for the new Administrative Secretary, Hubert Boyden, was to edit the PDA Letter. The assumption of his new duty occurred with the April issue, and his efforts to make this publication more responsive to the interests of PDA members quickly became evident. The PDA Letter regularly was planned to contain introductions to programs of upcoming meetings and summaries of those most recent, and such features as "Washington Action", "Personnel Changes", "PDA Welcomes" (new members), "Book Review" and "Coming Events." More photographs were to be included as appropriate and available. These changes were received with enthusiasm by the membership.

At the April Board Meeting, Joseph W. Kouten, Treasurer of the PDA form 1956 to 1964 and a Director, was recognized for his dedication and many contributions to the work of the Association by being proposed as an Honorary Member, an honor reserved for only a few individuals. Joe was a careful and prudent guardian of the finances of PDA. This action was approved by the membership at the June Meeting.

At the recommendation of the Research Committee, late in 1967, the Board had begun consideration of the possibility of implementing another one of its objectives, the promotion of research in the area of parenterals, a strikingly new initiative, that of assisting the development of an automated method for inspecting ampuls for particulate matter. Previously, PDA had not had the funds to consider such an initiative, and several Board members continued to have misgivings. However, as an outcome of these discussions, President Avis announced at the Philadelphia Meeting (See Table 8) that PDA had entered into a contract with the Emhart Corporation to assist in the development of an in-line inspection device. PDA provided a financial stimulation of $10,000 (which eventually rose to $25,000) and cooperated in developing the technology. The schedule called for completion of the project within one year. While numerous delays were encountered, PDA's initiative was the stimulant for a significant advance in parenteral technology. This new role for the Association resulted in benefits for the entire industry.

Further, at the June meeting, to enhance wider participation in the affairs of the Association, an increase in corporate representatives from 4 to 6 and increased corporate dues to $200 per year was authorized.

Since the 25th anniversary of PDA would occur in 1971, an Anniversary Committee was appointed, chaired by William Bucke, and discussions concerning the nature of the celebration were begun. In response to a recommendation of the Committee, at its November meeting the Board made the decision to make the annual meeting an especially memorable one by holding it in a resort area, later decided to be in Las Vegas, Nevada.

A new effort in publication was undertaken by the Board at its November meeting, namely, the decision to print 500 copies of an annotated bibliography covering the literature relevant to the parenteral field during the years 1959 through 1963. The manuscript for the bibliography, consisting of approximately 950 entries, was presented to PDA by its authors, Carolyn G. Hall, M.L.S., and Kenneth E. Avis, D.Sc. The project was undertaken at The University of Tennessee College of Pharmacy in recognition of the fact that there was no comprehensive compilation of the literature pertinent to the parenteral field covering this time period. Copies were offered at a prepublication price of $5.00 and $7.50 after publication, at a price intended to cover costs only, as a service to the membership.

The 1968 PDA Research Award was presented to Victor A. Yanchick, Assistant Professor, University of Texas, at the Annual Meeting for his paper entitled, "The Effects of Rubber Closures on Benzyl Alcohol-7-14-C in Parenteral Solutions." Dr. Yanchick did his research under the direction of Glen Sperandio at Purdue University.

Robert E. King was reappointed editor of the Bulletin and commended for the improved quality of the publication, the gains toward achieving the goal of publishing acceptable articles within six months, and the reduction of the backlog of papers. After a study by the Publications Committee it was agreed that the format and size should not change. It was noted that domestic subscriptions to non-members had reached 120 and foreign to 160, a further indication of its improving status as a specialty scientific and technical publication.

1969 - Kenneth E. Avis was reelected President for 1969. Early in the year the Board acted on the recommendation of the Publications Committee and authorized that the Directory of Membership be published as a separate entity, previously having been published in the Bulletin. All individual members and corporate representatives were listed alphabetically along with their affiliation and their preferred mailing address. All corporate members were also listed along with mailing addresses and the corporate representatives.

The Research Committee, under the chairmanship of Leon Lachman, continued to be a very active committee. Three subcommittees were working diligently at this time on problems of interest in the parenteral field, namely, 1) monitoring particulate matter developed from the washing and handling of rubber closures, 2) the efficiency of flushing and effectiveness of monitoring inert gas flushing of ampuls and vials and 3) the development of equipment for the automatic detection of particulate matter in vials and ampuls (the Emhart project). At the October Board Meeting it was reported that, after extensive reworking of the prototype machine, field trial runs had been conducted at Hoffmann-LaRoche, Inc. on sample lots of 2 ml ampuls, with substantial success. Operation at the rate of approximately 1600 ampuls per hour and approximately 95% replication of previously manually inspected containers of product was achieved. It was generally found that the machine was more sensitive and more consistent than the average visual inspection tool but that it has promise for use in monitoring present inspection methods.

At the Annual Meeting, Earl L. Meyers, Director, Division of Oncology and Radiopharmaceuticals, Office of New Drugs, Bureau of Medicine, FDA, was the featured speaker. His appearance again was reflective of the developing relationship between the FDA and PDA. Over the previous several years FDA representatives had been increasingly present at PDA meetings and were often program participants. Remarks had become increasingly common of the FDA's respect for the technical quality and commitment of PDA and PDA, in turn, had actively cultivated open dialogue at a technical level with FDA.

Also at the Annual Meeting, Frank Paul Castronovo, Jr. presented his 1969 PDA Research Award winning paper, "The Development of a Closed

System for the Sustained Intravenous Infusion of a Sterile Pyrogen Free Solution of 137mBa-EDTA." His research was performed under Henry Wagner at the Johns Hopkins Medical Institutions. The Award consisted of $1,000 and an engraved plaque to the recipient and an engraved plaque to the institution in which the research was performed, with the director of the research named on the plaque.

1970 - One of the first actions of President Charles P. Schaufus was the appointment of committees for detailed planning of the 25th anniversary celebration of PDA in 1971. Early in the year it was announced that a very special Annual Meeting would be held at Caesar's Palace in Las Vegas on November 10-12, 1971.

One of the notable events for the year was the first PDA meeting held outside of the USA. On April 10, 1970, PDA met in Montreal, Canada. The featured speaker was Armand Frappier, C.C., O.B.E., M.D., Director, Institute of Microbiology, University of Montreal, on the subject, "Methods for the Production and Control of BCG Vaccine." Comments from those present indicated that this first international PDA meeting was highly successful. Canadian members of PDA worked diligently to make the meeting successful.

In order to try to increase the interest and appeal of the PDA Research Award, the Board initiated the offering of a $1,000 award to both the student researcher and the college in which the research is performed. The faculty member who had directed the research must use the funds for further research. Both recipients will receive travel funds to a maximum of $500 to accept the awards. Further, the Award was opened to a student enrolled in any accredited college or university. This revision of the Award applied to the college year ending June 1971.

At the November meeting of the Board, testimonial plaques were authorized to be awarded to past presidents at the Annual Convention following their last term, and they will be guests of the Association. However, plaques to retiring members of the Board will be awarded only upon specific action of the Board. Also, action was taken to admit all speakers on a given program at no charge to all sessions, including social activities.

Administrative Secretary Boyden reported a large increase in subscriptions to the Bulletin, from 164 foreign and 122 domestic in 1969 to 212 and 139 respectively, at the end of 1970. Also, the special seal for the 25th anniversary year was approved for use on the Bulletin and other publications during 1971.

The response to the first volume of the annotated bibliography had been so favorable that the Board approved a proposal from Dr. Avis for preparation of a second volume at the University of Tennessee, to begin with the literature of 1964 and progress toward 1970 as rapidly as possible. A grant of $7800 was authorized to cover the cost of the first year of effort.

An external issue of great interest to PDA members was the announcement of the beginning of talks between the United States Pharmacopeia Convention, Inc. and the American Pharmaceutical Association toward greater cooperation and possible merger of the USP and NF into one compendium.

Reports were given by members of the Research Committee at the Annual Convention on the progress of three subcommittee studies, Paul R. Rasanen of Hoffmann-LaRoche on "The Detection of Particulate Matter in Injectables," Joachim Anschel of Ciba Limited on "Problems and Methods of Flushing with Inert Gas," and William K. Hallock of Lederle Laboratories on "Problems with Washing of Closures." These reports summarized the extensive volunteer work, the first such organized efforts, being done by members of the Research Committee to help improve the processing of parenteral products.

Also at the Annual Convention, Brandt Rowles, Assistant Professor of Pharmacy, Ferris State College, presented his 1970 PDA Research Award paper entitled, "The Effects of Elastomer Closures on the Absorption of Certain 14C-Labeled Drug and Preservative Combinations." Dr. Rowles had conducted his research while a graduate student at Purdue University under the direction of Glen Sperandio and Stanley Shaw.

1971 - The 25th anniversary year began with the usual winter meeting on February 5th in New York City, the city where PDA began and where winter meetings had been held every year since. President Schaufus announced that plans were progressing for a traditional technical program coupled with a gala dimension of activities for the 25th Anniversary Convention. The special logo designed for the anniversary year was used on publications and stationery. (See Figure 3).

The Training Film Committee, chaired by Tom Riggs, began work early in the year on the first PDA training slide/sound product. It will be prepared professionally with the active involvement of Committee members and with hopes that it can be ready to show at the 25th Anniversary Convention.

At its June Meeting the Board approved the recommendation of the Planning Committee to reduce the number of regular PDA meetings to three, one-day meetings in March and June and the three-day annual meeting in the fall, beginning in 1973. The objective was to be better able to concentrate on quality papers for the programs. The winter meeting program always was the most difficult to develop because of following so closely after the Annual Meeting and the Christmas holidays. A revised registration fee schedule also was approved for full-day meetings of $35 for members and $50 for non-members and for the annual convention of $60 and $90 respectively.

The 25th Anniversary Convention of PDA at Caesars Palace in Las Vegas was an outstanding success. There were nearly 500 registrants and 41 booths leased to exhibitors. All technical sessions were well attended in spite of the visitor attractions of the locale. Recreational events, including tours and golf games, were included in the program plans. William S. Bucke, Chairman of the general convention planning committee, expended untold energy and planning innovations to make this meeting the memorable one that it proved to be.

The Convention program was opened with a welcome by Oran K. Gragson, Mayor of the City of Las Vegas. The technical program, planned with outstanding insight by William Artz' committee, was designed to meet the technical objectives of PDA. Outstanding speakers of national reputation included John Jennings, M.D., FDA Associate Commissioner for Medical Affairs, speaking on "Some Regulatory Aspects of Parenteral Drugs," and Thomas J. Macek, Ph.D., Director of Revision of the USP, speaking on "Biological Indicators - A USP Review." Selected other speakers and their topics included:

> Nancy Hall, Manager of Microbiology for Barnes-Hind Pharmaceuticals, on "Good Manufacturing Procedures for Single Dose Ophthalmic Products," Wallace L. Guess, Dean of the University of Mississippi, School of Pharmacy, on "Some Effects of Packaging Materials on Ethylene Oxide Sterilization," Eiko M. Stapert, Head of Microbiological Testing for the Upjohn Company, on "The Design and Monitoring of a Sterility Test Facility," Andrew J. Schmitz, Jr., Assistant Director, Quality Control, Pfizer Pharmaceuticals on "Auditing of Bulk Pharmaceuticals - Methods, Facilities and Controls," William S. Miller, Director, Biological Safety and Control Department, Becton-Dickinson, on "Establishment of Sterilization Cycles," Gerald Hecht, Head, Product Development Department, Alcon Laboratories, on "Considerations in the Development of Parenteral Quality Agents for use in Ophthalmology," and W.R. Howarth, E.R. Squibb & Sons, Inc., on "Volume Filling of Parenterals with Mass Air Transfer and Monitoring Controls."

Many other outstanding speakers participated in the program.

The 1971 PDA Research Award paper was also presented at the Convention by Betty H. Tusa, M.S., Pharmacist, The Veteran's Administration Hospital, Memphis, TN, entitled "Studies of Dimethylpolysiloxane Compared to Sesame Oil as a Vehicle for Progesterone Injection." The research was performed at The University of Tennessee College of Pharmacy under the direction of Kenneth E. Avis, D.Sc., in partial fulfillment of the M.S. degree requirements. The Award, for the first time, included a plaque and $1,000 for research to the University in addition to the plaque and $1,000 to the recipient.

1972 - Under the presidency of Gordon Personeus, the Association voted to approve, at its March 3rd meeting, the recommendation of the Board of Directors that the By-Laws be changed to require not less than two meetings a year in addition to the annual convention. This action essentially reduced the number of one-day meetings from three to two but increased the ability to attract high quality presentations by giving the Program Committee more time to recruit speakers.

At the March 2nd meeting of the Board, Mr. Boyden, Administrative Secretary, reported that there were then 187 foreign subscribers and 499 total subscribers to the Bulletin. A progress report on Volume II of the Bibliography, covering the literature of 1964-1967, identified a completion goal of April 1972 with over 1,000 abstracts. (Upon completion, 1125 literature citations were included in 380 pages.) Dr. Avis also submitted a proposal for continuation of the project with Volume III to cover the literature of 1968-1971. This proposal was approved because of the enthusiastic acceptance of this literature resource for those involved in the parenteral field.

The first training slide/sound series prepared by the Film Subcommittee of the Research Committee, under contract with a professional producer, was not ready for the 25th Anniversary Convention but had its initial showing during the 1972 Annual Convention. The product was an 11 minute slide/narrative entitled "Sterile Products and You." The theme of this training aid is the motivation of workers to perform in accordance with good manufacturing practices in the production of sterile products. Response to the slide/-sound series was highly complimentary, providing a stimulus for the preparation of other training aids. Each set was sold for $250, slightly above cost, as a service to the PDA membership.

The 1972 PDA Research Award was presented to Patrick B. Ryan, a graduate student at the University of Kentucky College of Pharmacy, for his research paper entitled, "In-Line Filtration - A Method of Minimizing the Risk of Bacterial, Fungal and Particle Contamination in Intravenous Therapy." The paper was presented during the Convention, as were the Awards, one to Mr. Ryan and the other to Robert Knapp, his faculty advisor. Also serving as coinvestigators in this pioneering research were Patrick P. DeLuca, Ward O. Griffen, Jr., Joseph D. Clark and Don Cloys.

Many considered the 1972 Convention one of the best ever, in large measure due to the quality and quantity of exhibits. Thirty five suppliers of high repute with product lines of particular interest in the parenteral field were exhibitors. The Exhibits Committee considers the exhibits an important educational experience for conventioneers to learn of new developments or new information about older developments. Time is always allotted within the program for viewing the exhibits. Further, it should be acknowledged that the fees paid by exhibitors are an important source of income for PDA. Exhibitors also make other contributions, such as sponsoring the supplier's reception.

An external committee that was to have a significant impact on the field of parenterals was the "National Coordinating Committee on Large Volume Parenterals" (NCC-LVP), organized jointly by the FDA and the USP to address problems associated with the production, handling and administration of large volume parenteral solutions. The stimulus for its formation was the nationally significant contamination problem encountered with large volume parenteral solutions in 1971. Patrick DeLuca was appointed by the Research Committee to be PDA's representative to that Committee.

1973 - At the March 1st meeting of the Board of Directors, President Personeus presided at the Board's first meeting of his second term. The Research Committee reported that a news letter questionnaire was nearly ready to be published requesting participation in an ethylene oxide sterilization project. The Arrangements Committee recommended that the Spring 1974 meeting be held in Puerto Rico because of the large number of parenteral production plants on the island. This recommendation was unanimously approved.

The Mid-West Meeting at the new Regency Hyatt House, at Chicago's O'Hare Airport, took an unexpected turn when a fire broke out in the first floor night club at 4:20 a.m. and filled the atrium with smoke. The hotel was evacuated, except for Hubert Boyden who slept through the whole event, including the pounding on the door of his

room directly above the fire location. Everyone agreed that Hubert had another "talent", he is a deep sleeper. Another talent was exhibited by the hotel staff, they reorganized and recovered from the fire emergency so that the events of the meeting went on with only minor hitches.

At the June 21st Board meeting it was reported that individual membership had grown to 769, there were 328 foreign and 179 domestic subscribers to the Bulletin, 441 copies of Vol. I and 172 copies of Vol. II of the Bibliography had been sold and 57 copies of "Sterile Products and You" have been sold. Also, a record 25,000 copies of the 11972 PDA Research Award Paper were ordered. These PDA services are, obviously, being well received. In addition, the Board also authorized continuation of the bibliographical project into Volume IV covering the literature on 1971-1973.

Other actions taken at the June 21st Board meeting included approval of a proposal by the Arrangements Committee that the Spring Meeting in Puerto Rico be scheduled for April 4 and 5, 1974 with one or two plant visits on the first day and technical sessions on the second day. This plan was approved. The Film Committee announced that the next training slide/sound series would be on the subject of cleaning.

At this meeting, the Board took very important action by electing William S. Bucke as the fifth Honorary Member of PDA for his many significant contributions and his outstanding leadership in the organization. Formal induction took place on November 1, 1973 at the Annual Convention.

At the Annual Convention the Film Committee announced that it had selected six subjects for the development of slide/audio training aids, namely, cleaning, gowning, handling of materials, aseptic filling techniques, documentation of process data, and inspect and measure. An appeal was made to the membership to become involved in the preparation of one or more of the visual training aids.

Also at the Convention General Business Meeting on October 31st, the proposed extensive By-Law changes, which had been two years in preparation, were approved unanimously by the membership. While there were numerous changes most were housekeeping in nature rather than major in their effect.

The 1973 PDA Award was received by Hans G. Schroeder, of the University of Kentucky, for research entitled, "A Study on the In Vitro Precipitation of Poorly Soluble Drugs from Nonaqueous Vehicles in Human Plasma." Patrick P. DeLuca served as the faculty advisor. Each received a plaque and a check for $1,000, with Dr. DeLuca's to be used for further research.

1974 - Plans for the first PDA meeting in Puerto Rico moved toward finalization early in the year. The two-day meeting, on April 4-5, was to consist of a plant tour the first day and a technical program the second day. In addition to fifteen technical and scientific papers on the second day, the luncheon speaker was Teodoro Moscoso, Administrator Fomento, Commonwealth of Puerto Rico, and a pharmacy graduate of the University of Michigan. He spoke of the economic opportunities for the pharmaceutical industry in Puerto Rico. Registrants were encouraged to extend their stay and enjoy some of the Puerto Rico sun and surf.

The third volume of the Annotated Bibliography, covering the literature of the years 1968-1970, became available. The three volumes in print now providing literature coverage for 1959-1970.

The first PDA training slide/audio presentation, "Sterile Products and You," was introduced to the membership by Thomas H. Riggs, Chairman of the Training Film Committee, at the Mid-West Meeting in Chicago in June. The response to this first product of the Committee's effort to aid in the training of operators and other parenteral plant personnel was very positive. By April 1975 a total of 112 copies had been sold.

Under the chairmanship of Patrick DeLuca (University of Kentucky), the Research Committee was reorganized to consist of a ten-member core committee with, initially, five Task Groups to involve the expertise and effort of more members of PDA to address the specific problems. The initial five problems were: 1) to deal with the recommendations received by PDA from the USP-FDA NCC-LVP, 2) to review recommendations received from the NCC-LVP dealing with micro-

biological contamination, 3) to develop general guidelines for the visible inspection of parenteral products, 4) to develop general guidelines for the processing of containers and closures for parenteral products, and 5) to review and suggest revisions of proposed definitions for incompatibility and instability.

The 1974 PDA Award winning paper entitled, "Extraction Rates of Marker Compounds from Rubber Closures for Parenteral Use," was presented by Joe Bruce Boyett of the University of Tennessee during the Annual Meeting. Kenneth E. Avis was the faculty advisor. Both Boyett and Avis (for the University) received a plaque and a check for $1,000.

1975 - On January 2 an event external to PDA but of great significance to the entire pharmaceutical industry took place, that of the formal purchase of the National Formulary from APhA by the USP Convention. Not only will the two compendia be merged but USPC has taken over the Reference Standards program and the Drug Standards Laboratory that had been operated by APhA.

During the year Patrick DeLuca, chairman of the Research Committee, announced the formation of four additional task force groups, namely, 7) to explore the use of ethylene oxide for the sterilization of bulk pharmaceuticals, 8) to address the new GMP regulations for processing large volume parenterals, 9) to explore the possibility of developing standards for particulate matter in small volume parenterals and 10) to study the development of guidelines for radiation sterilization of pharmaceutical products and components.

President Artz announced that Millipore Corporation had proposed, and the Board had accepted, offering an award to honor and perpetuate the memory of the late beloved Charles P. Schaufus. The award of $1,000 and a permanent plaque will be administered by the PDA Research Awards Committee and will be given for the best publication(s) in the scientific literature within the last five years that has contributed to the advancement of parenteral technology.

Administrative Secretary Boyden reported to the Board in June that there were 439 foreign and 198 domestic subscriptions to the Bulletin, not including those sent to members. This reflected the technical and scientific recognition that the Bulletin has achieved under the editorship of Dr. King.

At the Annual Meeting Banquet in New York the 1975 PDA Research Award was presented to Chong-Heng Huang for his research paper entitled, "Formulation of a Parenteral Solution of Acetylacronycinium Perchlorate: A Soluble Prodrug of the Antitumor Agent Acronycine." His research was performed at the University of Kansas under the guidance of A.J. Repta.

Also at the Banquet, the first Schaufus Parenteral Technology Achievement Award was presented to Patrick P. DeLuca of the University of Kentucky in recognition of his published contributions during the past five years to the scientific literature on parenteral technology. This prestigious Award was sponsored by Millipore Corporation in memory of Charles P. Schaufus who contributed so much to the parenteral field through his voluntary efforts with PDA and his employment at Millipore.

The Fourth Decennium - 1976 - 1985

Under the leadership of President George Hopkins (West Co.), the thirtieth year of the founding of the Parenteral Drug Association was characterized by the response to a number of challenges. First, Solomon C. Pflag (Captain, USN, Retired), an individual with proven administrative experience and knowledge of the parenteral drug industry, was appointed to replace Hubert E. Boyden, Administrative Secretary, under whose direction for ten years the PDA had grown, was accomplished on March 1, 1976.

PDA undertook a new initiative by preparing a formal response to the FDA request for comment on the proposed "Good Manufacturing Practices for Large Volume Parenterals" relating to its applicability to small volume parenterals. The draft response, prepared by the PDA Research Committee, was reviewed at a special meeting on interested members. PDA then met with Bernard Loftus and Oliver Goldbaum of the FDA on the subject matter. A final response was then prepared and delivered to the FDA. Another outcome of this activity was the establishment of the first intercommunication relationship with the Pharmaceutical Manufacturers Association (PMA) as a basis for exchange of technical information and the avoidance of unnecessary duplication and expense for both organizations.

At the Spring Meeting (Table 11), the PDA was pleased to have Carl Bruch of the FDA speak on "Sterility Assurance for Medical Devices Processed by Ionizing Radiation" and Frank Korun, also of the FDA discuss "Proposed Current Good Manufacturing Practice and Supplemental Regulations" intending to update the 1963 regulations and the 1971 revision. Among other subjects of further interest were "Warehousing of Parenteral Closures" (Gary Greene of Faultless Rubber Co.), "Preparation and Handling of Pharmaceutical Grade Water" (H. Hyde, Abbott Laboratories), "High Purity Water Systems" (F. Vlasak, Abbott) and "Porosity Aspects of Membrane Filters" (Theodore Meltzer, Gelman Instrument Co.).
The Summer Meeting was highlighted by Benito Couriel (Lemery, S.A.) who discussed "Advances in Lyophilization Technology" while Richard Shepherd of the FDA spoke on "FDA Inspection of Large Volume Parenteral and Small Volume Parenteral Manufacturers."

Kenneth Avis (U. of Tennessee), an individual whose name had grown synonymous with sterile products and parenteral technology, was selected as the recipient of the prestigious Schaufus Parenteral Technology Award.

The winner of the 1976 PDA Research Award was Simon Rusmin (U. of Kentucky) for his paper, "Microbial Assessment of a Clinical Investigation on Filtration and Infusion Phlebitis."

1977 - In recognition of the need to assure that all drug products produced have the safety, quality and potency they possess, the concept of validation became a subject of emphasis by the FDA. The concept of PDA sponsoring workshops on microbiology and engineering processes was proposed to the Planning Committee by Frederick J. Carleton (Pfizer Inc.) and the first PDA workshop subsequently developed from a proposal to the Board of Directors by Nathan Kirsch (Schering Corp.). Irving Pflug, University of Minnesota, was selected as the course director and the author of the comprehensive text and syllabus for the course. Thus was the start of one of the most rewarding and appreciated contributions to the scientific community by the PDA. Since that time, hundreds of continuing education workshops and courses have been developed and presented in the United States, Latin America, Europe and Asia.

A major effort of the Publication Committee, under the chairmanship of Frederick D. Simon (Merck, Sharp & Dohme), was the publication of the first "Report to the Membership." This booklet, typically, contained reports from the President, Administrative Office, Treasurer and all of the Standing committees of their activities during the year.

Demand for PDA training slide series (Table 13) was overwhelming. The initial slide/sound training program, "Sterile Products and You" was oversubscribed while "Aseptic Filling" and "Cleaning" sales exceeded those of past years by a wide margin. Two new slide/sound programs, "Gown-

ing for Aseptic Areas" and "Documentation of Process Data" were first shown at the Annual Meeting and scheduled for review and release in 1978. The advance demand for these offerings was very heavy, attesting to the wide interest and importance the membership attached to these training series.

Before giving up the reigns as chairman of the Research Committee to Sol Motola (Schering), James Boylan (Lilly or Abbott) reported on the accomplishments of its nine task groups, three of which completed their assignments in 1977, namely: Glass Containers and Rubber Closures; Chemical and Physical Incompatibilities in LVPs; and Visual Inspection of Injectable Products. All three reports resulted in publications.

L. David Butler, University of Kentucky, was the recipient of the 1977 PDA Research Award for his research manuscript entitled, "The Detection of Ampul Leakers Using Short-lived Radionuclides". Co-authors were John J. Coupal and Patrick P. DeLuca.

The Annual Meeting continued to grow in quality, in attendance and the number of exhibits and exhibitors. More than one hundred educational and scientific exhibits filled the available exhibit space at the Statler Hilton Hotel (New York City) in contrast to the seventy exhibits the previous year (Table 12). For those involved in the preparation and presentation of papers, a "Guide for PDA Writers and Speakers" was prepared and issued. Further, a "Guide for PDA Program Chairmen and Program Committees" was developed to assist writers, speakers, program chairmen and program committees in the task of more efficiently structuring future programs.

The two classes of memberships in the Parenteral Drug Association, namely Honorary and Active, were increased by the addition of "student" and "retiree."

Finally, in 1977, to more fully reflect the nature of the content of the Bulletin of the Parenteral Drug Association, and to give a clearer definition of its purpose, the Bulletin was retitled The Journal of the Parenteral Drug Association. The first issue, scheduled for January-February 1978, had a newly designed cover.

1978 - Early in the year, President Frederick Carleton (Pfizer Inc.) established ad hoc committees, appointed chairmen and developed charges for eight major areas of concern. These were:
Assessment of Near Term and Long Term objectives
Revision of the By-Laws and preparation of Job Objectives
Financial Planning
Establishment of a Research Foundation
Internationalization
Expansion of Workshops and Tutorials
Income-producing Projects to Fund Research
Permanent Home

Of interest was that there were 43 active committees with the involvement of 262 PDA members.

The Research Committee published an information bulletin entitled, "Ethylene Oxide Usage, 1976-77 Industrial Survey" which was very timely due to the Environmental Protection Agency's (EPA) intent to issue limitations on the use of ETO. "Validation of Steam Sterilization Cycles" Technical Monograph No.1 was also published in 1978 (Table 15). This monograph became the "bible" for validation of the initial, most critical process in the new thrust of FDA toward validation of all processes. Another task group was charged with the responsibility of generating information which could lead to the development of a method for the quantitation of particulates isolatable from parenteral solutions and to consider such standards for small volume parenterals. Extractibles from elastomeric closures were the concern of another task group, resulting in a set of recommendations from the PDA to the USP/NF for revisions of NF XIV Chapter on Rubber Closures for Injections.

A "Code of Ethics" (Figure 4) was prepared by Fred Simon (Merck) and Stan Sklar (Wyeth) who also revised the "History, Activities, and Objectives" brochure.

The Training Film Committee completed work on the sixth training slide/sound series, "Handling and Control of Materials" and had 10 slide/sound series in various stages of completion, two of which were completed in 1978. These PDA training products were designed for use as orienta-

tion and introduction vehicles in conducting in-house training of operating and control personnel.

The Internationalization Committee was established with the objective of developing cooperative, technical exchange programs between professional organizations outside the United States and the Parenteral Drug Association..

Among the challenges presenting themselves in 1978 was the need to seek a suitable replacement for Robert E. King, a very gifted, precise and thorough individual who served the Association as the Journal of the Parenteral Drug Association Editor for 14 years. A new dynamic Editor for the Journal was found in the person of Joseph Robinson of the University of Wisconsin.

The liaison with fellow organizations increased considerably in 1978 and included the Pharmaceutical Manufacturers Association, Health Industries Manufacturing Association, United States Pharmaceutical Convention, Inc., Parenteral Association, American Society of Quality Control, American Pharmaceutical Association, American Society of Hospital Pharmacists, and others.

The practice of planning and establishing workshops in highly technical areas was continued and expanded. Since the concept was first presented to the Board of Directors the previous year by Fred Carleton, the workshops have been the subject of undiminished enthusiasm and attention. Nine additional workshops were developed.

Stanley Dudrick, (U. of Texas) was the recipient of the Schaufus Parenteral Technology Award for his published innovative research in intravenous hyperalimentation, and Bailey Lipscomb (U. of Tennessee) received the PDA Research Award for his manuscript entitled, "Aerobiological Model for Assessing Microbial Contamination." New awards for 1979 were approved by the Board of Directors. These were: PDA Grants for Stimulation of Research in the amount of $7500 for the best proposals submitted to stimulate research in the area of parenteral medications; and the PDA Research Achievement Award in the amount of $3000, together with a plaque to be presented every third year, in recognition of an individual's overall contribution to the advancement of science and technology in parenteral medications.

The Board of Directors awarded three special one-time grants in the form of $5000 to the University of Tennessee in support of training courses and services given under Kenneth Avis's direction to be offered to personnel representing the parenteral industry and regulatory agencies. A one time grant of $5000 was made to the United States Pharmacopeial Convention in support of standards developing activities in the field of sterile pharmaceutical preparations. A grant of $4000 was made to the University of Minnesota to enable Irving Pflug to continue his work in sterilization as it applies to parenteral technology.

A new approach was employed by the National Program Committee in which members were selected on the basis of their expertise and abilities in defined categories, such as sterilization, production processes and facilities, product development, clinical and packaging components, government, compendia, etc. The members were then given the responsibility of soliciting papers in their respective subject category to cover the requirements of the one and three day meetings.

The highlight of the Annual Convention was the address by FDA Commissioner Donald Kennedy, referred to by the Secretary of HEW as "one of the nation's most distinguished scientists." He spoke on the reaction of the Food and Drug Administration to a fundamental change in the nature of regulation. Commissioner Kennedy's presentation represented a significant recognition for the PDA, in that this was the first time that an FDA Commissioner had addressed the PDA at one of its meetings.

1979 - The highlights of the core strategies, under the leadership of President Frederick Carleton (Pfizer Inc.), that were undertaken in 1979 and the progress achieved are noted below.

The Parenteral Drug Association Foundation for Pharmaceutical Sciences, Inc. was incorporated in 1979 with its own Board of Directors. Nina Demuth (Demuth Development Corp.) and her committee were instrumental in the establishment of the foundation. This step was deemed appropriate by the PDA Board of Directors to enhance the advancement of the art and science of parenteral dosage forms of drugs and promote research in the field, as identified in the purposes for which

PDA was organized. To this end the Foundation's mission is stated to be "to promote the good of the public by identifying needs in the fields of parenteral and related sciences and technologies and by dispensing funds in support of research and educational activities that meet those needs." Beginning in 1981 and continuing through 1994 the Foundation awarded 59 grants, amounting to more than 1.2 million dollars, in accord with the above mission statement. This is an achievement that can be applauded currently but only long-term history will be able to adequately evaluate for its impact on the developments in parenteral and related sciences and for its impact on the developments in parenteral and related sciences and for the ultimate benefits to society. A list of those grants and their recipients will be found in Table 21.

An Internationalization Committee was created by President Carleton in 1978 with the appointment of an ad hoc committee, chaired by Jack Cole (Pall Corp) and charged with the task of developing cooperative technical exchange programs between professional organizations outside the United States and PDA. Jack Cole visited several Latin American countries among which were Argentina and Brazil in order to establish contact and gage first-hand their interest in PDA activities. In the subsequent series of lectures by Jack Cole at the pharmacy schools of the University of Buenos Aires and Sao Paulo, the audiences were acquainted with PDA activities. Visits to England, France and Germany by Michael Anisfeld (Arnar-Stone) and Nathan Kirsch (Schering), acting in behalf of the Internationalization Committee disclosed great interest in a PDA technical meeting to be held in Europe. The popular "Microbiology and Engineering of Sterilization Processes" course was presented in London by Irving Pflug. It was expected that this course would provide some measure some of the needs of both our European colleagues and PDA to which both can contribute. Further, it can aid in acquainting PDA with experiencing any problems associated with the logistics of setting up a PDA meeting in England. The Parenteral Society, in recounting its history, cited this course as a seminal event in stimulating interest for a UK-based counterpart of PDA.

An international meeting was proposed and approved by the Board to be held in Mexico City in the Spring of 1979.

The workshop programs proved to be exceptional and the following new programs were offered in the U.S.:

Validation of Steam Sterilization Processes
Metrology-The Calibration of Instruments
Ethylene Oxide Validation
Microscopy Fundamentals and Techniques for Identifying Parenteral Contaminants
High Pressure Liquid Chromatography
Introduction to Vacuum Technology and Process Controls for Vacuum Freeze-Dryers
Photomicrographic Techniques
USP XIX

The American Council on Pharmaceutical Education, after evaluating PDA's offerings, approved PDA as a provider of continuing pharmaceutical education. A system was established so that attendees at all workshops and technical meetings will be awarded appropriate continuing education units of credit (CEU's.)

Paul Kiritsy (Astra) and his committee revised the By-Laws which were unanimously approved by the membership on June 22, 1979. Among the major changes were the addition of the Training, Awards, Budget, Audit, and Regulatory Affairs Committees as Standing Committees. In addition, articles for Liquidation and Indemnification were developed. The classes of memberships were expanded to include Student and Associate memberships. The immediate past president, who by virtue of having served a full term as President, automatically assumes the office of Director for not more than four additional years, the term being reduced from six years.

The Journal continued to increase in the number and variety of articles published. Editorials were added and a new section entitled, "Parenteral Fundamentals," was introduced. Reprints of Journal articles will be prepared by the Mack Printing Company, the printer of the Journal. Printing costs continue to escalate due to inflation as well as the highly volatile silver market. President Carleton proposed to the Board that the

Journal accept advertising, which was approved by the Board and Editor.

The revised award program of PDA resulted in the following grants being awarded:

PDA Schaufus Parenteral Technology Award of $1000 and a plaque to Hans Bundgaard and Claus Larsen of the Institute for Farmaci, Denmark, for the publication which appeared in the Journal of Chromatography entitled, "Polymerization of Penicillins V. Separation, Identification and Quantitative Determination of Antigenic Polymerization Products in Ampicillin Sodium Preparations by High-Performance Liquid Chromatography."

PDA Student Research Award of $1000 plus a plaque to the student and faculty advisor to Nilsuwan Leelarasamee (West Virginia U.) and Prof. Stephan A. Howard for the research entitled, "Visible Particles in Small Volume Parenterals."

PDA Grants for Stimulation of Research in the amount of $7500 to Hani M. Sadek (U. of North Carolina) for the research proposal entitled, "Monitoring and Determination of Ethylene Oxide in Gas Sterilization."

The first PDA Research Achievement Award in the amount of $3000 and a plaque to Kenneth E. Avis (U. of Tennessee) for continuing contributions to the advancement of the science and technology of parenteral medications.

The Research Committee's first Technical Monograph, "Validation of Steam Sterilization Cycles" was followed by Technical Information Bulletin No. 2, "Generic Test Procedures for Elastomeric Closures". Another technical monograph, "Validation of Aseptic Practices" was being evaluated for subsequent distribution. Six additional projects were under study by this committee.

1980 - The Research Committee, chaired by Michael Enzinger (Upjohn) continued to address important industry issues, expanded their research programs and published technical monographs and bulletins as well as responding to FDA proposed regulations as needed and on a timely basis. Several task groups were formed to address: Validation of Aseptic Filling; Validation of Dry Heat Sterilization-Depyrogenation; Extractibles from Elastomeric Closures; Test Methods for Parenteral Glass; Limulus Amoebocyte Lysate; Filtration; Gamma Irradiation of Pharmaceutics; Mechanism and Kinetics of Solute Permeation Through Containers and Closures; and Pathological Assessment of Particulate Matter.

The Quality Control Committee actively pursued three topics of interest. These were:

The criteria to be used for the microbiological release of aseptically filled parenteral products;

Factors that can be standardized for non-automated visual inspection of small volume parenterals for particulate matter; and

Guidelines for Validation of Water for Injection Systems.

Jeffrey T. Taylor (University of Wisconsin) was awarded the 1980 PDA Student Research Award for his paper, "A Convective Diffusion Model for Estimating Drug Loss to Tubing: Sorption of Vitamin A."

Two recipients for the 1980 PDA Grants for Stimulation of Research were Michael J. Akers (U. of Tennessee) for his proposal, "LAL Testing for Depyrogenation in the Validation of Convection and Infrared Dry Heat Sterilizers," and James W. Sieg (U. of Kentucky) for his proposal, "Determination of Optimal Retention Characteristics for Ophthalmic Microsuspensions." Beginning in 1981, these awards and the Schaufus Award were authorized to be funded and operated through the PDA Foundation.

The Spring Meeting held in Mexico City was characterized by scientific and technical programs distinguished for their excellence and relevance to parenteral technology and its associated disciplines. It was the only occasion during which our Mexican colleagues and scientists have joined their colleagues in the United States in the planning and participation in a PDA meeting in Mexico and provided an effective atmosphere for a positive learning experience and cultural exchange. In addition, the hosts, representing the Mexican Pharmaceutical Association opened their

homes and hearts to their U.S. guests. Mexican graciousness and warmth will long be remembered.

At the Annual Meeting, held in New York City, the exhibit show was the largest exhibition of scientific equipment, information systems, suppliers, and services ever hosted by PDA. Poster sessions were first introduced as a part of the program at this meeting.

The USP Convention held its 1980 Quinquennial Meeting in April in Washington, D.C.. During the three-day session, PDA was voted in by over 200 delegates as an eligible organization, thereby permitting PDA to officially participate in and vote on USP policy matters. Frederick J. Carleton (Pfizer Inc.) was selected as the PDA delegate.

"Maintenance in the Pharmaceutical Plant" was the seventh in a series of slide/sound training programs produced by the PDA as a non-profit service to its members and to the industry. In addition, "Wash Those Hands" was also made available.

1981 - President Jack Cole (Pall Corporation) noted that PDA's dramatic growth in scope and services has been achieved as a result of highly motivated committeemen under the leadership of skilled and imaginative chairmen who have adopted and implemented the strategies of the officers and Board of Directors.

The Research Committee again, in 1981, expanded its activities, addressing topics of importance to parenteral drug manufacturers. Thirteen task groups were involved in the following areas:

Limulus Amoebocyte Lysate: Prepared a response to FDA Draft Guidelines, and FDA accepted the recommended PDA proposals. The task group continued by developing an extensive review of depyrogenation procedures.

Validation of Filtration processes for sterilization of liquids.

Irradiation Sterilization of Pharmaceuticals: This group studied the feasibility of gamma irradiation and its use for pharmaceuticals.

Validation of Water for Injection Systems: Addressing concepts that may be considered in the design and validation of such systems.

Selection and Evaluation of Sanitizing Agents: A literature review addressed effectiveness, methods of application, residuals and effects with contact on personnel and products for various types of sanitizing agents.

Light Inspection for Particulate Matter: A survey will be used as the basis for an Exchange Forum at a future PDA meeting.

Mechanisms and Kinetics of Solute Permeation Through Containers and Closures.

Inert Gassing of Parenteral Products

In-Process Particulate Monitoring

Use of Process Control Computer Systems in the Pharmaceutical Industry

Evaluation of Extractibles from Glass

Determination of Container/Closure Integrity

Pathological Assessment of Particulate Matter

A quarter of a century was required for the Association to grow from a handful of members to approximately 1300 members in 1981. The Association continued to grow, albeit at a moderate rate, not withstanding the plethora of new associations and the resultant onset of the recession.

The 1981 Spring Meeting, held in Philadelphia was a balanced program of wide appeal to scientists representing the varied disciplines. It was characterized by two innovative features namely, exchange forums and a plant tour of Wheaton Glass Company. The exchange forums were conceived with the hope that the reluctance to exchange certain scientific and technical information as well as ideas, could and should be overcome if the best interest of the parenteral industry is to be served. Particulate Matter Monitoring and Accelerated Stability Studies were the subjects of the forums, characterized by lively dialogues.

The Summer Meeting, held in Chicago was comprised of a host of scientific subjects including novel cell culture systems, manufacturing of SVP's in an unusual controlled environmental system, the use of Bacillus coagulans as a biological indicator, microscopic methods for analyzing particles in solution, energy saving original approaches for producing sterile pharmaceutical grade water and bioassay monitoring of therapeutic drugs. In addition, two forums were held as well as a tour of Smith Laboratories.

The Publications Committee introduced and the Board approved a new Journal title, namely, Journal of Parenteral Science and Technology, as a more accurate reflection of the goals and objectives of the Association. In addition, a larger size providing greater flexibility for construction of articles and making the publication easier to read and more cosmetically appealing, was approved. For the convenience of the PDA's Spanish speaking readers, Spanish language abstracts of all Journal articles were initiated.

The PDA Foundation for Pharmaceutical Sciences presented awards for the first time at the Annual Banquet. The Student Research Award for 1981 was presented to Ronald G. Garrell of the Philadelphia College of Pharmacy and Science Grants for his paper "Stabilization of a Homatropine Hydrobromide Ophthalmic Preparation by Lyophilization" while grants for Stimulation of Research were awarded to Patrick P. DeLuca (U. of Kentucky) on "Interaction of Microspheres with Blood Constituents and Effect on Immune Response" and to Alan P. MacKenzie (U. of Washington) on "Freezing and Freeze-Drying of Pharmaceutical Models." The new William S. Bucke Grant of $20,000 for Research in the Field of Parenteral Nutrition was given to J. R. K. Robson, M.D., (U. of South Carolina) for his research proposal entitled, "Vitamin Status and Metabolic Control in Cancer."

1982 - While the formal and structured meeting programs had contributed enormously to the exchange of information, the rapid technological explosion had created technical education obsolescence at an almost exponential rate which required PDA to consider a new approach to examine, discuss and debate the new advances, breakthroughs, innovations, research and issues. In response to this challenge, President Leon Lachman (Lachman Consultant Services) created an Education Committee with the charged to implement the short courses which would continue to serve as continuing education opportunities and provide a forum for the exchange of ideas and useful practical information for faculty and students alike. Thirty-four short courses were developed by the Committee of which nine courses were given at the Spring and Annual Meetings and an additional fourteen courses scheduled for the following year (see Table 14).

An Executive Committee was formed to handle the day to day running of the Organization, freeing the Planning Committee to concentrate on long term concerns of the PDA. The need for additional income was paramount in order to maintain grants for research and development and to forestall increasing dues and registration fees. Fred Carleton proposed the inclusion of paid advertisements in the Journal which could generate needed revenue for the Association and the advertisements would also fill an informational role. After due consideration, the Board finally approved this new approach. The first advertisements appeared in the Jan/Feb 1982 issue of the Journal of Parenteral Science and Technology.

New publications by the Research Committee in 1982 included "Glass Containers for SVP Products," Technical Methods Bulletin No. 3; "Aspects of Container/Closure Integrity," Technical Information Bulletin No.4; and "Design Concepts for the Validation of Water for Injection Systems," Technical Report No.4 (scheduled for publication in January 1983). Also, four exchange forums were developed on "Validation of Filtration Processes" and presented.

Major changes in the awards program were made; some changes effective in 1982 and some in 1983. The first PDA Journal Award was presented to L. Tensmeyer, P. Wright, D. Fegenbush and S. Snapp (Eli Lilly) for their paper entitled "Sterilization of Glass Containers by Laser Initiated Plasmas" which was judged to be the best manuscript published in the Journal during 1981. Grants for Stimulation of Research were awarded to P. DeLuca, M. Kanke and I. Sniecinski (U. of Kentucky) for "Interaction of Microspheres with Blood Constituents and Effect on Immune Re-

sponse" and to R. Pearlman and J. W. McGinity (U. of Texas) for "Intravenous Fat Emulsions as Drug Delivery Systems." The William S. Bucke Grant for Research in the Field of Parenteral Nutrition was awarded to J.M.Daly and M.H. Mihranian (Sloan Kettering Memorial Cancer Center) for "Evaluation of the Metabolic Efficacy of Intravenous Amino Acid Solutions High in Branched Chain Amino Acids."

1983 - Under the leadership of President Leon Lachman (Lachman Consulting Services), expansion of the PDA office physical Facilities and staff was undertaken to accommodate the expanding services to the membership. The office space was enlarged, in-house computer capabilities were introduced and a search was initiated for an assistant director.

The Planning Committee, under the chairmanship of Clarence A. Kemper (Kaye Instruments), completed a long range strategic plan designed to interpret and enlarge PDA's original objective and to ensure that PDA would continue to be the primary source of practical, technical and scientific information in parenteral technology. To accomplish that goal, all programs and services offered to the membership would have to be of the highest possible quality including technical programs at meetings, workshops and courses, slide series and other training aids, research reports and bulletins, the content of the Journal and the PDA Letter. As a corollary to the above, PDA would continue to assist the industry in solving specific problems through promoting and supporting research and conducting forums or other special discussion conferences.

The two-day Spring meeting in San Juan, Puerto Rico on April 7-8 was preceded by a workshop and three short courses as well as an optional visit to the DuPont Pharmaceutical plant in Manati. Over 300 members and guests participated in the events which included a gala torchlight reception hosted by Wheaton Industries at Fort San Jeronimo, accompanied by buglers in the ramparts and hotel staff in Conquistador costumes.

The Summer meeting in Chicago on April 24 was preceded by a plant tour of Radiation Sterilizers, a mini-symposium, four short courses and a concurrent offering of Irving Pflug's course.

The twelfth slide/sound training program was released for sale. The program defines "inspect and measure" and their application in a pharmaceutical plant, the responsibility of the parenteral inspector and inspect and measure methodologies during processing including examples of how defects should be handled.

The 37th Annual Meeting Banquet in Philadelphia on October 11 was the occasion for the presentation of the increasing number of annual awards. Most notable was the presentation of the first PDA Distinguished Service Award to Nathan C. Kirsch (Schering Corp.) who had served PDA with distinction in many roles for over two decades. This award was established to recognize members of PDA who contributed outstanding and sustained service to PDA and the award represents the highest recognition for overall contributions to the Association.

The PDA Foundation Awards Committee gave two Grants for Stimulation of Research of $10,000 each for: "Mineral and Bone Metabolites in Patients Receiving Long Term Parenteral Nutrition" by Moishe Shike (Sloan Kettering Institute for Cancer Research) and "Formulation of Poorly Soluble Drugs for Parenteral Use" by S. H. Yalkowsky, J.A. Blanchard and J.T. Rubino (School of Pharmacy, U. of Arizona).

The George H. Hopkins Grant for Stimulation of Research ($10,000) was given to A. J. Repta U. of Kansas School of Pharmacy) for "Pro-Drugs of Amines for Alteration of Physical and Chemical Properties of Drugs for Parenteral Formulations."

N. R. Anderson (Purdue U. School of Pharmacy) was awarded the Charles P. Schaufus Grant for Research in the Field of Parenteral Processing Technology ($10,000) for "Sterilizing and Depyrogenating Properties of a Plasma Initiated by a Laser and Sustained by an Electro-magnetic Field."

The Research Achievement Award of $3000 plus a plaque was given to S. J. Turco of Temple University School of Pharmacy, for his overall contributions to the advancement of parenteral science and technology.

The PDA Journal award for the best published paper in 1982 was presented to N. R. Anderson and J. J. Motzi of Purdue University School of Pharmacy for "Permeation of Preservative through Rubber Membranes as a Basis for Predicting Loss of Preservatives into Rubber Closures."

The PDA had been considering for some time how best to assist academia in funding graduate students interested in performing research in parenteral science and technology. As an outcome of these considerations, the Board approved the support of two graduate students, beginning in 1984 under the PDA Scholars Program.

Technical Reports 4, 5 and 6 and Technical Bulletin 3 emanating from the Research Committee were completed . They are:

Sterile Pharmaceutical Packaging: Compatibility and Stability (J. Wang and Y. Chien), Technical Report No. 5

Validation of WFI Systems (R. Kieffer, D. Conrad and F. Carleton), Technical Report No. 4

Depyrogenation (F. Pearson), Technical Report No. 6 and

Aspects of Container/Closure Integrity (F. Keim), Technical Bulletin No. 3

The Annual Meeting, held in Philadelphia, established a new attendance record. Approximately 40 scientific presentations, 19 poster presentations, a mini-symposium on ethylene oxide and 125 scientific and educational exhibits characterized the meeting attended by over 1300 industry, government, education and supplier personnel.

Thirteen courses were given in 1983, most of them oversubscribed. Every effort was made to ensure that the membership received educational offerings of the highest quality. In recognition of their over-lapping roles, the Education Committee was expanded to include the duties of the Workshop Committee, thereby providing a unified approach to the development, administration and execution of educational activities by PDA.

1984 - In remarks before the Association, President Sol Motola applauded the involvement of PDA members in their Association in that approximately 200 members were actively involved working on the various PDA committees and that more than 40 percent had attended one or more scientific meetings or education courses during the past year.

The Spring meeting, held in Chicago, was preceded by three mini-symposia on validation of computer processes and a visit to the American Critical Care's R & D Computer Application Facility.

Following an extensive search, John T. Tighe III was appointed to the new position of Assistant Director. He was formerly Assistant to the Executive Vice-President of the National Association of Retail Druggists (NARD).

One of the objectives of PDA was an on-going development of closer liaisons with the Food and Drug Administration and the United States Pharmacopeia Convention. Among efforts to this end, FDA draft guidelines and USP proposed monographs were reviewed and official PDA responses were prepared for the second draft of the FDA "Guidelines on General Principles of Process Validation," the FDA "Draft Guidelines for the Submission of Supporting Documentation for Stability Studies for Human Drugs and Biologics," and USP's proposed new general tests chapter "Particulate Matter in Small Volume Injections." Following a meeting with USP officials, it was agreed to delay implementation of particulate standards for SVP's until July 1985.

In a further effort to involve more FDA and USP personnel in meaningful dialogue and open exchange of information with PDA members, the summer meeting was scheduled for the Washington D.C. area. Both the formal presentations and discussion groupings were
planned to encourage discussion. A mini-symposium was held the day prior and five courses were offered the two days prior to the meeting.

The problem of declining financial support faced by colleges of pharmacy had by the previously cited grants and awards programs. A new program has been implemented to provide a compli-

mentary subscription to the Journal of Parenteral Science and Technology to every college of pharmacy library in Canada, Mexico and Europe (a total of 140). This was an extension of PDA's program of offering gratis subscriptions to every U.S. college of pharmacy library.

A reorganization of the Program Committee into a Coordinating Committee and four Technical Committees representing Production and Engineering, Quality Control/Quality Assurance, Research and Development and Regulatory Affairs was accomplished to aid in implementing the strategic plan adopted in 1993. In addition, traditional Meeting Committees were formed having primary responsibility for the program at each of the three meetings during the year. The role of the Technical Committees was to help Meeting Committees obtain papers and develop programs of interest and value to the entire membership. The Coordinating Committee is composed of the chairmen of the Program Committee, the chairmen of the four Technical Committees, the Chairmen of the active Meeting Committees and others that the Program Committee chooses to appoint. The role of the Coordinating Committee is to oversee all program activities and to provide a forum for discussing and evaluating past and future programs.

The continued viability of the Education Committee was confirmed by its designation as a permanent Standing Committee of the Association. The Education Committee planned course offerings which reprisee earlier successful courses and introduced a number of new courses on timely subjects. Among them were: Container Closure Integrity, Media Fills, Clean-in-Place, Steam-in-Place, Fundamentals of Computers, Automated Systems Validation, Validation of Water Systems, Validation of 0.2 Micron Filtration, Design and Operation of Sterile Heating, Ventilating and Air Conditioning, Validation of Sterile Air Systems, Calibration and Certification of Instruments, Auditing Sterile Operations, Closure Fundamentals, Process Control, Technology Transfer, Writing a Technical Paper, Making an Oral Presentation, Viable and Non-Viable Monitoring, Fundamentals of Lyophilization and Microbiology and Engineering of Sterilization Processes. The Exhibits Committee was named a Standing Committee.

At the Annual meeting in Philadelphia, Round Table Discussions were introduced for the first time; the topics were Computer Systems Validation, Biological Indicators, Change Control, Particulate Matter for SVPs, Current FDA Investigational Trends and Stability Programs. Two plant tours were offered, one to Kimble Glass Co. and the other to Smith Kline and French Laboratories. Prior to the meeting, three courses and two workshops were also offered.

Grants and awards were presented at this meeting.. The 1984 PDA Journal Award for the best paper published in the Journal of Parenteral Science and Technology during 1983, entitled, "Inventory and Measurement of Particulates in Sealed Sterile Containers," was presented to Julius Z. Knapp (Schering) and his co-authors, John C Zeiss (Schering), Brian J. Thompson, Joe S. Crane and Paul Dunn of the University of Rochester. Two Grants for the Stimulation of Research, in the amount of $10,000 each, were given to Theodore D. Sokolosky (Ohio State U.) for "Drug Entrapment within Native Albumin Beads" and to J. Richard Thompson (Mose H. Cone Memorial Hospital) for "Relationship of Serum Morphine Concentration to Analgesia in Cancer Patients Receiving Continuous Intravenous Morphine Infusion." The PDA Foundation presented the Student Research Award to Wendy Ann Preston (Purdue U.) and to Neil Anderson, her faculty advisor; the Charles P. Schaufus Grant was given to J. Howard Rytting (U. of Kansas) for his proposal "Effects of Temperature and Pressure on the Stability of Blood Platelet Preparations;" the George H. Hopkins Grant was awarded to Milap C. Nahata (Ohio State U.) for his proposed studies on "Evaluation of Methods for the Administration of Parenteral Medications" while the Parenteral Nutrition Grant was given to John T. Pinto (Sloan-Kettering Memorial Institute) for his proposed research on "Selective Adriamycin-Induced Inhibition of Flavin Metabolism in Rat Heart: Implications for Adequate VitaminB2 Supplementation During Chemotherapy."

1985 - PDA's continual readiness and ability to address important issues facing the parenteral industry, in a rapid and effective manner, distinguishes PDA as a proactive organization which is continuously recognized as the key spokesman for the industry. Among the issues addressed in 1985

was the comprehensive analysis and response from PDA on the FDA "Draft Guideline on Sterile Drug Products Produced by Aseptic Processing." Following a special symposium relative to the Guideline was subsequently held. This was followed by a meeting at FDA headquarters among PDA, PMA and FDA personnel. Then, at the Annual Meeting, Edmund Fry, Director of FDA's Division of Drug Manufacturing, and his FDA associates discussed the draft guideline with specific reference to the responses received from PDA, PMA and industry.

In addition to the plethoric scientific program characterized by high quality presentations of appeal to PDA's multi disciplinary scientific membership, at the Annual Meeting in Philadelphia, a tour of the new Squibb state-of-the-art parenteral manufacturing facility was scheduled and implemented.

The exhibits at the Annual Meeting established new records. One hundred and sixty exhibit booths (the maximum) were sold. The exhibits were also characterized by their outstanding educational value and great variety of equipment displayed and services offered.

The Fifth Decennium - 1986 - 1995

1986 - A thorough examination of PDA's mission, services and structure was undertaken through the establishment of a new strategic plan. Interviews with members and competitors in order to obtain feedback on PDA's strengths, weaknesses and opportunities was completed. During 1987, the key issues and basic directions for the organization will be clarified, a total membership survey will be conducted, the plan written and approved and a start made on its implementation. James Dunlop and Company, Marblehead, MA was selected as consultant for the strategic plan.

The Board of Directors and the Awards Committee, assisted by an ad hoc committee of academicians chaired by Joseph Robinson, awarded, at no cost, PDA's technical reports to colleges of pharmacy and approved funds to support a junior faculty development grant in the parenteral area. A formal liaison with the PDA Foundation was established to better coordinate activities between the two organizations. As a result, the funding of a literature search and evaluation of existing methodology for determining particulates in parenteral products was funded. Opportunities in the area of biotechnology were advanced and John Bontempo, chairing an ad hoc committee, developed a comprehensive report for evaluation. A biotechnology committee was then set-up and together with the Planning Committee, would continue to explore additional ways to involve PDA in this field.

The Spring Meeting, held in New York City was characterized by heavy emphasis on biotechnology and particulate matter issues. FDA representatives contributed substantially to the discussions on biotechnology by presenting papers on biotechnology plant layout and the impact of biotechnology on government regulations, recombinant DNA technology and the FDA. Additional FDA presentations covered "After the Inspection" themes. Another high interest subject was the rationale for the new elements in Federal Standard 209C.

The Summer Meeting, held in Chicago, was focused primarily on "Validation" which was well received. FDA presentations were "Validation of Automatic Control Systems" and "Validation of Biological Indicators" which added an additional dimension to the discussions that covered a wide range of issues.

The Annual Meeting in San Francisco was perhaps the highlight of the 1986 meeting programs. The Program Committee was compelled to take into account the attractiveness of San Francisco as a potential for luring meeting attendees away from the meeting room during the program, for which they succeeded enormously. By creating a program replete with high interest issues and subjects for management personnel and focusing on biotechnology issues, the meeting rooms were filled to capacity until the last presentation was given, discussed and debated. The round table sessions on Water Systems, Aseptic Processing, Particulate Matter, Current Compliance Issues and Productivity Opportunities were oversubscribed and had to be repeated to accommodate interested members and guests. The innovative Vendor Technical Presentations, PDA's first venture into this mode, were also heavily attended and enthusiastically received. Such presentations will be continued with every effort to seek out objective and non-commercial information.

The Education courses given in 1986 were mostly oversubscribed. These included Microbiology and Engineering of Sterilization Processes, Validation of Aseptic Processing, Validation of Water Systems, and others. Other courses given were Validation of 0.2 micron Filtration, Visual and Optical Detection of Particulates and Fundamentals of Lyophilization.

In recognition of outstanding service to PDA and the parenteral manufacturing industry, Honorary Membership in PDA was bestowed on Nathan C. Kirsch by unanimous acclamation of the Board of Directors. This honor has been given to fewer than 10 members in PDA's 41 year history.

The Distinguished Service Award is presented in recognition of outstanding contributions to the Parenteral Drug Association and to the advancement of parenteral science and technology. The award has been presented twice before. The

recipient of the 1986 award was Frederick J. Carleton (Pfizer Inc.)

The Superior Service Award was given to Frederick D. Simon for his outstanding contributions for the period 1963-1986.

A Scholar Grant Award was given to S. L. Sylvestri, U. of Connecticut for his proposal "Microemulsions as Parenteral Drug Delivery Systems."

The Journal Award went to Brian Park of Manor Park Hospital, Bristol, England for the best scientific paper published in PDA's Journal in 1985 which was entitled, "A Model for Predicting the Stability of Autoclaved Pharmaceuticals Using Real Time Computer Integration Techniques."

1987 - The most significant activity in 1987 was the development, approval, initiation and implementation of the new strategic plan for PDA. The plan provided direction relative to each of PDA's major activities : publications, education, programs, research, regulatory, etc. The two key features were those that addressed organization and scope.

"Organization" entailed strengthening the role of the Executive Director, expanding the professional staff, establishment of an operating committee, emphasizing the policy-setting role of the Board and the position of the President as chairman of the Board. "Scope" encompassed thoughtful expansion; care being taken not to weaken PDA's position as the premier technical organization in the parenteral field. Initially, the strategic plan focused on biotechnology and education, with longer term investigation of the possibility of using PDA's strengths in other pharmaceutical dosage areas such as tablets, non-sterile liquids, etc.

Another key development was the announcement from Captain Solomon C. Pflag of his desire to retire in early 1988 after having served so successfully as PDA's Executive Director for twelve years.

The proposal and plan by Frederick Carleton (Pfizer Inc.) for PDA to host an International Conference on Liquid Borne Particle Inspection and Metrology was approved by the Board. The Conference was held in Arlington, VA. The purpose of this landmark meeting was to explore, on an international level, the problems associated with particulate matter in parenteral products; the theory, methodology, instrumentation, metrology and technical capabilities and limitations of techniques for the quantification of liquid borne particles in solutions. Not for two decades had such a distinguished group of scientists been gathered in a single forum to discuss the issues involved. More than 150 American, European and Asian scientists from government, industry, various pharmacopeias and academia interacted with their peers and debated the issues which were subsequently published in a proceedings made available worldwide for those who could not attend.

President Robert Kieffer, James Agalloco and Executive Director Solomon Pflag met with PMA officials and reestablished lines of communication at the executive level. Copies of all Technical Reports and Bulletins were furnished for the PMA technical library. In addition, PDA will furnish PMA with scientific and technical documents of mutual interest. The existing PDA/PMA liaison, ably conducted by Max Kalm (Schering), will continue.

In view of the need for additional headquarter staffing, larger quarters for the office would be required and a search for additional space was instituted. Purchase vs. leasing would be explored.

Ray Pocoroba (Organon Inc.), chairman of the Education Committee, has offered a wide variety of technical presentations at the three regional meetings and a single stand alone session. Several new courses were added to the well established core of courses, which continually attract large audiences. In 1987, 30 classes were held. The PDA education arena will be expanded to include technical offerings in biotechnology, solid dosage technology as well as investigating course opportunities for overseas locations. Approximately 155 courses have been conducted under the auspices of the PDA in the U.S. and Europe. Thousands of our members thus sharpened their professional skills at nominal costs.

The Research Committee (Michael Korczynski, chairman) Task Forces accomplishments in 1987 were clearly demonstrated by the number of technical publications that were generated. Among them were:

Factors for Consideration in Safe Handling of Biological Materials
Current Practices in the Use of Media Fills for the Validation of Aseptic Processing
Parametric Release of Parenteral Solutions Sterilized by Moist Heat Sterilization
Sterility Testing Practices Survey
Sterility Testing Sampling Survey
Formulation of Proteins and Peptides: Stability and Stabilizers

Perhaps unknown or unseen by many members was that it has taken time, work and dedication by relatively few individuals to bring to fruition these publications which benefit the entire industry.

The PDA Journal Award was given to S. Borchert, R. Maxwell, R. Davison and D. Aldrich for their paper, "Standard Particulate Sets for Visual Inspection Systems: Their Preparation, Evaluation and Application."

The Scholar Grant was awarded to K. Patel (U. of Kansas) for his proposal, "Deamination of Asparagine and Glutamine Residue in Proteins and Peptides" while the Faculty Development Grant was given to Hans Shreier, U. of Florida, for his proposal, "Mixed Micelles for Parenteral Delivery of Doxorubicin."

1988 - The PDA's Strategic Plan stressed the need to shift from a volunteer-driven organization into one that is more staff-driven. It was not that the PDA Board of Directors or Planning Committee members lacked the vision but rather that their time and energy was available in limited quantities. Solomon Pflag, who had served as PDA's Executive Director for twelve years retired in January 1988. Frederick J. Carleton, past president and a member of the Board for 15 years, was chosen as the new Executive Director.

The Strategic Plan, which the Board of Directors adopted in 1987 enumerated several directions and strategies. These were:

1. Realign the management structure of the PDA.

2. Expand PDA's scope to fully cover the parenteral area, particularly biotechnology products. This expansion of scope should be within a long-range context, that of ultimately becoming a scientific and technical umbrella organization for the pharmaceutical industry.

3. Significantly increase PDA's education and training activities.

4. Strengthen PDA's position vis a vis other associations and organizations in the pharmaceutical field.

5. Improve the utility of PDA's publications.

6. Improve PDA's ability to publish timely and appropriate technical information.

7. Strengthen PDA's ability to provide technical information to industry.

8. Strengthen PDA's ability to influence the development of standards and regulations.

9. Make PDA programs more accessible and attractive to the members.

The need to find new quarters was essential since the 1800 square feet that the staff occupied was obviously insufficient. An intensive search by the Executive Director resulted in the leasing of a suite of rooms at One Penn Center, occupying 4000 square feet, which would allow additional room to accommodate the expanding services being provided the membership. The new office was directly above commuter and airport rail service and it also incorporated new technology in the use of micro-computers and fax communications to facilitate the management of the association.

Although the number of staff members remained the same, the emphasis was shifted to account for new duties. An Associate Director of Education & Programs, Suzanne Stone, was hired as well as a Coordinator of Education, taking the place of two staff members who departed. Frederick

Simon was appointed Associate Director of Scientific & Regulatory Affairs.

A major goal was to have the office operations completely computerized. This was accomplished. A data base providing demographic and specialty mailing lists for publications, meetings, advertisements, etc. was established. A facsimile machine was installed and a modern photocopying machine was purchased. A technical information center was organized. A membership recruitment program was implemented with the resultant increase of 22 percent in 1988. Education programs, under the responsibility of the Associate Director of Education and Programs, were increased 100 percent while a further increase of 30 percent of the number of courses would be anticipated in 1989.

One of the Executive Director's objectives was to develop a ten year plan for hotel meeting space. This objective was fully implemented to the extent that hoteliers would permit.

Early in 1988, the Executive Director and Vice-President Michael Korczynski proposed that PDA establish chapters, as a start, in the northeast, Midwest, west and in areas outside of continental U.S.A. For those individuals in the U.S., chapters would make available services and PDA objectives to international affiliates of current PDA member firms and the pharmaceutical technology community at large; it would provide parenteral sciences to non-traveling technical personnel; it would expand membership; it would establish a greater participation in pharmaceutical technology education courses; it would encourage participation in specific areas, e.g biotechnology in the west coast, and would encourage membership in the PDA; and it would remain a viable, contributory organization for the purpose of promoting science and education within the pharmaceutical industry. Outside of continental U.S.A., chapters would encourage international membership in the PDA; promote relationship with other bodies in other countries; develop biotechnology interest for the PDA within the international area; promote and develop PDA presence at international pharmaceutical meetings; and encourage PDA workshops and seminars in their and other countries. Following Board approval of the proposal, a position description for a Director-at Large who shall act as a facilitator, coordinator and group leader for a designed International or Regional Chapter of the PDA was drawn-up. The Executive Director, with the Board's approval, then appointed the following individuals to the Director-at-Large positions:

Edmund Fitzgerald (Canada)
Robert Garnick and John Geigert (West Coast)
Robert Pazzano (East Coast)
Masayoshi Nishiyama (Japan)
Franco Devecchi (South America)
Teresita Garrido (Puerto Rico)
Simon Rusmin (Asia)
Michael Bennett (Scandinavia)
David Couriel (Mexico)

In addition to the above, Michael Korczynski undertook the establishment of a mid-west chapter.

In 1988, the Executive Director met with officials of The Parenteral Society in the United Kingdom, the Association Pour Les Produits Parenteraux et Steriles (A_3P) in France and the R^3-Nordic Society (Sweden, Norway, Finland, Iceland, Denmark) in order to establish liaison relationships. The Executive Director informed the Parenteral Society and A_3P that PDA would not attempt to establish chapters in their countries.

PDA's educational courses, addressing subjects critical to pharmaceutical operations, continued to gain momentum. A record number of courses of 47 offerings were given which included 38 different courses. The first efforts in Europe were scheduled for 1989 in Great Britain and Germany.

Awards in 1988 were presented to George Truskey, Ph.D. (Duke U.) for his paper "The Effect of Membrane Filtration on Protein Conformation" (PDA Journal Award for the best paper) and to Diana Burgess, Ph.D. (U. of Chicago) for "Investigation of Absorption of Blood Proteins onto Parenteral Drug Carrier Systems" (Faculty Development Grant).

1988 was a year of growth and development for the Journal of Parenteral Science and Technology. Joseph Schwartz, Ph.D. of the Philadelphia College of Pharmacy and Science, assumed the editorship of the Journal following the resignation

of Robinson, who had performed magnificently as editor of the Journal for 11 years. Under Schwartz, the Journal's contents page were included in the renowned abstracting service, Current Contents. The applications side of the Journal was expanded without sacrificing the science or the research side.

As a result of earlier PDA/FDA meetings, the Regulatory Affairs Committee (Richard Kiernan Jr., chairman) concluded work on the Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics. A monthly column was published in the PDA Letter alerting members to recent issues of regulatory concern, as well as providing a source for publications as published by FDA.

A two hour panel discussion developed by the Regulatory Affairs Committee was held at the Annual Meeting on "Regulatory Decision Making: Industry Perspectives, the Process and Pitfalls."

The Research Committee, under the chairmanship of James Akers, completed seven publications, presented four podium talks and chaired several round table discussions during PDA meetings. The Committee prepared responses to regulatory/compendia initiatives on Aseptic Processing; USP Proposed Endotoxin Limits; Parametric Release; and Product Stability. Committee members also participated with PMA representatives in a meeting with FDA in which the FDA Aseptic Processing Guidelines were discussed in depth.

1989 - The two key words that best describe 1989 are "growth" and "change." Since one of the major strategies for PDA was to bring the most current pharmaceutical science and education to the membership, chapters in Canada, the West Coast, Puerto Rico, the East Coast and the mid-West were established. Successful scientific meetings at each chapter location were developed together with a number of educational course series. Chapters in Mexico, Brazil, Japan, Scandinavia, North Carolina and Asia were undergoing recruitment.

Through the formation and growth of these PDA chapters and on the strength of PDA's programs, PDA's membership grew during 1989 by almost 1200 members to 2867 members.

With the Association's growth, there was a need to adopt new strategies. Thus the bylaws, which were in effect for five years, were modified.

Among the major changes were: (1) elimination of the Second Vice President office; (2) the number of Directors were increased from 12 to 13; (3) establishment of a President-Elect in place of the First Vice President; and (4) Officer terms were increased from one year to two years.

Consistent with these bylaws modifications and the long-term direction for the Association that spurred them, the Board voted to increase the level of staff responsibility. The Executive Director, as Chief Operating Officer, would determine the direction and operating practices to be utilized and, as Chief Executive Officer, would be the principal driving force behind the implementation of the strategic plan.

Miliza Godzieba was hired as Manager, Publications and Marketing and Joseph Katz (CPA) was employed as Manager, Administrative Services.

A total of 68 courses were offered in 1989 which were held at 11 locations, including two sites each in Canada and in Frankfurt, Germany and London, England. Of these, 19 were new courses. This years first courses were offered at chapters in Canada, San Francisco and Cambridge. It also saw the education department and committee being responsive to the needs of the biotechnology community in which seven of the new courses addressed biotechnology subjects.

The expense budget was the highest experienced in the Association's history. New people hired increased yearly costs by $82,000; the Retirement Fund required $50,000 (an unexpected expenditure); office rental increased operating costs by $22,000 while salary increases were proposed at about $20,000 (4.8%). The Executive Director reinvested all CD's at the highest rates available (from 4% to an average of 9%); canceled the advertising contract for the Journal to an in-house function swelling the coffers by about $75,000; and instituted advertising in the PDA LETTER alleviating a $30,000 per annum strain. Xeroxing costs were reduced dramatically from 7.5c/page to 5.5c/page, a savings of $17,000 per annum. Joseph Katz undertook a major restructuring of

the Association's financing. The first computerized report (SBT system) was forwarded to the Board in October.

The Executive Director reported that after several meetings with the Food and Drug Administration that they agreed to have a two day joint meeting with PDA in 1990. Carleton has secured meeting room space at the Holiday Inn in Rockville, MD. A joint PDA/IES scientific meeting was also held in 1990. Board approval was obtained for both meetings.

The PDA Letter was expanded from 4 pages to 8 and then 12 pages. New columns on FDA happenings as well as news from USP were now included in each issue. A Presidential report was planned. A "Position Wanted" column was established gratis for PDA members while a "Position Available" column was made available to prospective employers at a minimum charge.

PDA sponsored five meetings in 1989. In addition to the annual and two regional meetings, chapter meetings were held in San Francisco, CA and in Toronto, Ontario, Canada .

An innovation at the annual meeting was program evaluations to determine its relevance to the attending members.

Considerable planning occurred in 1989 for jointly sponsored meetings, to be held in 1990 and beyond. The Board adopted the strategy of joint meetings as a means of expanding knowledge horizons. As the concept of a global village becomes more of a reality, the awareness grew of the benefits to be joined by sharing information with similar professions and with pharmaceutical personnel in other countries.

Major plans were initiated to increase the visibility of exhibits at meetings and to meet the needs of the vendor community. At regional meetings, 45 minutes of non-competing time in both morning and afternoon sessions were instituted. At the annual meeting, in addition to the 45 minute exhibit showrooms, a two hour session in mid-day was instituted.

Reports from the Scientific and Technical Committee (previously called the Research Committee) were published as follows:

Supplier Certification-A Model Program
Review of Biosafety Guidelines
Current Practices in Endotoxin and Pyrogen Testing in Biotechnology
Fundamentals of an Environmental Monitoring Program
Rapid Automated ID Survey
Endotoxin and Pyrogen Survey
Gowning Survey

In recognition of outstanding contributions to the Parenteral Drug Association and to the advancement of parenteral science and technology, Honorary Membership, the highest honor awarded by the Parenteral Drug Association, was bestowed upon Kenneth E. Avis, D.Sc., School of Pharmacy, University of Tennessee.

1990 - The strategic plan, developed in 1987, continued to guide the establishment of new activities and programs to ensure that the PDA's endeavors meet well-tested goals and objectives. A major change mandated by the Strategic Plan was the development of local chapters. Chapters in Brazil and Japan were inaugurated and existing North American chapters (New England, Puerto Rico, Canada, mid-West and the West Coast) continued successful programming. Plans began in 1990 for a PDA and industry first for a Spanish-speaking conference for the pharmaceutical industry in Latin America (scheduled for 1992).

An unprecedented number of meetings were sponsored in 1990. The Board adopted the strategy of joint meetings as a means of expanding knowledge horizons.

The PDA and the Institute of Environmental Sciences presented an "International Conference on Particle Detection, Metrology and Control" in Arlington VA focused on advances in particulate measurement and theory.

The Spring Meeting focused, in part, on facility design, gowning, personnel training and new developments in equipment in which FDA personnel participated in great numbers. A half-day session concentrated on lyophilization which was

then followed by a special tour of the Bristol-Myers Squibb Company's new lyophilization facility (oversubscribed).

An outstanding Biotechnology Process Validation meeting, sponsored by the West Coast Chapter in San Francisco, provided individuals working in the biotechnology industry a perspective and understanding of the current issues relating to the validation of biotechnology processes. The areas covered validation of prokaryotic, eucaryotic fermentation processes and chromatographic purification processes that directly impact the production of biotechnology products. A session on the regulatory concerns of process validation for biotechnology products featured FDA experts in this area.

The PDA Canadian Chapter held a one day meeting in May in Ottawa, Ontario, and presented process-oriented topics such as filtration, lyophilization and chromatographic purifications as well as innovations in sterile packaging and clean room technology. Interests to production, quality assurance and biotechnology personnel were emphasized.

Innovative technologies and problem-solving techniques in manufacturing, engineering, QA/QC and validation areas were featured at the PDA Summer Meeting in Rosemont, Illinois. A half-day session was devoted to "Water for Injection" while an interesting session explored the use of robotics at manufacturing facilities.

PDA joined with the PMA to co-sponsor an international conference on "Sterilization in the 1990's." This exceptionally well-attended meeting covered regulatory perspectives worldwide, sterilization technology and advanced aseptic processing. Participants from the United States, The United Kingdom, Japan, Australia, France and Canada contributed vastly to the success of this meeting.

September witnessed the first of a series of annual conferences sponsored in cooperation with the Food and Drug Administration. Keynote speakers were Ronald Chesemore (Associate Commissioner of FDA Regulatory Affairs), and Ronald Saldarini, Ph.D. (President and CEO of Lederle-Praxis Biologics, Inc.). Among the FDA speakers were Daniel Michels, Raymond Hamilton, Robert Sorensen, Michael Beatrice, Joyce Johnson, Arthur Levine, Nathaniel Geary, John Levchuk, Katherine Zoon, Albert Rothschild, Philip White and Henry Avallone.

The PDA Annual Meeting addressed "Parenterals: A Vision of the Future." Presentations addressed all aspects of parenteral operations, engineering, production, manufacturing, quality control/quality assurance as well as biotechnology which were designed to assist the industry in the coming decade.

Gordon R. Personeus, Lederle Laboratories, was elected as an Honorary Member by the Board of Directors. Mr. Personeus served on the Board for 19 years and was president of PDA in 1972-73.
A number of Science and Technology Committee projects are under way or pending release for publication. Among these are:

A bibliography of papers pertaining to irradiation sterilization.
Terminal Sterilization vs. Aseptic Processing.
Irradiation of Rubber.
Revision of Technical Report #2 "Validation of Aseptic Filling for Solution Drug Products."
Revision of Technical Report #6 "Validation of Aseptic Drug Powder Filling Processes."

Seven other projects await completion.

The Committee made a response to a Federal Register notice proposing establishment of aluminum specifications for Parenteral Products and to the USP Committee on Revisions on Microbiological Clean Room Standards.

In 1990, Maureen Donovan, Assistant Professor of Pharmaceutics, U. of Iowa, was funded $15,000 for "Molecular Weight Dependent Absorption following Intraperitoneal, Intramuscular and Subcutaneous Administration" as well as a $15,000 grant to Kentaro Murakami, Assistant Professor of Biochemical Pharmacology, State University of New York at Buffalo for research on "Cis-Fatty Acid Activation of Protein Kinase C in the Hippocampus."

The Journal Award went to Michael Roy and Michael Pikal (Eli Lilly & Co.) for their paper

"Process Control in Freeze Drying: Determination of the End Point of Sublimation Drying by an Electronic Moisture Sensor."

1991 - The Parenteral Drug Association has seriously implemented many of the strategies in fulfilling its mission to become the premier technical and scientific pharmaceutical association. The concept of the chapter structure now exists in several key regions within the United States as well as in Puerto Rico, Canada, Brazil and Japan. The Association made the bold and vitally important decision to relocate PDA's headquarters to Bethesda, Maryland in 1992. The relocation was an element of the Strategic Plan and was necessary to position PDA closer to regulatory bodies, other associations and scientific institutions in Washington D.C. and its environs.

As the Association moves forward, change is inevitable. Frederick J. Carleton, Executive Director, retired after 30 years of active involvement with the PDA. Fortunately, Carleton sought out Edmund M. Fry who accepted the Executive Director's position. Subsequently, Mr. Fry's title was changed to Executive Vice President.

In 1991 , a Chapter Council under the chairmanship of John Geigert, Ph.D., was established to work with the eight existing chapters to provide a forum for discussing the challenges and opportunities, both current and future.

The Canadian Chapter, Brian D. Reid, Ph.D., President, moved into high gear with two very successful seminars which were held in Montreal and Toronto and were conceived as a way to meet the unique needs of this Chapter.

The Delaware Valley Chapter, spearheaded by Regina McCairns, was formed in 1991, to benefit the parenteral industry in that region. Charles Cherundolo was elected President. The Chapter held three meetings in 1991, the first of which featured Lynn Bonnere (FDA) who spoke on "Communication with the FDA." Elastomeric Closure Processing was subject of the second meeting while James Agalloco was the featured speaker at the third meeting whose subject was entitled "Equipment Cleaning Issues and Answers." In its eight months of existence, the Chapter has identified leaders, written Chapter bylaws, established committees and managed its own finances.

Frederick Carleton, retired PDA Executive Director, in his several memoranda to the Board, cites the magnificent work performed by Masayoshi Nishiyama (presently secretary of the Japan Chapter) in developing the Japan chapter with an anticipated membership of 400 individual members and 30 corporate members. Nishiyama met with Mr. Carleton several times at PDA headquarters while Carleton visited Nishiyama twice in Japan to meet with Japanese officials (e.g. Japanese PMA, officials of pharmaceutical companies, Japanese food and drug officials and university personnel). It was Nishiyama who invited Carleton as a guest speaker at a technical meeting in Japan. And it was Nishiyama who, in cooperation with Susanne Stone, Associate Director of Education and Programs, brought the first of a series of workshops which were held in Osaka, Japan. On December 2, 1991, the "Opening Memorial Lecture" of the PDA Japan Chapter was held with Edmund Fry in attendance together with 197 individuals and more than 20 invited guests. GMP and validation were among the topics discussed. T. Aoyama (Kyusyu University) was elected President while K Kawamura (Takeda Chemical Ind. Ltd) was elected Vice President of the Japan Chapter. Both of these gentlemen contributed heavily to the establishment of the Japan Chapter.

The PDA Metro Chapter (Leonard Mestrandrea, Ph.D., President) was formed in 1991 through the efforts of several dedicated PDA members. The Chapter invited Anthony Panzica, formerly the FDA Director of Compliance, Newark District and now Director for Warner Lambert as their first speaker on the subject of Aseptic Processing and Terminal Sterilization. The second meeting of the Chapter focused on Cleaning Validation while the third meeting featured Roger Dabbah of the USP who outlined the USP proposal on Microbial Control of Clean Rooms and Clean Zones. A fourth meeting concentrated on Computer Systems Validation. In less than eight months, the PDA Metro Chapter held four excellent technical sessions, identified interim leaders, developed an internal committee structure, managed its finances and served the needs of its localized members.

The Midwest Chapter (Carol Lampe, President) held three evening meetings in 1991. Michael Pikal (Eli Lilly) spoke to more than 120 attendees at the March meeting on "The Role of Water in Lyophilization: Control of Residual Moisture and the Impact of Moisture on Stability." In August, Wayne Taylor (Baxter Healthcare Corp.) gave an excellent presentation on "Quality by Design-Statistical Process Control and Beyond." Arlyn Baumgarten (FDA) spoke on "The FDA Preapproval Program for NDA/ANDAs" which was the largest meeting of the year.

The New England Chapter (Robert Pazzano, President) conducted two evening meetings, two days of PDA courses focusing on the biotechnology industry and a highly acclaimed annual vendors evening meeting. At the evening meeting in February, William Morton presented Product Design and Qualification of FDA Approvals for Test Marketing Medical Devices while Ira Krull (Northeastern U.) spoke on Modern Methods of Analysis. Topics at the May meeting were Clinical Trials of Pediatric Vaccines (Colin Marchant, Genzyme Inc.) and Clinical Trials of the Orphan Drug (Marsha Simon, Genzyme Inc.). A Vendor Night and Dinner, held in October with over 40 exhibitors was very successful with over 40 exhibitors. Attendance exceeded 175 people and the guest speaker was Edmund Fry. PDA courses were also held whose contents were highly rated by the attendees.

The Puerto Rico Chapter (Irene Ortiz, President) sponsored several educational opportunities among which included "Environmental Law and the Pharmaceutical Industry in Puerto Rico" and "Problem Solving Techniques". In addition, two chapter members participated in the selection of the District Outstanding Teacher.

The West Coast Chapter of the Parenteral Drug Association (Robert Garnick, President) has had numerous speaker/dinner meetings and has presented three symposia lasting from one to three days for each presentation. In 1991, the West Coast Chapter presented Carleton with a check for $20,000 to further the PDA Awards programs. In 1991, the decision was made to form individual committees with defined functions and fund these committees with an annual budget. The working committees were Events, Symposium. Education, Intergroup Liaison, Membership Newsletter and Bylaws.

The National Program Committee (Regina McCairns, Chairman) continued to integrate biotechnology papers into the regular program format. Roundtables and focus groups continued to provide opportunities to discuss current industry trends and to network with peers. Poster sessions were reintroduced at the Annual Meeting while a New Member Breakfast provided these individuals the opportunity to discover the advantages of PDA membership. A banquet was held at the Annual Meeting to present awards and to honor Frederick Carleton's retirement from PDA.

Clarence Kemper (Kemper-Masterson Inc.), Bernard Kronenberg (Bakrona Basel AG) and Frederick Carleton were instrumental in developing plans for the PDA International Congress. Fred Carleton met with Bernard Kronenberg in Switzerland and toured the country seeking a suitable site for the Congress. Clarence Kemper had performed preliminary visits. Carleton proposed that Basel, Switzerland be selected as the meeting site which proposal the Board approved. Edmund Fry subsequently assumed the task of coordinating the meeting plans after Fred Carleton's retirement.

The Faculty Development Grants for 1991 were awarded to Paul Bummer, Ph.D. (U. of Kentucky) for "The Effect of the Gas/Aqueous Interface on the Structure of Globular Proteins" and to Muhammad Habib, Ph.D. (Howard U.) for "Formulation of Hemoglobin-containing Liposomes for Extended Circulation Time." Joseph Rubino, Ph.D. (Dupont Merck) received the Journal Award for his paper, "The Influence of Charged Lipids on the Flocculation and Coalescence of Oil-in-Water Emulsions II".

The late Timothy J. Leahy of Millipore Corporation was the first recipient of the newly created Gordon R. Personeus Memorial Award which was established by the Board of Directors in memory and in recognition of the significant contributions made by the late Gordon Personeus to the PDA which spanned more than three decades. The award was in the form of a gold medal, which was funded by Lederle Laboratories, in recognition of Gordon's 50 year career at Lederle.

Frederick D. Simon retired as PDA's Associate Director of Scientific and Regulatory Affairs. The Board of Directors also bestowed honorary membership on Frederick Simon and Frederick Carleton.

1992 - PDA headquarters was relocated from Philadelphia, PA where it had presided for 45 years to Bethesda, Maryland, a Washington, D.C. suburb. For a variety of reasons, only Suzanne Stone, Senior Director, Education and Programs, was able to join Edmund Fry in Bethesda. The tireless energy of Suzanne and the conscientious continuing support of former staff members such as Joseph Katz (formerly Manager of Administration) enabled PDA to conduct business as usual while hiring and training new people.

Margaret Wanca joined PDA in January 1992 as Manager of Marketing and Member Services. James C. Lyda, Director of External and Regulatory Affairs was recruited from FDA to manage regulatory and international affairs, chapter affairs and science and technology projects. Amber L. Ozbey was hired as Manager of Administration had the responsibility for the implementation of a new accounting system.

During 1992, PDA implemented a new computerized management system which integrates membership records, meetings, course and conference registrations, accounting information, sales and vendor exhibitions which project was managed by Suzanne Stone.

The Education Committee broadened and strengthened course offerings with the development and presentation of a number of new programs. New courses were: Advanced Environmental Monitoring, Handling Sterility Test Positives, Veterinary Parenterals, Clean in Place, Using Lotus and several biotechnology offerings. Courses held in Puerto Rico were given in Spanish, a notable first in 1992. Another notable first involved courses at PDA's International Congress held in Basel Switzerland. For the second successful year, courses were held in Japan and in Lake Tahoe, NV.

The establishment of a Hospitality Committee (Jack Cole, chairman) was to develop, at each location in which PDA's meetings are held, unique cultural and social opportunities to enhance PDA's meetings. This opportunity was demonstrated by the very successful banquet held in the Cable Car Museum in San Francisco. This event conceived by Jean LaDouceur, provided attendees a unique glimpse of the history and culture of a very unique city. This policy extends to all locations and Vera Kronenberg of the Hospitality Committee would organize hospitality events at the 1993 International Congress in Basel, Switzerland.

Seven program meetings were held in 1992, under the chairmanship of Regina McCairns, National Program Committee, which were:

PDA/IES meeting on Clean Rooms (Arlington, VA), Advanced Technologies for Manufacturing of Aseptic and Terminally Sterilized Pharmaceuticals and Bio-Pharmaceuticals (Basel, Switzerland), Validation for Pharmaceutical and Biological Products (Philadelphia, PA), Pharma Caribe Meeting (San Juan, PR), PDA/FDA Joint Conference (Rockville, MD), Computer-Integrated Manufacturing Meeting (New Brunswick, NJ), PDA Annual Meeting (San Francisco, CA).

The Planning Committee recommended that 80% of PDA's resources be invested in the traditional areas of parenterals and biotechnology and the remainder in the areas of sterile bulk chemicals, veterinary products and clinicals. Sterile diagnostics, topicals and non-sterile bulk chemicals were considered to have lower priorities.

Current regulatory issues published in the PDA Letter were: USP New Packaging and Labeling Requirements for Potassium Chloride for Injection Concentrate; Prescription Drug User Free Act of 1992; FDA's Medical Device Reports; and Medical Devices User Facilities.

FDA's Roger Williams, Director of the Office of Generic Drugs (OGD), and members of his staff met with Edmund Fry and PDA Regulatory representatives to establish ways in which PDA and OGD can act more effectively to understand the key issues and concerns currently impacting the industrial sector.

The 1992 recipients of the Faculty Development Grants ($15,000 each) were Tae Gwan Park of Temple University for his proposal, "Protein

Stabilization and its Controlled Release from Biodegradable Polymer Microspheres," and Paula Jo Meyer Stout of West Virginia University for her proposal, "The Influence of Metal Ion Complexation on Protein Solution Properties- A Study of Zinc Insulin Dissolution."

Unfortunately, PDA lost its valued colleague Frederick D. Simon, who died June 3, 1992. In his memory, the Board of Directors named the PDA award for the previous year's best paper in the Journal of Parenteral Science and Technology to the "Fred Simon Award."

The first "Fred Simon Award" was given to Howard L. Levine, Tom C. Ransohoff, Russell T. Kawahata and W.C. McGregor (Xoma Corp.) for their paper, "The Use of Surface Tension Measurements in the design of Antibody-Based Product Formulations." The paper was published in the May-June 1991 issue of the Journal.

The first Frederick J. Carleton Award, created by the Board of Directors "to honor the Board Member who best exemplifies Fred Carleton's dedication and leadership," was presented to Regina McCairns at the annual banquet held at the San Francisco Cable Car Barn and Museum during the PDA Fall Meeting.

Another service for PDA members completed in 1992 was the compilation of a directory of consultants for the pharmaceutical and medical device industry. These were provided without cost to those members who requested a copy.

The Board of Directors approved for distribution the first PDA-sponsored video training program, "Keep it Clean", which was introduced at the 1992 Annual Meeting. The video covered topics such as entering the changing area, handwashing practices, gloving techniques, gowning, proper behavior in the cleanroom and interaction with those outside the aseptic area. The video was produced by the Upjohn Co. for PDA, and would subsequently be translated into German, Spanish and Japanese. There were 112 copies sold during its first year of availability.

1993 - The 1987 strategic Plan developed by the board of Directors recognized the need for greater responsibility by the staff for day-to-day operations of PDA. Accordingly, for 1993, James E. Akers, President, announced that the Board had appointed Executive Vice President Edmund M. Fry as chairman of the Operating Committee, effectively designating him as PDA's Chief Operating Officer.

PDA's Second International Congress was held in Basel, Switzerland, February 22-27, and consisted of technical presentations, exhibits and educational courses. During the meeting a memorandum of understanding for the joining of forces in areas of mutual interest was signed with the Association Pour Les Produits Parenteraux et Steriles (A_3P), France; the Parenteral Society in the United Kingdom; and the Nordic Association for Contamination Control (R3-Nordic). This historic liaison was intended to enhance technical information exchange in the parenteral field between Europe and the US. These developments were under the guidance of the newly formed International Operations Committee.

PDA has continued to participate actively in the International Organization for Standardization (ISO) through Technical Committee 198. PDA Director Michael Korczynski (Abbott) is serving as Convener of its Working Group 9, authoring the proposed international standard "Aseptic Processing of Health Care Products."

The Spring Meeting was held in Philadelphia, March 10 -1 12, and featured technical sessions, round tables, panel discussion groups, and over 100 vendors with booth exhibits. Prior to the meeting eleven courses were offered. A special social feature was a reception held at Philadelphia's premier scientific museum, the Franklin Institute.

The Science and Technology Committee completed its survey of current practices in the validation of aseptic processing and reported the results from 77 responses as Technical Report No. 17, published as a supplement to the Journal of Parenteral Science and Technology. Also, the Committee was active in preparing responses to the USP <1116> "Microbiological Classification of Clean Rooms and Clean Zones," and <788> "Particulate Matter in Injections."

The PDA office staff announced that they had instituted use of a new integrated computer system for all member information, including, meeting attendance, dues payments, registrations, and publications orders. Members can expect better service as a consequence.

At its June meeting the Board established a building fund and decided that the Bylaws needed to be completely rewritten. Further, a special committee, chaired by Raymond Shaw, Ph.D. (Merck), was set up to explore the feasibility of establishing a training institute. The concept envisioned that such a center could greatly improve the setting for PDA's educational courses and provide leading-edge facilities for experiential training and research.

A special forum was held at PDA headquarters on the "Impact of Barr Decision on Test, Retest, and Laboratory Investigations." The far-reaching decision by the U.S. District Court for the District of New Jersey in February was expected to have a significant impact on the pharmaceutical industry. The prompt scheduling of the forum signals PDA's determination to assist the industry in assessing their response to technical and legal issues.

During the year educational courses were offered at Lake Tahoe, NV., February 8-11; Hershey, PA, May 12 -14; Chicago, IL, June 9 - 11; Tokyo, Japan, June 28 - July 2; Toronto, Can., July 30 - 31; New Brunswick, NJ, Sept. 8 - 12; and Boston, MA, Oct. 6 - 9, as well as in conjunction with the 2nd International Conference in Basel, February 22 - 27; Spring Meeting in Philadelphia, PA, March 8 - 12; Canadian Chapter Meeting in Montreal, Can., April 28 - 30; the Annual Meeting in Orlando, FL, Nov. 1 - 5; and in cooperation with R3-Nordic in Stockholm, Sweden. A total of 65 courses were offered with 1,803 attendees.

The PDA Awards Committee selected two recipients of the 1993 Faculty Development Awards: Thomas P. Johnson, University of Illinois at Chicago received $15,000 to study the effects of a model surfactant used in parenteral formulations on lipid metabolism and Steven L. Nail, Purdue University, received alike award to study the effect of surface interaction between antigen and vaccine adjuvant on immune response in an animal model. Upon completion of the research they are to submit a manuscript for publication in the Journal. Also, Jack H. Young and Barbara L. Ferko, Pennsylvania State University at Erie, received the Fred Simon Award for the Best Paper published in the Journal in 1992, entitled, "Temperature Profiles and Sterilization within a Dead-ended Tube."

PDA participated in IBEX '93, the International Biotechnology Conference & Exhibition in San Francisco, October 26-28, with three special sessions and an exhibitor booth.

The fourth annual PDA/FDA Joint Conference in Rockville on September 27-29 was attended by nearly 400 persons. One comment heard that attests to the achievement of PDA's goal for the Conference was, "This is the best meeting I have attended in many years. I was very impressed with the level of FDA participation. Their apparent willingness to engage in dialogue with industry must be built upon. The PDA is fulfilling a serious void for industry."

On September 27, Millipore Corporation established the Tim Leahy Memorial Speakers Endowment, an annual endowment of $4,000 to provide funds for travel and related expenses to bring special guest speakers to local PDA chapter meetings. This Endowment honors the memory of Tim Leahy who was instrumental in forming PDA chapters worldwide.

During the banquet at PDA's Annual Meeting on November 3, several awards were presented: Doris Conrad (SmithKline Beecham) received the Frederick J. Carleton Award; Anne Marie Dixon (Cleanroom Management Associates) received the James P. Agalloco Award (Agalloco & Associates), newly created to honor the best instructor in the PDA educational course program; and Jeanne D. White, FDA's Assistant Director of Office of Small Business, Scientific and Trade Affairs, received the PDA Distinguished Service Award. Also, another award was recently created to honor Michael Korczynski's (Abbott) role in the internationalization of PDA by providing funds for defraying travel expenses for a distinguished speaker from another country to present a paper (The "Korczynski Paper") at a national PDA meeting.

A further indicator of the internationalization of PDA was the election of Kunio Kawamura (Takeda Chemical Ind.) as the first overseas member of the Board of Directors.

During 1993 the PDA Letter underwent a major transformation from an eight page newsletter to a 40-plus page magazine with extensive information about industry and regulatory happenings, domestic and international news and, of course, PDA news.

Domestic PDA Chapters, under the guidance of the Chapter Council, chaired by John Geigert, Ph.D. (Immunex Manufacturing), continued a high level of activity in support of the local needs of PDA members. Of the domestic chapters the following items are noted:

Capital Area Chapter held its first meeting on May 26.

Delaware Valley Chapter held four dinner meeting during the year, under the leadership of President Charles J. Cherundolo (Pall Trincor). The Chapter established the "Fred Simon Memorial Award" for excellence in Microbiology and the initial $500 savings bond was given to Anne Nelson, a seventh grader at Germantown Academy.

New England Chapter held four educational/social events during the year, under the leadership of Robert Pazzano (Transkaryotic Therapies).

Metro Chapter, led by Laura Bogdanowich (Schering Plough Res. Institute), held four meetings during the last year.

Midwest Chapter held five dinner meetings on topics chosen to benefit the pharmaceutical industry in the Chicagoland region. Carol Lampe (Baxter Healthcare) served as president.

Puerto Rico Chapter, chaired by Irene Ortiz (Lederle Parenterals), held three meetings, two of which were joint meetings with other technical groups. The chapter also provided two speakers for the Pharmaceutical Sciences Congress held in Costa Rico on October 26-30.

West Coast Chapter held six dinner meetings during the year, under the presidency of Jim Fernandez (Berlex Biosciences). A quarterly newsletter has continued to increase its role on the life of the Chapter.

Two international chapters of PDA were also active during the year:

Canadian Chapter, led by Brian Reid, Ph.D. (Nordion), held an annual meeting on April 28-30 with two days of courses and a scientific meeting, a half day meeting on November 22 in Toronto and a full day meeting on November 24 in Montreal.

Japan Chapter, in its second year of operation, had 453 members (168 individual and 48 corporate), according to T. Aoyama (Kyushu University), President. The Chapter hosted PDA courses in Tokyo June 28 - July 2, held an annual meeting October 4-5 and a special lecture on September 8. Its members are heavily involved in working with PDA staff to plan the first Asian Symposium in Tokyo in 1994.

1994 - President Clarence A. Kemper (Kemper-Masterson) announced that effective with the January-February issue, the Board had approved a change in the name of the Journal of Parenteral Science and Technology to the PDA Journal of Pharmaceutical Science and Technology. Further, it identifying a "new PDA", President Kemper stated, "In recognition of the evolution the association has made in addressing the scientific, regulatory, and technical issues affecting all pharmaceutical products, this year we adopted PDA as our official name. This name more accurately reflects our association; many members have technical needs that are not strictly parenteral. Of course, we have not lost or diminished our focus on sterile products technology. Our leadership in this field is extremely important to the pharmaceutical industry, and our recognition as the foremost source of information of sterile products technology is essential to the future of PDA." For clarification, he also indicated that after much though and deliberation, the Board had decided to reaffirm that PDA will continue to focus on sterile products technology but will extend the scope of its activities to include biotechnology and select non-sterile dosage forms. A survey of PDA members conducted in late 1993 revealed that 37.6% and 28.3% respectively, were primarily involved with biotechnology products and solid dosage forms. A new service mark and logo (See Figure 6) also has been developed to convey these changes as well as the new international involvement of PDA.

The January issue of PDA Letter carried the announcement of the appointment of Russell E. Madsen, formerly Director, Technical Services for Bristol-Myers Squibb, as Director, Scientific and Technical Affairs for PDA. His duties will include analyzing emerging scientific and technical needs of PDA members, working with the Planning Committee and the science and Technology Committee, and coordinating PDA scientific and technical activities, at a time when these activities has assumed expanded and more critical importance for PDA and its members.

PDA, in its increasing role as a premier organization for promoting international information sharing, cooperated with A_3P, the Parenteral Society and R3Nordic, in hosting the 1994 International Congress (the third) in Basel, Switzerland, with the theme, "Advanced Pharmaceutical and Biopharmaceutical Developments, Manufacturing and Control in Europe and the USA." Approximately 375 people from 20 countries participated and there were 56 exhibits by companies from US and Europe. Lennart Ernerot (Pharmacia) and James C. Boylan (Abbott Labs.) co-chaired the Congress. PDA also hosted, in cooperation with its Japan Chapter, the first Asian Symposium and Exhibition in Tokyo on November 14-16, with nearly 350 attendees from 19 countries.

Relationships with associate organizations were strengthened with discussion of reciprocal memberships with R3-Nordic and the Parenteral Society. These resulted in a system of secondary membership between PDA and R3 Nordic by which members of one association can join the other at a reduced rate. Also a collaborative relation was developed with Asociacion Farmaceutica Mexicana (AFM), leading to a jointly sponsored week-long series of educational courses.

PDA has continued to support the work of ISO Technical Committee 198 in the development of an international aseptic processing standard, "Sterilization of Health Care Products," under the chairmanship of Michael Korczynski, Ph.D. (Abbott Labs.). Also, support has continued for the work of ISO Technical Committee 209 in the development of a standard for cleanrooms, "Cleanrooms and Associated Controlled Environments."

Two volunteer Interest Groups were launched, designed to provide forums for information exchange, networking and leadership development: the Isolation Technology Users Group (ITUG), chaired by Carmen Wagner, Ph.D. (Lederle-Praxis), and the Blow-Fill-Seal Interest Group (BFSIG), chaired by Royal Hathaway (Glaxo). These, and other groups in the planning stage, were designed to take the place, in time, of some task forces and subcommittees of the Science and Technology Committee. Current subcommittees include QA/QC, Validation of Software, Microbiology, Biotechnology, Packaging Science, and Irradiation Sterilization. Operating under the direction of the subcommittees were 20 specific task forces.

The Spring Meeting, held in Chicago, featured a one-day session on Computer Integrated Manufacturing. Round Tables and Focus Groups provided opportunities for members to exchange ideas on procedures and problem solving, a feature that is increasingly of interest to members. A Poster Session, 13 educational courses, the technical sessions, over 100 exhibitors and a special reception at Chicago's Shedd Aquarium all contributed to making this a truly outstanding meeting.

To fulfill in part a critical need of the membership, that of maintaining interaction with FDA, PDA commented to FDA on its "Guideline on Submission of Documentation for Sterilization Validation" and responded to the Agency's request for input on contemplated revisions of the biologics general and licensing regulations, during 1994.

In July the PDA Awards Committee announced the selection of two applicants to receive $15,000 Faculty Development Grants for 1994. The recipients were Dexi Liu, Assistant Professor at the University of Pittsburgh, for the research proposal "Long-circulating Emulsions (o/w) as Targetable Carriers for Lipophilic Drugs", ad William F. Ebling, Assistant Professor at the State University of New York at Buffalo, for the research proposal "Intravenous Fat Emulsions and Their Effect on Site Drug Delivery". In September the Committee announced that the Fred Simon Award for the best paper published in the Journal of Parenteral Science and Technology in 1993 was "Thermal Mechanical Analysis of Frozen Solutions of Mannitol and Some Related Stereoiso-

mers: Evidence of Expansion during Warming and Correlation with Vial Breakage during Lyophilization." The authors were N. Adeyinka Williams, Ph.D., and Joyce Guglielmo of the R.W. Johnson Pharmaceutical Research Institute.

The fifth annual PDA/FDA Joint Conference was held in Bethesda on September 19-21 and was chaired by Jennie Allewell (Cell Therapeutics). The Conference featured 11 forum-type discussion groups, with attendees able to participate in two forums each day. The plenary session featured prominent FDA and industry leaders with the presentation of plenty of issues for thought.

A major revision of the bylaws was proposed by the Board of Directors to the membership at the Annual Meeting on November 2. President Kemper stated that the general objective was "...to eliminate those provisions in the current bylaws that specify in detail how PDA should be managed on a day-to-day basis." The growth of PDA and its changing needs have required frequent changes in the bylaws in the past. It was hoped that the current revisions would adequately guide the Board and staff without restricting them from making beneficial changes. In the October issue of PDA Letter, President Kemper summarized the principle changes. These included: (1) the primary name to be "PDA," (2) individual benefits, except to vote and hold office, will be established by the Board, (3) change of titles for the top elected officers to "Chairman" and "Chairman-elect" and for the top staff officer to "President" from "Executive Director"; the latter change to help the chief staff executive in his role as PDA's primary spokesman, (4) selection of candidates for Director and vacant offices by the Nominating Committee, and (5) giving the Board the authority to establish or dissolve committees, except for the Executive and Nominating Committees. At the Annual Meeting the new bylaws were approved unanimously by the membership.

Suzanne Stone, Vice President, Programs and Education, presented a summary of the dynamic growth of PDA education courses (See Table 14) in the November PDA Letter. She listed 23 courses that had been offered for the first time during the previous three years, and 14 to be introduced in 1995. Attendance in 1994 reached 2,755, an approximately 50% increase over 1993. Courses were offered in the U.S. in Boston, MA; Cherry Hill, NJ; Chicago, IL; Danvers, MA; East Brunswick , NJ; Lake Tahoe, NV; Malvern, PA; Raleigh, NC; Philadelphia, PA; and San Francisco, CA. International presentations included: Basel, Switzerland; Jerusalem, Israel; Mexico DF, Mexico; Stockholm, Sweden; Tokyo, Japan; and Toronto, Canada.

Awards were presented to several outstanding members at PDA's Annual Meeting. The Carleton Award was given to Jack Cole (Pall Corp.) and to Robert Kieffer (RGK Consulting). Both had served as President of PDA and had contributed in many other capacities to the work and development of PDA. The Distinguished Service Award was presented to G. Willard Webster, who had served for over 20 years at Treasurer and Financial Secretary. The James P. Agalloco Award for the best PDA course instructor of 1994 was presented to L. David Duff (A-Metrology-Z) for his course "Fundamentals and Concepts of Calibration and Metrology." The Board also gave special recognition to the PDA newsletter staff for developing the new PDA Letter as a valuable source of timely news on current regulatory, industry and PDA activities. These included James C. Lyda, Russell E. Madsen, Trish Rafferty, Suzanne Stone, Blake H. Stenning, Margaret A. Wanca and Edmund M. Fry.

Professor William Whyte, University of Glasgow, Scotland delivered the first Korczynski Paper at the PDA Annual Meeting, on the subject, "In support of Settle Plates." The grant making the lecture possible, by covering travel and related costs, was established to honor Michael S. Korczynski, who initiated much of PDA's international developments during his presidency. Dr. Korczynski was also recently honored by being named Researcher of the Year for Abbott Laboratories.

During the sixth year since the founding of the first PDA chapter, the Chapter Council developed a set of proposed policies for chapters and submitted it to the PDA Board. The current nine chapters each had productive with numerous events and accomplishments. The following items of interest are noted for each chapter:

Canada Chapter, led by Suzanne Levesque (Sabex), held their Annual Meeting in Toronto in May, consisting of a successful half-day meeting and two days of courses. No other meetings were held but the first issue of their "information Letter" was published in November.

Capital Area Chapter, chaired by Rande Leibowitz (Univax Biologics), became an official chapter with the acceptance if its charter by the PDA Board. Meetings were held in February, April, June and a joint meeting with the MD/DC Chapter of the Society for Industrial Microbiology in the Fall.

Delaware Valley Chapter sponsored a vendor night in April and three additional meetings. The June 15 meeting featured the **Fred Simon Award** winners from the Delaware Valley Science Fair from eighth grade through high school. Charles Cherundolo (Pall Trincor) continues as president.

Japan Chapter had a memorable year with the co-sponsorship with PDA of the PDA Asian Symposium and Exhibition in Tokyo, November 14-16, followed by two days of educational courses. The Chapter sponsored the translation of four PDA technical reports (nos. 1, 3, 8 and 11) to help improve understanding of the concept and method of validation in Japan.

Metro Chapter began the year with the Second Annual ASQC/PDA Seminar in February. The subject was a panel discussion on "Filters and Filter Quality." The May event was a vendor exhibit/speaker presentation, the September dinner meeting had a speaker format, and the final meeting of the year was a panel discussion on barrier technology. Laura Bogdanowich (Schering-Plough Res. Inst.) is president.

Midwest Chapter, with Carol Lampe (Baxter Healthcare) as President, held five dinner meetings during the year. The March meeting was the annual meeting and was co-hosted with the Chicagoland Pharmaceutical Discussion Group. Ronald Tetzlaff, Vice President, Kemper-Masterson, Inc., spoke on "Requirements of Retrospective Documentation."

New England Chapter organized and conducted four scientific meetings, an evening summer cruise in Boston Harbor, and a vendor exhibition. Robert Pazzano (Transkaryotic Therapies), President, reported that attendance reached as high as 200 with enthusiastic participation by the membership. The Chapter's first Massachusetts Science Fair Award of $500 was given to a Taunton student for excellence in science.

Puerto Rico Chapter, chaired by Brenda Rodriguez de Damiani (Schering-Plough Products), experienced the effect of budget cutbacks and decreased participation by the members. However, plans made for 1995 were laced with optimism.

West Coast Chapter reported having a very successful "Symposium on biotechnology Process Validation and Multi-Product Facility Issues" on April 21-22 in San Francisco with over 350 participants. The Chapter newsletter continued to grow and to expand its coverage, not only of news items but to assist in furthering pharmaceutical education. James Fernandez (Berlex Biosciences) served as Chapter President.

1995 - In the January issue of the PDA Letter, President Edmund Fry announced sending the PDA response to FDA's proposed rule on electronic signatures. He congratulated the FDA for incorporating many of industry's suggestions from former communications and their efforts to work with the industry in resolving difficult technical issues. Also, Dick Manassa (Center Labs) presented orally to the FDA Center for Biologics Evaluation and Research (CBER) PDA's statement relative to pending changes in the general biologics licensing regulations on January 16, 1995. Continuing PDA's role of supporting industry's concerns regarding pending regulatory issues, PDA also responded to the USP request for comments on its in-process revision of <1116> "Microbiological Evaluation of Clean Rooms and Other Controlled Environments," and to <71> "Sterility Tests."

The January PDA Letter also announced that PDA will regularly provide summaries of developments from the International Conference for Harmonization (ICH) because of the magnitude of the guidance and the potential impact they will have on the entire industry as these guidelines gain regulatory acceptance. The October PDA Letter carried a list and a report of the status of 15 ICH Guidelines and 23 active projects. The third meeting of ICH was held November 29-December 2, 1995, in

Yokohama, Japan. Over 2,400 registrants attended.

In a further expansion of PDA's international affiliations, Chairman Clarence Kemper signed an agreement with the Taiwan Pharmaceutical Manufacturers Association in Taipei in November 1994 to cooperate in various ways, including exchange of technical and regulatory documents. Also, statements of common interest were signed with the Thai Pharmaceutical Manufacturers Association, the Pharmaceutical Sarjana Farmasi Indonesia, ISFI). However, the announced PDA/GPF Drug Quality for October in Jakarta, was indefinitely postponed due to time constraints and scheduling conflicts.

An Advanced Barrier Technology Conference, jointly sponsored by PDA and ISPE, was held January 17-18, 1995 in Atlanta, with Carmen Wagner (Lederle Praxis) and Jack Lysfjord (TL Systems) as co-chairmen.

The Spring Meeting was held in San Francisco on March 15-17, on the theme "Practical Manufacturing for Future Pharmaceutical and Biopharmaceutical Applications." Don Elinski (Geneva) was program chairman. One topic receiving attention was the new technology of blow-fill-seal, lauded as a process for increasing sterility assurance in aseptic processing.

PDA held another in the continuing series of special scientific forums in Bethesda on May 3. Five panelists representing industry and the FDA explored the subject "Sterile Bulk Pharmaceutical Chemicals." Another such forum on "Validation of Microbial Retention of Sterilizing Filters" was also held in Bethesda on July 12-13. The participants in this forum discussed current FDA policy regarding filtration validation, particularly matrixing or bracketing of products. A special international seminar was held in Frankfurt, Germany on June 26, 1995 on "FDA Inspections: What You and Your Company Can Expect."

The winners of the 1995 Faculty Development Grants were Ming Hu, Ph.D., Assistant Professor of Pharmaceutics, College of Pharmacy, Washington State University, for his proposed research on "Development of Sterically Stabilized Liposomes Containing Polidase for Parenteral Administration" and Jeffrey Hughes, Ph.D., Assistant Professor of Pharmaceutics, University of Florida, College of Pharmacy on his proposed research "Pharmaceutical Stability Investigations with Oligonucleotides."

The American Society for Quality Control (ASQC) authorized credit for PDA courses provided it covers an area "...of the body of knowledge in which you are seeking recertification or job enhancement." This adds recognition of PDA's educational course and meeting programs to that long accorded by the American Council on Pharmaceutical Education (ACPE). One Continuing Education Unit (CEU) of ACPE is equal to one ASQC RU. the rapidly growing list of courses offered by PDA is summarized in Table 14. Since the first course offered in 1978, "Microbiology and Engineering of Sterilization Process," by Irving Pflug, Ph.D., University of Minnesota, 120 difference courses have been offered by PDA.

PDA updated its "Listing of Consultants, Consulting Firms and Contract Manufacturers" and again offered it without cost to interested parties.

PDA has participated in the development of an innovative set of voluntary skill standards for entry level personnel in pharmaceutical and biotechnology industries, published in "Gateway to the Future: Skill Standards for the Bioscience Industry." Two PDA staff members, Russell E. Madsen, Vice President, Scientific and Technical Affairs, and Trish Rafferty, Manager, Education and Programs, served on the technical committee for the project.

In an effort to enhance information exchange and increase networking opportunities for members, the development of Interest Groups has been encouraged. In a little over a year the number of Interest Groups has increased to 14, namely, Barrier Technology, Biotechnology, Blow-Fill-Seal, Filtration, Inspection Trends, Lyophilization, Microbiology/Environmental Monitoring, Packaging, Production and Engineering, Quality Assurance/Quality Control, Regulatory Affairs, Solid Dosage Forms, Training and Validation. These groups will meet during PDA major meetings.

The Pan American Conference, presented jointly by PDA and the Asociacion Farmaceutica

Mexicana (AFM), with t he theme "Advanced Technology in Pharmaceutical Manufacturing," was held June 7-9 at the Hotel Presidente Intercontinental Mexico in Mexico DF. Benito David Couriel C., Ph.D. (Benica SA de CV) served as program chairman. A number of the speakers addressed the policy implications of the North American Free Trade Agreement, GATT and ICH.

The annual PDA/FDA Conference, chaired by Donald E. Baker, J.D. (Fujisawa) and enthusiastically assisted by Jeanne D. White, Office of the Deputy Commissioner for External Affairs, featured 12 forums during the afternoon sessions on September 18-20. Six of these popular forums were repeated to allow maximum attendance. Panelists included both FDA and industry speakers, with ample opportunity for discussion and other forms of interchange. At the conclusion of her address, FDA Deputy Commissioner for External Affairs Sharon Smith Holston, surprised the assemblage with the presentation of a special award, the FDA Commissioner's Special Citation, to Edmund M. Fry, President, and the Parenteral Drug Association. The citation reads, "In recognition of your outstanding performance in promoting cooperation between the Food and Drug Administration and the Parenteral Drug Association in developing educational programs for the pharmaceutical and biopharmaceutical industries." In responding to the Award, Mr. Fry said "It is profoundly gratifying to me for FDA to have recognized the efforts of the PDA staff, Board of Directors and other volunteers in developing effective cooperative programs with FDA."

A contract to develop methodology for parenteral container/closure integrity studies was awarded to the University of Iowa College of Pharmacy, with Lee F. Kirsch, Ph.D. as principal investigator. The resulting technology "...should demonstrate a scientific rigor commonly acceptable to the regulatory agencies, as appropriate." The work is scheduled for completion by the end of March 1996.

The kick off of PDA's Golden Jubilee celebration was announced in the October PDA Letter, with the introduction of the anniversary logo. See Figure 7. Jack Cole (pall) is chairman of the anniversary celebration committee, and he promised an outstanding year-long celebration, culminating at the 50th Annual Meeting in Philadelphia in November 1996. Kenneth Avis, D.Sc. and Fred Carleton, both past presidents, have been working for over a year in writing a detailed history of PDA.

FDA held an open meeting on proposed changes in the 1993 medical device CGMPs on August 23 in Rockville and a workshop on "Characterization of Biotechnology Pharmaceutical Products" in Washington on December 11-13.

PDA's Science and Technology Committee is compiling the results of a survey on current industry practices regarding selection, efficacy and validation of disinfectants and another on the use and validation of sterilizing filters in the industry. Both will eventually be published.

A new organizational structure, consisting of three units, to handle science and technology issues and activities was approved by the Board of Directors in September. A Science Advisory Board was created to establish the strategic perspective for scientific and technical activities. It will make long-range planning recommendations to the Board. The Technical Council will serve as the communication and coordination body for Interest Groups and Task Groups and will replace the existing Science and Technology Committee. The Editorial Review Board is an identified group of experts from which an Editorial Review Team will be selected to provide comprehensive peer review of documents arising within PDA prior to submission to the Board for action.

At the Gala Banquet during PDA's 1995 Annual Meeting, Chairman Clarence Kemper (Kemper-Masterson, Inc.), presented seven awards. James P. Agalloco (Agalloco & Assoc.) received the Frederick J. Carleton Award for "selfless dedication and commitment to the members and goals of PDA" during 12 years on the Board of Directors; Joseph B. Schwartz, Ph.D., (Philadelphia. College of Pharm. & Sci.) received PDA's Distinguished Service Award for "seven years of exemplary service as editor of the *PDA Journal of Pharmaceutical Science and Technology*;" Irving Pflug, Ph.D., (Univ. Minnesota) received the James P. Agalloco Award for "excellence in education," having aught his course multiple times for PDA since 1978; Lennard Ernerot, Ph.D. (Medical

Products Agency, Sweden) received the Michael S. Korczynski Grant in recognition of "international contributions to the pharmaceutical sciences;" Leon Lachman, Ph.D., (Lachman Consulting Services) received Honorary Membership "in recognition of his distinguished service to PDA and the pharmaceutical industry;" Edward J. Smith, Ph.D. (Helvoet Pharma) was presented with the Gordon R. Personeus Award, "in recognition of his outstanding contributions to PDA;" and Drs. Sean A. Evans, Nicholas G. Lordi, Kenneth R. Morris, Donald E. Schuele and Alan P. MacKenzie received the Fred Simon Award for Best paper published in 1994 in the *Journal of Pharmaceutical Science and Technology*, entitled "Prediction of Lyophile Collapse Temperature by Dielectric Analysis."

PDA Published its first book in 1995, "Cleaning and Cleaning Validation: A Biotechnology Perspective," edited by Jon Voss (Biopure) and a product of a special committee of authors.

Late in 1995 an eighth domestic chapter of PDA was organized and its charter approved, the Mountain States Chapter, largely due to the efforts of Roger Notarian (Roger Notarian & Assoc.) and John Elvig (Somatogen). The other seven domestic and two international chapters were active during the year. For a complete listing of the chapters and their officers from inception, see Table 20. some activities of particular interest during 1995 were:

Canadian Chapter, led by Shirley Gallaugher (Abbott), held a two day meeting on January 30 and their Annual Meeting on Sept. 1 with two days of courses prior to the Annual Meeting. The first was held in Toronto and the latter in Montreal.

Capital Area Chapter: The first officers of this chapter included Rande Leibowitz (Univax Biologics), President, and Bill Stoedter (Chesapeake Biological), President-Elect. four meetings were held during the year.

Delaware Valley Chapter, chaired by Charles Cherundolo (Pall Trincor), presented the Chapter's Fred Simon Award of $250 to each of four winners in the 1995 Delaware Valley Science Fair. On October 17 the Chapter held its third Vendor Night Exhibit along with a panel discussing barrier technology.

Japan Chapter held a series of six seminars in Tokyo on the subject of "Validation of Sterile Products." The Chapter recently completed the translation into Japanese and publication of four PDA Technical Reports and is pursuing translation of other PDA reports. Four PDA courses were given in July. The Technical Committee had worked diligently on the preparation of a booklet entitled "Technical Explanation on WHO/GMP Chapter 17," which also was presented at two seminars, one in Tokyo and the other is Osaka. The Annual Meeting of the Chapter was held November 8-9. Kunio Kawamura (Otsuka Pharm.), so instrumental in the development of the Japan Chapter, announced his resignation as president, effective December 31.

Metro Chapter President, Laura Bogdanowich (Schering-Plough), reported that a successful seminar and panel discussion on "Barrier Technology - Current Trends" was conducted by the Chapter with a very distinguished panel of speakers. On June 1 the third annual joint meeting with the Metropolitan Section of the American Society for Quality Control was held with Janice Berger, Regional Inspector for FDA, as speaker on the topic "Inspection of Sterile Processes."

Midwest Chapter held a series of six dinner meetings during the year. The final meeting was held on December 7 with Michael Anisfeld, President, Interpharm Group of Companies, as the speaker on the topic of vendor audits.

New England Chapter's annual summer event was the highlight of the year with over 100 people participating in a festive cruise around Boston Harbor aboard the Spirit of Boston cruise ship. Five other meetings were held, ranging from an evening dinner meeting to an all-day seminar. The Chapter has provided an annual second prize award of $500 for the Massachusetts State Science Fair since 1993. Robert Pazzano (Transkaryotic Therapies) is Chapter president.

Puerto Rico Chapter hosted three highly successful one-day meetings during the year, featuring speakers and roundtables. The first was held in San Juan on February 23, the second on June 15

at Humacao and the third, the annual meeting, in Ponce. At the annual meeting Brenda Rodriguez de Damiani (Schering-Plough) was re-elected president.

West Coast Chapter hosted PDA Chairman Clarence Kemper, Ph.D.(Kemper-Masterson, Inc.) at its March 2 dinner meeting. He spoke on the topic, "Elements of the PDA Technical Report on Validation of Computer Related Systems." At the June 15 dinner meeting Mark Roh, Small Business Representative from FDA spoke on the topic, "FDA Update: Biopharmaceutical Production in Multi-use Facilities and clinical Manufacturing Issues."

Appendix

Figures

Tables

Figure 1: Program of Annual Meeting and Dinner for 1951

PROGRAM

ANNUAL

MEETING

AND

DINNER

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PARENTERAL DRUG ASSOCIATION, INC.

FRIDAY AND SATURDAY, OCTOBER 26, AND 27, 1951

New York Academy of Sciences
2 East 63rd Street, New York, N.Y.

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DINNER AND EVENING SESSION

Sherry-Netherland Hotel
Fifth Avenue and 59th Street, New York, N.Y.

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ANNUAL MEETING

PARENTERAL DRUG ASSOCIATION, INC.

AFTERNOON SESSION — NEW YORK ACADEMY OF SCIENCES

Chairman, Mr. PAUL DE HAEN,
Vice President, Ames Company, Inc.
Elkhart, Indiana.

●

1:30 P.M. *OPENING REMARKS BY CHAIRMAN*

2:00 P.M. *"THE STERILIZATION OF PARENTERALS"*
By Dr. LOUIS GERSHENFELD,
Philadelphia College of Pharmacy
and Science, Philadelphia, Pa.

2:45 P.M. *"THE PHYSICIAN AND THE PARENTERAL MANUFACTURER"*
By Dr. EDWARD B. SCHLESINGER,
Neurological Institute, The Presbyterian
Hospital, and Institute for the Crippled
and Disabled, New York, N. Y.

3:30 P.M. *"COUNCIL ACCEPTANCE OF PARENTERAL MEDICATION"*
By Dr. PAUL L. WERNER, *Assistant Secretary*,
Council on Pharmacy and Chemistry,
Secretary, Committee on Research,
American Medical Association,
Chicago, Illinois.

4:15 P.M. *GENERAL DISCUSSION OF DELIVERED PAPERS*

5:15 P.M. Motion Picture -
"THE BUILDING OF A PHARMACEUTICAL PLANT"
Courtesy, Sandoz Pharmaceuticals,
Division of Sandoz Chemical Works, Inc.,
East Hanover, N. J.

6:30 P.M. Reception -
Gold Suite, Sherry-Netherland Hotel

7:00 P.M. Dinner -
Chanteclair Room, Sherry-Netherland Hotel

8:00 P.M. *"THE 3RD U.S.P. SUPPLEMENT: HOW IT AFFECTS PARENTERALS"*
By Dr. LLOYD C. MILLER,
Director of Revision,
Pharmacopeia of the United States,
New York, N. Y.

8:45 P.M. *"PARENTERALS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT"*
By Mr. JOHN L. HARVEY,
Associate Commissioner of Food and Drugs, Federal Security Agency,
Washington, D. C.

9:30 P.M. *GENERAL DISCUSSION OF DELIVERED PAPERS.*

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MORNING SESSION SATURDAY — NEW YORK ACADEMY OF SCIENCES

S Y M P O S I A

10:00 A.M. *"CONTROL PROBLEMS IN PARENTERAL PRODUCTION"*
Moderator, Dr. ABRAHAM TAUB, Columbia
University, School of Pharmacy,
New York, N. Y.

10:45 A.M. *"PRODUCTION PROBLEMS IN PARENTERAL MANUFACTURE"*
Moderator, Dr. HUGO H. SCHAEFER, *Dean*,
Brooklyn College of Pharmacy,
Brooklyn, N. Y.

11:30 A.M. *"REGULATORY PROBLEMS OF THE MANUFACTURER"*
Moderator, Mr. ARTHUR D. HERRICK,
General Counsel,
Parenteral Drug Association,
New York, N. Y.

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EQUIPMENT EXHIBIT

Figure 2: Original Logo

Figure 3: 25th Anniversary Logo

Figure 4: PDA Code of Ethics, 1978

PARENTERAL DRUG ASSOCIATION
CODE OF ETHICS

Preamble

The principles of conduct for members of the Parenteral Drug Association are established to guide the professionals in their relationships with their fellow members, other individuals concerned with parenteral activities, and the public.

- Every individual elected to membership in the Parenteral Drug Association incurs an obligation to advance the science and art of the parenteral industry, to uphold its standard of honor, and conform to the highest principle of professional conduct.
- Every individual member shall carry on his professional work in the strict spirit of fairness to employers, customers, and in a spirit of personal helpfulness and fraternity toward others involved in parenteral activities.
- Every individual member has the duty to observe the law, to uphold the dignity and honor of the profession, and to accept its ethical principles. The member should not engage in activities that will bring discredit to the Association.
- Every member shall cooperate in upbuilding the profession by exchanging general information and experience with his fellow members and by contributing to the work of his Association where such information does not conflict with the interests of his employer or client.
- A member shall refrain from associating with or allowing the use of his name by an enterprise of questionable character.
- A member shall never knowingly condone the manufacture, or distribution of parenterals or other products under his jurisdiction which do not meet standards required by law.
- A member shall not use any unfair, improper, or questionable methods of securing professional work or advancement.
- A member shall be obligated to report any infractions of the above principles of professional conduct and behavior by individuals subject to this code which may come to his attention to the Board of Directors of the Parenteral Drug Association.

Figure 5: Calendar of Regulatory Activities 1985

1985 Calendar of PDA Regulatory Activities

January
PDA responded to FDA's "Guidelines on Sterile Drug Products Produced by Aseptic Processing."

February
PDA Regulatory Affairs Committee chairman Robert Kieffer met with FDA headquarters personnel to discuss issues of mutual concern.

April
Ad hoc committee formed by President Sol Motola to address FDA's "Guideline on Sterile Drug Products Produced by Aseptic Processing."

Ed Fry, Director, Division of Drug Quality Compliance, FDA, presented "Update on FDA Activities in Aseptic Processing" at PDA Spring Meeting.

A symposium on "Sterile Drug Products Produced by Aseptic Processing Guideline" was held at the PDA Spring Meeting. The symposium was especially timely in view of the date that comments were to be submitted to FDA.

May
PDA forwarded to FDA a comprehensive document on "Aseptic Processing Guidelines," containing comments relative to air quality conditions; components liable to contamination; container/closures; media fills; production and process controls; filtration and "worst case"; laboratory controls; sterility testings; and the need for a lexicon of terms.

PDA President Sol Motola sent letter to the USP (re: postponement of implementation of SVP particulate matter requirements); PDA members were contacted and encouraged to support this response to USP.

June
PDA submitted to FDA a request for extension of time relative to comments regarding parenteral drug products containing Benzyl Alcohol.

Panel on Particulate Matter presented at PDA Summer Meeting in Montreal.

New Regulatory Affairs column initiated in PDA Letter.

July
FDA extended period for comments (re: Benzyl Alcohol) to September 1, 1985, stating that "this action responds to a request from PDA to permit sufficient time for interested parties to fully develop their comments on this matter."

USP extended implementation date (re: SVP particulate matter requirements) from July 1, 1985 to January 1986.

August
Responded to the FDA proposal to prohibit the use of any antimicrobial preservative in single-dose parenteral drug products.

PDA responded to USP proposal on "Visible Particulates in Large- and Small-Volume Injections."

September
PDA and PMA met with FDA to discuss Aseptic Guidelines; agenda included the following:

- Sterility Test Requirements
- Media Fills
- Air Quality
- Laboratory Controls
- Pyrogens

PDA offered Electronic Particle Counting course in conjunction with HIAC/Royco in an effort to acquaint industry personnel with USP's electronic particle counting procedure for particulates in SVPs.

October
PDA submitted to USP comments with respect to the USP proposal on "Visible Particulate Matter in Large-Volume and Small-Volume Injections" as published in the Pharmaceutical Forum.

November
At PDA Annual Meeting, FDA representative and PDA member moderated roundtable discussion on "Prospective Aseptic Processing Guidelines."

Panel consisting of six FDA personnel, headed by Ed Fry, discussed the draft guideline with reference to responses received from PDA, PMA and the industry. The discussion was also a sequel to dialogue in September.

PDA Board of Directors approved the issuance of a series of timely communications which will promulgate to the PDA Membership PDA developed responses to FDA proposed regulations and guidelines, USP proposals and other regulatory information. Its title—PDA Regulatory Communication.

26

Figure 6: Logo Introduced in 1994

Figure 7: Logo for the Fiftieth Anniversary Celebration

Table 1: 1946 Certificate of Incorporation

CERTIFICATE OF INCORPORATION

- of -

PARENTERAL DRUG ASSOCIATION, INC.
pursuant to the Membership Corporations Law

The undersigned, for the purpose of forming a membership corporation pursuant to the Membership Corporations Law of the State of New York, do hereby certify:

1. The name of the proposed corporation shall be PARENTERAL DRUG ASSOCIATION, INC.

2. The purposes for which it is to be formed are:

To foster and advance, in the interest of public health, the art and science of parenteral therapy, and to preserve and improve the integrity and stability of the parenteral drug industry;

To provide and disseminate information relating to parenteral drugs and parenteral therapy;

To foster and encourage a spirit of friendly co-operation among its members, and promote favorable relations between its members and the medical and pharmaceutical professions;

111

To cultivate and maintain cooperative relations with governmental departments and agencies, medical and pharmaceutical organizations, and other branches of the drug and related industries; and to originate and participate in cooperative enterprises and undertakings with them;

To collect and disseminate, for the benefit of members, such business and scientific information as may be of value to them;

To sponsor research projects into matters of scientific and technical interest in the field of parenteral medication;

To review the labeling and advertising of its members in the light of current regulation and advances in medical science, and to dispel uncertainty in such matters;

To promote higher standards in the production of parenteral drugs.

3. The territory in which its operations are principally to be conducted is the United States of America.

4. The city and county in which its office is to

4[illegible]-111-1

5. The number of its directors shall be not less than five (5) nor more than ~~fifty (50)~~ thirteen (13).

6. The names and residences of the directors until the first annual meeting are:

HAROLD H. LONDON, 4626-67 Street, Woodside, New York

RUDOLPH N. PRICE, 116 Chase Road, Manhasset, New York

~~XXXXXXXXXXXX~~ A.LINCOLN KONWISER, 407 North 7 Street, Newark, New Jersey

MAX GOLD, 1930 Anthony Avenue, Bronx, New York

ARTHUR D. HERRICK, 1700 Albemarle Road, Brooklyn, N.Y.

ABRAHAM P. WAGNER, 1575 Grand Concourse, Bronx, New York

7. All the subscribers to this certificate are of full age, at least two-thirds of them are citizens of the United States; at least one of them is a resident of the State of New York, and of the persons named as directors, at least one is a citizen of the United States and a resident of the State of New York.

IN WITNESS WHEREOF, we have made, subscribed, and acknowledged this certificate this 12th day of November, 1946.

Harold H. London

Rudolph N. Price

P. Lincoln Konwiser

Max Gold

Arthur D. Herrick

Abraham P. Wagner

434g-111-2

STATE OF NEW YORK,)
CITY OF NEW YORK,) ss:
COUNTY OF NEW YORK,)

On this 12th day of November, 1946, before me personally came HAROLD H. LONDON, RUDOLPH N. PRICE, A. LINCOLN KONWISER, MAX GOLD, ARTHUR D. HERRICK, and ABRAHAM P. WAGNER, to me known to be the persons described in, and who executed, the foregoing instrument, and they severally duly acknowledged to me that they executed the same.

Raymond Goldberg, Notary Public
New York County Clk's No.

4748-111-3

APPROVAL OF A JUSTICE

The undersigned, a Justice of the Supreme Court of the First Judicial District, hereby approves the foregoing certificate of incorporation of the Parenteral Drug Association Inc.

November 14, 1946

J. S. C.
JUSTICE OF THE SUPREME COURT
OF THE STATE OF NEW YORK.

AARON J. LEVY

474-111-4

Table 2: PDA Officers 1947-1955

Year	President	Vice-President	Regional V.P.	Secretary	Treasurer
1947	Rudolph N. Price, Metropolitan Labs, Inc.				
1948	Dr. Paul A. Naef Sandoz Chemical Works	Dr. Paul V. Maney, Barlow-Maney Laboratories, Inc.		John J. Miskel, Rare Chemicals, Inc.	Joseph Ushkow, Endo Products, Inc.
1949	Dr. Paul A. Naef	Dr. Paul V. Maney		John J. Miskel	Joseph Ushkow
1950	Dr. Paul A. Naef	Dr. Paul V. Maney		John J. Miskel	Joseph Ushkow
1951	Paul DeHaen, Ames Company, Inc.				
		Eastern V.P.	Mid-West V.P.		
1952	Paul DeHaen	Joseph Ushkow, Endo Products, Inc.	C.H. Taylor, Jr., Chicago Pharmacal Co.	L. James Graham, Burroughs Wellcome & Co.	Dr. Lionel Mellini, Sandoz Pharmaceuticals
1953	Joseph Ushkow	Dr. Charles H. Mann, Bristol Laboratories	Arthur G. Sherman,Jr. Sherman Laboratories	Dr. David M. Ashkenaz Wyeth Laboratories, Inc.	Dr. Lionel Mellini
1954	Dr. David M. Ashkenaz, Wyeth Laboratories	Dr. Harold Blumberg, Endo Products, Inc.	Dr. Floyd P. Hallett, Mallinckrodt Chemical Works	Fred C. Ninger, Warner-Chilcott Research Laboratories	L. James Graham
1955	Dr. David M. Ashkenaz	Dr. Harold Blumberg	William S. Bucke, Lafayette Pharmacal, Inc.	Fred C. Ninger	L. James Graham

Table 3: List of Active Members, 1951

(Corporate Members are marked *)

F. Abarno	*Sandoz Pharmaceuticals, Hanover, NJ
T. Anderson	*Kimble Glass Division, New York, NY
Normal Barsel	*International Hormones, Inc. Brooklyn, NY
E.H. Beardsley	*Ames Company, Inc., Elkhart, IN
Hubert E. Boyden	Wm. H. Rorer, Inc., Philadelphia, PA
S.B. Bradshaw	*The Armour Laboratories, Chicago, IL
John H. Brewer	*Baltimore Biological Laboratories, Inc., Baltimore, MD
John D. Brown	Testagar & Co., Inc., Detroit, MI
H.L. Carlson	*Kimble Glass Division, New York, NY
Richard Carrigan	Testagar & Co., Inc., Detroit, MI
Theodore J. Carski	*Baltimore Biological Laboratories, Inc., Baltimore, MD
W.A. Compton, M.D.	*Ames Company, Inc., Elkhart, IN
R.L. Conklin, M.D.	*Ames Company, Inc., Elkhart, IN
Geo. V. Cremieux	Organon, Inc., Orange, NJ
Paul DeHaen	*Amex Company, Inc., New York, NY
Harold Dembo	*Chicago Pharmacal Co., Chicago, IL
Milton Feier	*The Panray Corp., New York, NY
Irv FeldmanByrde	Richard & Pound, New York, NY
Robert L. Forman	*International Hormones, Inc., Brooklyn, NY
C.K. Garay	*The Panray Corp., New York, NY
H. Noel Genung.	Chatham Pharmaceuticals, Inc., Newark, NJ
J.H. Gillon	*Carron Products Co., Philadelphia, PA
J.H. Glynn, M.D.	*The Armour Laboratories, Chicago, IL
Max Gold	*Gold Leaf Pharmacal Co.,Inc., New Rochelle, NY

Ray Goldberg	*The Vitarine Co., Inc., New York, NY
J.J. Goodman	*International Hormones, Inc., Brooklyn, NY
Samuel M. Gordon	*Endo Products, Inc., Richmond Hill, NY
L. James Graham	Burroughs Wellcome & Co., Tuckahoe, NY
Edward Green	U.S. Vitamin Corp., New York, NY
J.F. Greene	*Kimble Glass Division, Owens-IL, Glass Co., Vineland, NJ
Edward Hagerthey	*J.C. Wheaton Co., New York, NY
S.G. Halley.	*Sandoz Pharmaceuticals, Hanover, NJ
Clarence A. Halm	Riker Laboratories, Inc., Los Angeles, CA
S.J. Heinrick	*Testagar & Co., Inc., Detroit, MI
Peter C. Hereld	Chemo Puro Manufacturing Corp., Long Island City, NY
M.S. Herman	*Testagar & Co., Inc., Detroit, MI
J.A. Hubata, M.D.	*The Armour Laboratories, Chicago, IL
E. Hutton	*Sandoz Pharmaceuticals, Hanover, NJ
H.H. Kahlenberg	Kahlenberg Laboratories, Sarasota, FL
D.W. Kallman	*The Panray Corp., New York, NY
Dennis J. Kertesz	Chicago Pharmacal Co., Chicago, IL
David L. Klein	*Endo Products, Inc., Richmond Hill, NY
A. Lincoln Konwiser	*C.F. Kirk Co., New York, NY
Walter S. Konwiser	*C. F. Kirk Co., New York, NY
Irving Levenstein	Leberco Laboratories, Roselle Park, NJ
Irving Levine	*Gold Leaf Pharmacal Co., Inc., New Rochelle, NY
Sol Lidsky	*Gold Leaf Pharmacal Co., Inc., New Rochelle, NY
Wm. Douglas McAdams	Wm. Douglas McAdams, Inc., New York, NY
P.J. McCall	*The Armour Laboratories, Chicago, IL
Joseph Majaske	*J. C. Wheaton Co., Millville, NJ
George N. Malpass	Chemical Specialties Co., Inc., New York, NY
Fred J. Mann	Mann Fine Chemicals, Inc., New York, NY
Leonard W. Maxey	Hollister-Stier Laboratories, Inc., Spokane, WA
L. Mellini	*Sandoz Pharmaceuticals, Hanover, NJ
Joseph P. Miale	Walker Vitamin Products, Inc., Mt. Vernon, NY
Paul A. Naef	*Sandoz Pharmaceuticals, Hanover, NJ
Harold Newmark	*The Vitarine Co., New York, NY
R.A. Ottman	*Sandoz Pharmaceuticals, Hanover, NJ
Myron Pantzer	*The Panray Corp., New York, NY
Rudolph N. Price	Metropolitan Laboratories, Inc., Oyster Bay, NY
R.S. Reamer	*Ames Company, Inc., Elkhart, IN
Harvey Reisman	New York, NY
L.H. Rohde.	The West Co., Inc., Pheonixville, PA
Paul A. Rohde	*Baltimore Biological Laboratories, Inc. Baltimore, MD
Harry Rosenzweig	*International Hormones, Inc., Brooklyn, NY
Dr. Hugo H. Schaefer	Brooklyn, NY
John E. Scott	Lincoln Laboratories, Inc., Decatur, IL
Ewart L. Shattuck	Abbott Laboratories, New York, NY
I.F. Shaw.	*The Vitarine Co., Inc., New York, NY
Sam Shovitz	*Gold Leaf Pharmacal Co., Inc., New Rochelle, NY
J.R. Sims	*Kimble Glass Division, New York, NY
Mel Stern	*The Vitarine Co., New York, NY
John F. Stucky	Pitman-Moore Company, Indianapolis, IN
Dr. Abraham Taub	New York, NY
C.H. Taylor, Jr.	*Chicago Pharmacal Co., Chicago, IL
W.B. Taylor, Jr.	*Chicago Pharmacal Co., Chicago, IL
Edgar E. Theimer	Metropolitan Laboratories, Inc. Oyster Bay, NY
Joseph Ushkow	*Endo Products, Inc., Richmond Hill, NY
Meyer Ushkow	*Endo Products, Inc., Richmond Hill, NY
Harriette D. Vera	*Baltimore Biological Laboratories, Inc., Baltimore, MD

Table 4: PDA Officers, 1956-1965

Year	President	Vice President	Regional V.P.	Secretary	Treasurer
1956	L. James Graham, Burroughs Wellcome & Co.	Dr. Harold Blumberg, Endo Laboratories, Inc.	William S. Bucke, Lafayette Pharmacal, Inc.	Walter S. Konwiser, C.F. Kirk Co.	Joseph W. Kouten, Caroll Dunham Smith Pharmacal Co.
1957	L. James Graham	Dr. Harold Blumberg	Harold Dembo, Chicago Pharmacal Co.	Hubert E. Boyden, William H. Rorer, Inc.	Joseph W. Kouten
1958	William S. Bucke	John Henderson, Chase Equipment Corp.	Raymond W. Barton, Mead Johnson & Co.	Hubert E. Boyden	Joseph W. Kouten
1959	William S. Bucke	John Henderson	Raymond W. Barton	Hubert E. Boyden	Joseph W. Kouten, Smith, Miller & Patch, Inc.
1960	John Henderson	Raymond W. Barton	Harold Dembo	Hubert E. Boyden	Joseph W. Kouten
1961	Harold Dembo	Dr. Harold Blumberg	H.Z. Hays, Armour Pharmaceutical Co.	Hubert E. Boyden	Joseph W. Kouten
1962	Harold Dembo	Dr. Harold Blumberg	H.Z. Hays	Hubert E. Boyden	Joseph W. Kouten
1963	Hubert E. Boyden	Nathan C. Kirsch, Schering Corporation	H.Z. Hays	William J. Artz, Smith, Kline & French Labs.	Joseph W. Kouten
1964	Hubert E. Boyden	Nathan C. Kirsch	H.Z. Hays	William J. Artz	Joseph W. Kouten
1965	Nathan C. Kirsch	William A. Thawley, S.B. Penick & Co.	Dr. Glen Sperandio, Purdue University	William J. Artz	Norman L. Hobbs, Wyeth Laboratories, Inc.

Table 5: PDA Meetings, 1952-1965
(Program Chairman)

Year	Winter	Spring	Summer	Annual(Fall)
1952	Jan. 21, New York	Apr. 3, New York	June 5, New York	Oct. 30-Nov.1, New York (Max Gold)
1953	Jan. 29, New York	June 23, New York		Oct. 28-30, New York
1954	Feb. 25, New York	Apr. 30, New York	June 18, Philadelphia	Oct. 20-22, New York
1955	Jan. 28, New York	Apr. 1 New York	June 10, Philadelphia	Oct. 25-27, New York (Dr. H. Blumberg)
1956	Jan. 27, New York	Apr. 20, Philadelphia	June 8, Chicago	Oct. 31-Nov. 2, New York (Dr. H. Blumberg)
1957	Feb. 1, New York	Apr. 12, Chicago	June 7, Philadelphia	Nov. 6-8 New York (Dr. H. Blumberg)
1958	Feb. 7, New York (Dr. H. Blumberg)	Apr. 18 Philadelphia	June 6, Chicago	Oct. 22-24, New York (Dr. H. Blumberg)
1959	Feb. 6, New York	Apr. 17, Chicago	June 5, Philadelphia	Oct. 14-16, New York (Dr. H. Blumberg)

1960	Feb. 5, New York	Apr. 29, Philadelphia (Dr. K. Avis)	June 24, Chicago (H.Z. Hays)	Oct. 19-21, New York (Dr. H. Blumberg)
1961	Feb. 3, New York	Apr. 21, Chicago (H.Z. Hays)	June 3, Philadelphia (Dr. K. Avis)	Nov. 1-3, New York (Dr. H. Blumberg)
1962	Feb. 9, New York	Apr. 13, Philadelphia	June 29, Chicago	Oct. 10-12, New York (Dr. H. Blumberg)
1963	Feb. 8, New York	Apr. 26, Philadelphia (Wm. J. Artz)	June 28, Chicago (H.Z. Hays)	Oct. 30-Nov. 1 New York (N.C. Kirsch)
1964	Feb. 7, New York (N.C. Kirsch)	Apr. 24, Chicago (Dr. G. Sperandio)	June 19, Philadelphia	Oct. 14-16, New York
1965	Feb. 5, New York (G. Personeus)	Apr. 9, Chicago (Dr. K. Avis)	June 11, Philadelphia (Dr. Wm. Benica)	Oct. 20-22 New York (Dr. G. Sperandio)

Table 6: Growth During the Period 1959-1965

Year	Membership		Financial		Meeting Attendance		
	Individuals*	Corporate	Assets	NYC	Chicago	Phil.	Annual
1959	237	43	$10,652				
1960	248	45	$15,775				
1961	273	47					
1962	290	52	$26,398				
1963	307	54	$21,758		123		
1964	352	57	$37,455	82	211		322
1965	361	59	$32,350	103	138		318

*Includes Corporate Representatives

Table 7: PDA Officers 1966-1975

Year	President	Vice President	Regional V.P.	Secretary	Treasurer
1966	Nathan C. Kirsch Schering Corp.	William A. Thawley, S.B. Penick & Co.	Dr. Glen Sperandio Purdue University	William J. Artz, Smith Kline & French Laboratories	Norman L. Hobbs William H. Rorer, Inc.
1967	Dr. Harold Blumberg Endo Laboratories, Inc.	William J. Artz	Dr. Glen Sperandio	Dale C. Steiner Wyeth Laboratories, Inc.	Norman L Hobbs
1968	Dr. Kenneth E. Avis The University of Tennessee	Dr. Leon Lachman Endo Laboratories, Inc.	Kenneth G. Hewitt Abbott Laboratories	Dale C. Steiner	Norman L. Hobbs
1969	Dr. Kenneth E. Avis	Dr. Leon Lachman	Dr. Roy Kuramoto, Syntex Laboratories, Inc.	Dale C. Steiner	Norman L. Hobbs
1970	Charles P. Schaufus Millipore Corporation	Gordon R. Personeus Lederle Laboratories Inc.	Glenn Wickes Ben Venue Laboratories,	Dale C. Steiner	G. Willard Webster, National Drug Co.

1971	Charles P. Schaufus	Gordon R. Personeus	Thomas H. Riggs Abbott Laboratories	Dale C. Steiner	G. Willard Webster
1972	Gordon R. Personeus	William J. Artz	Thomas H. Riggs	Dale C. Steiner	G. Willard Webster
1973	Gordon R. Personeus	William J. Artz	Dr. Gerald Hecht Alcon Laboratories	Dale C. Steiner	G. Willard Webster, Merrill-National Laboratories
1974	William J. Artz	George H. Hopkins, The West Company	Dr. Gerald Hecht	Dale C. Steiner	G. Willard Webster
1975	William J. Artz	George H. Hopkins	Dr. Gerald Hecht	Leland W. Blazey, McNeil Laboratories, Inc.	G. Willard Webster

Table 8: PDA Meetings, 1966-1975
(Program Chairman)

Year	Winter	Spring	Summer	Annual(Fall)
1966	Feb. 4, New York (G. Personeus)	Apr. 15, Chicago (Dr. A. Kunz)	June 24, Philadelphia (Dr. Wm. Benica)	Nov. 2-4 New York (Dr. K. Avis)
1967	Feb. 3, New York (G. Personeus)	Apr. 7, Chicago (Dr. G. Sperandio)	June 16, Philadelphia (Wm. J. Artz)	Nov. 1-3, New York (Dr. K. Avis)
1968	Feb. 2, New York (J. Anschel)	Apr. 5, Detroit (W.R. Brownell)	June 21, Philadelphia (Wm. J. Artz)	Nov. 13-15, New York (G. Personeus)
1969	Feb. 7, New York (C. Schaufus)	Apr. 4, Detroit (N. Kartinos)	June 13, Philadelphia (Wm. J. Artz)	Oct. 29-31 New York (G. Personeus)
1970	Feb. 6, New York (C. Woodward)	Apr. 10, Montreal (G. Wickes)	June 19, Philadelphia (L. Blazey)	Nov. 11-13 New York (Wm. J. Artz)
1971	Feb. 5, New York (P. Rasanen)	Apr. 2, Chicago (T. Riggs)	June 18, Philadelphia (F.S. Simon)	Nov. 10-12 Las Vegas (Wm. J. Artz)
1972	Mar. 3, New York (C. Woodward)		June 16, Chicago (Dr. G. Sperandio)	Oct. 25-27, New York (C. Schaufus)
1973	Mar. 2, Chicago (Dr. G. Hecht)		June 22, Philadelphia (F.S. Simon)	Oct. 31-Nov. 2 New York (F. Carleton)
1974	Apr. 4-5, San Juan, PR (F. Carleton)		June 21, Chicago (Dr. G. Hecht)	Oct. 30-Nov. 1, New York (C. Woodward)
1975	Apr. 4, Toronto (Dr. P. Belcastro)		June 27, Philadelphia (D.B. Jacoby)	Oct. 29-31, New York (G. H. Hopkins)

Table 12: Growth During the Decennium 1976-1985

Year	Membership		Financial	Meeting Attendance			Exhibits
	Individuals	Corporate	Assets	Spring	Summer	Ann	Annual
1976	1,072	104	$169,570	343	461	744	70
1977	1,188	116	301,347			1,250	100
1978	1,425	121	357,431			1,350+	120
1979	1,488	140			400+		
1980	1,656		545,600	300	300+	1,300	125
1981	1,775	156	622,300	450+		1,000+	
1982	1,780	170	689,199			1,200	
1983	1,805		874,223	300+		1,200	125
1984	1,848		1,059,731		400+	1,700	151
1985	1,850	189	1,212,800		400+		158

Table 13: PDA Training Slide/Audio Tape Series, 1974-1995

Year	Title	Running Time
1974	Sterile Products and You	13 minutes
1976	Aseptic Filling	18 minutes
1976	Cleaning	33 minutes
1978	Gowning for Aseptic Areas	12 minutes
1978	Documentation of Process Data	16 minutes
1979	Handling and Control of Materials	15 minutes
1980	Maintenance in the Pharmaceutical Plant	12 minutes
1980	Wash Those Hands	4 minutes
1981	Standard Operating Procedures	9 minutes
1981	Grooming Aids	3 minutes
1981	Laminar Flow	6 minutes
1983	Inspect and Measure	18 minutes
1988	Compliance: The Self Audit and You	26 minutes
1992	Keep It Clean (Video)	16 minutes

Table 14: Education programs

First Taught	Name of Course	Faculty & Affiliation
April 1978	Microbiology & Engineering of Sterilization Processes	Irving Pflug, Phd., University of Minnesota
November 1979	Establishing & Operating a Metrology Lab to Support an In-house Calibration Program	
November 1980	Fundamentals of Lyophilization	Thomas A. Jennings, T.A. Jennings & Associates
June 1981	Limulus Amebocyte Lysate (LAL) Test Technology & LAL Workshop	Frederick C. Pearson, Travenol Laboratories, Inc.
November 1981	Validation & Regulatory Compliance	Bernard Loftus and Christopher Rhodes
June 1982	Production Problem Solving Strategy Workshop	Bruce White
June 1982	Obtaining Accurate Temperature Measurements in Process Validation	Clarence Kemper, Ph.D., Kaye Instruments
June 1982	Validation of Micron Filtration	Glen Howard, Jr., Ph.D., Pall Corporation
June 1982	Design and Validation of Sterilization Processes	Richard T. Wood, Ph.D., Pfizer Inc.
October 1982	Clean in Place	Thomas Grimes, Ph.D., and Steve Kovary
November 1982	Rubber for Medical and Pharmaceutical Application	Gary Greene, Faultless Rubber Company
November 1982	Aseptic Processing Audits	Kenneth Chapman, Pfizer Inc.
November 1982	Materials, Surface Finishes & Components for Sanitary Application	David Artiss, Valex Products Corp.
November 1982	Pharmaceutical Stills	Henry Kuhlman, Finn-Aqua America, Inc.
November 1982	Environmental Monitoring	Joachim Manning, Cutter Labs.
November 1982	Validation of Pharmaceutical Water	David Artiss, Valex Products Corp.
April 1983	Basic Sterilization Microbiology	Theron E. Odlaug, Ph.D., Travenol Laboratories Inc.
April 1983	ETO Sterilization	John Gillis, Ph.D., Skyland Scientific Inc.
June 1983	Validation of Lyophilization	Thomas A. Jennings, T.A. Jennings & Associates
March 1984	How to Buy a Steam and/or ETO Sterilizer	David Maynard, Skyland Scientific
March 1984	Evaluation of Non-Destructive Particulate Test Systems for Parenterals Products	Julius Z. Knapp, Ph.D., Schering Corp
March 1984	Fundamentals of HVAC Systems in the Pharmaceutical Industry	Steve Levay, Beecham Laboratories
June 1984	Validation of Aseptic Drug Powder Filling Process	John Wasynczuk, Ph.D., Pfizer Inc.
June 1984	Validation of Computerized Systems in the Pharmaceutical Industry	Phil DeSantis and Dennis Kochansky, E.R. Squibb Inc.
June 1984	Stability Testing Methods	John Urbigkit, Pfizer Inc.
November 1984	Particulate Counting	Carole S. Genovesi, Wyeth Laboratories, Inc.
November 1984	Sterile Bulk Pharmaceuticals	Robert DePhillips and Steve Newhard Wyeth Laboratories, Inc.
April 1985	Fundamentals of Computers	Ann Smyth, Pfizer Inc
April 1985	Aseptic Processing Validation: Trends & Issues	James E. Agalloco, E.R. Squibb & Sons
September 1985	Evaluating the HIAC/ROYCO Equipment	Alvin Lieberman and Louis Sarto, HIAC/Royco
March 1986	Evaluations of Microbiological Aspects	Gerry Prout, Roussel Labs.
March 1986	Lyophilization: A Short Course	Steve Nail, Ph.D., The Upjohn Co., and Michael Pikal, Ph.D., Eli Lilly & Co.

First Taught	Name of Course	Faculty & Affiliation
June 1986	Quality Audits	Len Steinborn
December 1986	Steam-in-Place Technology	James Agalloco, E.R. Squibb & Sons
January 1988	From Gene to Product: Fundamentals of Biotechnology	Doug Testa, Ph.D., Interferon Sciences, Inc.
March 1988	Microbiological Quality Assurance for Pharmaceutical Products	Richard T. Wood, Ph.D., Pfizer Inc.
June 1988	Automated Microscopic Analysis of Particulate Contaminants in Parenteral Solutions	Thomas Barber, Ph.D., Baxter Healthcare
June 1988	Fundamentals of Current Good Manufacturing Practices	Ralph Badagliacca, Pfizer Inc.
June 1988	Radiation Sterilization	Jeff Beck, Johnson & Johnson
September 1988	Pharmaceutical Water: System Design and Validation	Theodore Meltzer, Ph.D., Capitola Consulting
October 1988	Fundamentals of D, F, and Z Values	Raymond Shaw, Jr., Ph.D., Merck & Co., Inc
October 1988	Sterile Manufacturing with Blow/Fill/Seal Technology	Frank Leo, Automatic Liquid Packaging
October 1988	Cleanroom Management	Anne Marie Dixon, Cleanroom Management Associates
October 1988	Good Laboratory Practices/Quality Assurance Audits	Patricia O'Brien Pomerleau, Rorer Pharmaceuticals
December 1988	Validation of HPLC Methods	Ira Krull, Ph.D., Northeastern University
March 1989	Validation of Non-aseptic Processing	Margaret Szymczak, SmithKline Beecham Pharmaceuticals, Inc., and James Agalloco, E.R. Squibb & Sons
March 1989	How to Develop Validation Protocols	Ronald P. Thiboutot, Ph.D., E.R. Squibb & Sons, Inc.
March 1989	Troubleshooting Your Pharmaceutical Water System	Deborah Jackman
March 1989	Applications of Genetic Engineering	John Geigert, Ph.D., Cetus Corporation
April 1989	Quality Circles	Mitchell Manning
April 1989	Communicating with the FDA	Nat Geary & Carl Nielsen, FDA
April 1989	Vendor Audits and Supplier Certification	George Cochran &Wylie McVey Burroughs Wellcome Co.
April 1989	Batch Record Reviews	John Y. Lee, Altana Corp
April 1989	Licensing Biologics: Joint, Divided & Shared Contracts	William Srigley, Invitron; and Madge Crouch, FDA
April 1989	A Mock FDA Inspection	Ron Stellon, FDA
April 1989	Safety Considerations for Cell-Derived Products	Mary L. Cipriano, Abbott Diagnostics; and James Fenno, Microbiological Associates, Inc.
April 1989	Computer Aided GMP Audit Techniques	Ronald F. Tetzlaff, Ph.D., FDA
May 1989	Validation, Design, and Start-up of Biotechnology Plants	V. Kumar Gupta, Robert J. Giorgio, Kumar Gupta, Robert J. Giorgio, James J. Dougherty, and Paul Tubito, Life Sciences, Inc.
May 1989	Biotechnology Regulatory Basics	Larry Johnson, consultant, and James Fenno
May 1989	Analytical Chemistry and Biotechnology/Stability of Peptides and Proteins	Robert L. Garnick, Ph.D., Genentech Inc.
June 1989	Introduction to Process Validation	James Agalloco, E.R. Squibb & Sons;
June 1989	Laboratory Automation	Michael Forsyth
June 1989	Specification, Qualification, and Change Control of Computer-related Systems	Michael Masterson, Copas, Inc.; & Bruce Fowler, LabPro

Parenteral Drug Association - The First Fifty Years
Kenneth E. Avis, D.Sc. and Frederick J. Carleton

First Taught	Name of Course	Faculty & Affiliation
June 1989	Validation of Aseptic Audits	James Agalloco, E.R. Squibb & Sons, Inc.; Fred Carleton, PDA, Inc.; Franco DeVecchi,, VecTech, Inc.; and David Artiss,.Artiss & Associates, Inc.
September 1989	Aseptic Processing: A Human Resources Perspective	John Levchuk, Ph.D., FDA; William E. Hodge, Merck & Co.
November 1989	Downstream Purification of Proteins	Joseph Tarnowski, Ph.D., and Eric Sharps, California Biotechnology, Inc.
November 1989	Quality Control for Biotechnology	Gary Christiansen, Ph.D., Hybritech, Inc.; John Parker, Ph.D., Centocor; and Paul Winter, Burroughs Wellcome Co.
January 1990	Quality Control: Release and Stability Testing of Biotechnology Products	John Geigert, Ph.D., Cetus Corporation; and Robert Garnick, Ph.D., Genentech, Inc.
June 1990	Computer-Controlled Optical Particle Counters	Al Lieberman, Particle Measuring Systems, Inc.; and Thomas Barber Baxter Healthcare Corp.
July 1990	Biotechnology: QA/QC, Regulatory Concerns and Common Sense	John Geigert, Ph.D., Cetus Corporation; Marcia Federici, Ph.D., Genentech, Inc.; and Susan Hershenson, Ph.D., Cetus Corp
February 1991	Filter Integrity Testing	Theodore Meltzer, Capitola Consulting
February 1991	Filtration: Its Process & Validation (in Spanish)	Oliver Kilham, Ph.D., Caribbean Bioresearch, Inc.; and Hans Schroeder Ph.D., International Consultants Association
April 1991	Statistical Process Control	Mark Gershon, Ph.D., Temple University
June 1991	Environmental Monitoring (Advanced Level)	James E. Akers, Ph.D., Praxis Biologics
June 1991	Bulk Pharmaceutical Chemicals Production (overseas only)	Daniel H. Gold, Ph.D., Lederle Laboratories
September 1991	Regulatory Perspectives of Pharmaceutical Labels	Gary Yingling & Kathleen D. Blake, McKenna & Cuneo
February 1992	Investigation & Handling of Sterility Test Positives	Carol Lampe, Baxter Healthcare Corp., and Mary Sue Dorminy
February 1992	Facility Design Control	W. Lhoest, Ph.D., Lhoest-Vereeken Concepts
March 1992	Validating Spreadsheet-based Software Applications	Bruce Fowler, LabPro
March 1992	Bulk Pharmaceuticals: Qualification and Validation	A. Edwin Martin, consultant
April 1992	Application of CIP to the Pharmaceutical Process	Dale Seiberling, Seiberling & Associates
April 1992	Closure Fundamentals: Seal Integrity	Dana Morton Guazzo, R.W. Johnson PRI, and Edward J. Smith, Ph.D., The West Co.
April 1992	Veterinary Parenterals	Blair Conley, Gavin Pharmaceutical Services
May 1992	Parenteral Packaging: Rubber, Glass, Plastic, and Metal Seals	Patty Kiang, Ph.D., and Edward J. Smith, Ph.D., The West Co.
May 1992	Validation Protocols for Solid Dosages	Ronald P. Thiboutot, Ph.D., E.R. Squibb & Sons, Inc.
February 1993	Validation Issues in Chromatographic Processes	Gail Sofer and Anne Barry, Pharmacia Biotechnology, Inc.
March 1993	Implementing an Electronic Batch Record System	Sarah Norton, IBM, and Sheri Cashman, SmithKline Beecham Pharmaceuticals
June 1993	Advanced Topics in Process Validation	James Agalloco, E.R. Squibb & Sons, & Phil DeSantis, United Engineers and Constructors
June 1993	Manufacturing & Control of Sterile Bulk Powders	Henry Avallone, FDA; Dennis GuilfoyleFDA; and Robert Moore, Eutectic

First Taught	Name of Course	Faculty & Affiliation
September 1993	Basic Principles in the Preparation of Sterile Dosage Forms	Kenneth E. Avis,(Sc'D, University of Tennessee; John Ludwig, Ph.D., Burroughs Wellcome Co.
October 1993.	Development of Cell Culture Biopharmaceuticals: Manufacturing and Control	Anthony Lubiniecki, Sci.D., SmithKline Beecham Pharmaceuticals; James Fenno, Alexin Pharmaceuticals; William Srigley, Biotechnology Products; and Marcia Federici, Tektagen, Inc
1993	GLP Overview	Gary D. Christiansen, Ph.D., Hybritech, and Leslie Osmera-Rock, Advanced Tissue Sciences
February 1994	Assay Validation	Lynn Torbeck, Torbeck & Associates; and Ronald C. Branning, Genetics Institute
February 1994	Introduction to Barrier Technology	James E. Akers, Ph.D., Akers Kennedy & Associates, and Carmen Wagner, Ph.D., Lederle Praxis Biologics
February 1994	Cleaning Validation	Rebecca Brewer, Raytheon Engineering; and William Hall, Ph.D., Burroughs Wellcome Co.
January 1994	Preparing for an FDA Pre-Approval Inspection	Ronald Tetzlaff, Ph.D., Kemper Masterson, Inc.
February 1994	Current Good Manufacturing Practice and Compliance with US FDA Requirements	Edmund M. Fry, PDA
March 1994	Identification of Particulate Matter by Light Microscopy	Thomas Barber, Ph.D., and Damien Newberger, Ph.D., Baxter Healthcare Corp.
March 1994	Compendial Improved Microscopic Assay	Matt Lannis, Baxter Healthcare Corp.
April 1994	Design & Implementation of World Class Manufacturing	Robert G. Kieffer, Ph.D., RGK Consulting
September 1994	Packaging Component Control: The Use of Bar Code and Machine Vision Techniques	Robert Rack , RDG
September 1994	Controlling Biotechnology Risks: A Holistic Approach to Safety and Environmental Protection	J. Van Houten, Ph.D., Johnson & Johnson; Diane Fleming, Ph.D., Biosafety Consultant; Harry Meslar, Ph.D., Jacob-Sigel-Triad; and Anthony Moreira, Ph.D., University of Maryland
October 1994	Implementing an Electronic Document Management System for Manufacturing	Thomas Quinn & Barbara Meserve, The Hollis Group
December 1994	Validation of Biotechnology Products and Processes	Gail Sofer, Pharmacia Biotechnology Inc.
1994	Master Planning and Management of Validation	James Agalloco, Agalloco & Associates
January 1995	Writing and Editing Standard Operating Procedures for Compliance with CGMP Regulations	Larry Johnson, consultant, and Ralph Smalling, Amgen, Inc.
April 1995	Formulation of Stable Protein Pharmaceuticals	Eli Shefter, Ph.D., Consultant; Mark Manning, Ph.D., & John Carpenter, Ph.D., University of Colorado; and Praveen Tyle, Ph.D., Agouron Pharmaceuticals
April 1995	Solid Dosage Validation	Robert G. Kieffer, Ph.D., RGK Consulting; and Everard Walton
April 1995	GMP Biotechnology Facility Design and Validation	Antonio R. Moreira, Ph.D., University of Maryland; and Edward Sybert, Bioscience Contract Production Corporation
May 1995	Industrial Environmental Surveillance & Control	James Wilson, Isomedix, Inc.; and Kenneth Patterson, Patterstat
May 1995	Surviving PAIs/Technology Transfer for a Successful PAI	Ronald Stellon, Dupont Merck Pharmaceutical Co.
June 1995	Sterile Packaging: How to Select, Process, and Validate a Container/Closure System	Edward J. Smith, Ph.D., The West Co.; and Steve Goodsir, Wyeth-Ayerst Labs., Inc.

First Taught	Name of Course	Faculty & Affiliation
June 1995	Application of Containment Technology to Solid Dosage Processing	Dimitri Wirchansky, Gregg Herreman, and H. Walter Feier, Fluor Daniel
September 1995	Cleanroom Design Problems and Cleanroom Construction Protocols	Anne Marie Dixon, Cleanroom Management Associates
September 1995	GMPS For Bioprocesses	Antonio R. Moreira, Ph.D., University of Maryland; and Edward Sybert Bioscience Contract Production Corporation
September 1995	Terminal Sterilization of Injectables: Application of Advanced Concepts	Dominic Ventura, Ph.D., Wyeth Ayerst Laboratories, Inc., and Marlene Raschiatore, Elkins Sinn, Inc.
September 1995	Sterility Testing in Barrier Systems	Richard T. Wood. Ph.D., Pfizer Inc.
October 1995	CGMPS as They Relate to Drug Labels and Your Production and Guidelines for Conducting a Label Supplier Audit	James Stead, Ron Coward, and George Moses, Ph.D., Avery-Dennison Corporation, and Anthony Lord, FDA.
October 1995	Industrial Development of Parenteral Dosage Forms of Proteins and Peptides	John Bontempo, Ph.D., Consultant; Patty H. Kiang, Ph.D., The West Co.; Forest E. Badmington, Millipore Corp.; Basant Sharma, Ph.D., Robert Wood, Johnson Pharmaceutical Research Institute; and Edward J. Smith, Ph.D., The West Co.
November 1995	Ventilation and Airborne Contamination in Cleanrooms Technology	Bengt Ljungqvist, Royal Institute, and Berit Reinmuller, Pharmacia AB

Table 15: PDA Technical Publications

TECHNICAL MONOGRAPHS/TECHNICAL REPORTS

Validation of Steam Sterilization Cycles
Technical Monograph No. 1
1978, 36 pages

Validation of Aseptic filling for Solution Drug Products
Technical Monograph No. 2
1980, 28 pages

Validation of Dry Heat Processes Used for Sterilization and Depyrogenation
Technical Report No. 3
1981, 55 pages.

Design Concepts for the Validation of a Water-For-Injection System
Technical Report No. 4
1983, 12 pages

Sterile Pharmaceutical Packaging: Compatibility and Stability
Technical Report No. 5
1984, 137 pages

Validation of Aseptic Drug Powder Filling Processes
Technical Report No. 6
1984, 30 pages

Depyrogenation
Technical Report No. 7
1985, 116 pages

Parametric Release of Parenteral Solutions Sterilized by Moist Heat Sterilization
Technical Report No. 8
1987, 10 pages

Review of Commercially Available Particulate Measurement Systems
Technical Report No. 9
1988, 30 pages

Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers
Technical Report No. 10
1988, 26 pages.

Sterilization of Parenterals by Gamma Radiation
Technical Report No. 11
1988, 10 pages

Siliconization of Parenteral Drug Packaging Components
Technical Report No. 12
1988, 14 pages

Fundamentals of a Microbiological Environmental Monitoring Program
Technical Report No. 13
1990, 16 pages

Industry Perspective on the Validation of Column-Based Separation Processes for the Purification of Proteins
Technical Report No. 14
1992, 11 pages.

Industrial Perspective on Validation of Tangential Flow Filtration in Bio-pharmaceutical Application
Technical Report No. 15
1992, 13 pages

Effect of Gamma Irradiation on Elastomeric Closures
Technical Report No. 16
1992, 12 pages

Current Practices in the Validation of Aseptic Processing -1992
Technical Report No. 17
1993, 21 pages

PDA Report on the Validation of Computer-Related Systems
Technical Report No. 18
1995, 15 pages

Rapid/Automated ID Methods Survey
Technical Report No. 19
1990, 7 pages

Report on Survey of Current Industry Gowning Practices
Technical Report No. 20
1990, 5 pages

Technical Report: Bioburden Recovery Validation
Technical Report No. 21
1990, 8 pages

TECHNICAL INFORMATION BULLETINS

Generic Test Procedures for Elastomeric Closures
Technical Information Bulletin No. 2
1979, 4 pages

Aspects of Container/Closure Integrity
Technical Information Bulletin No. 4
1983, 7 pages

TECHNICAL METHODS BULLETINS

Extractables from Elastomeric Closures: Analytical Procedures for Functional Group Characterization/Identification
Technical Methods Bulletin No. 1
1980, 24 pages

Elastomeric Closures: Evaluation of Significant Performance and
Identity Characteristics
Technical Methods Bulletin No. 2
1981, 27 pages

Glass Containers for Small Volume Parenteral Products: Factors for Selection and Test Methods for Identification
Technical Methods Bulletin No. 3
1982, 19 pages

Table 16: PDA Officers, 1986-1995

Year	President	Vice - President	Second Vice - President	Secretary	Treasurer
1986	Dr. Robert G. Kieffer, Sterling International Group	Dr. R. Michael Enzinger, The Upjohn Co.	James P. Agalloco, E.R. Squibb & Sons, Inc.	David C. Fry, Bristol-Myers	Douglas B. Jacoby, Millipore Corporation
1987	Dr. Robert G. Kieffer, Sterling Drug, Inc.	Dr. R. Michael Enzinger	James P. Agalloco	David C. Fry, Bristol-Myers Industrial Division	Douglas B. Jacoby
1988	James P. Agalloco	Dr. Michael S. Korczynski, Abbott Laboratories	Dr. John A. Bontempo, Interferon Sciences, Inc.	Dr. Clarence A. Kemper, Kaye Instruments Inc.	Douglas B. Jacoby
1989	James P. Agalloco	Dr. Michael S. Korczynski	Dr. James E. Akers, Praxis Biologics, Inc.	Robert B. Myers, Schering-Plough Corp.	Dr. Raymond Shaw, Jr. Merck Pharmaceutical Manufacturing Division
		President - Elect			
1990	Dr. Michael S. Korczynski	Dr. James E. Akers		Dr. Clarence A. Kemper, Kemper-Masterson, Inc.	Dr. Raymond Shaw, Jr.
1991	Dr. Michael S. Korczynski	Dr. James E. Akers		Dr. Clarence A. Kemper	Dr. Raymond Shaw, Jr.
1992	Dr. James E. Akers, Akers Kennedy & Associates	Dr. Clarence A. Kemper		Dr. Joyce L. DeYoung, Ortho-McNeil Pharmaceuticals	Dr. Raymond Shaw, Jr.
1993	Dr. James E. Akers	Dr. Clarence A. Kemper		Dr. Joyce L. DeYoung	Dr. Raymond Shaw, Jr. Merck & Co., Inc.
1994	Dr. Clarence A. Kemper	Dr. Raymond Shaw, Jr., Merck & Co., Inc.		Dr. Henry K. Kwan, Schering-Plough Research Institute	Dr. Raymond Gabler, Millipore Corporation
	Chairman	Chairman - Elect			
1995	Dr. Clarence A. Kemper	Dr. Raymond Shaw, Jr.		Dr. Henry K. Kwan	Dr. Raymond Gabler

Table 17: PDA Meetings, 1986-1995
(Program Chairman)

Year	Spring	Summer	Annual (Fall)	National Program Cte
1986	March 13 - 14, NYC (Fred Carleton, Pfizer)	June 5 - 6, Chicago (Dr. Clarence Kemper, Kaye)	Dec. 3 - 5, San Francisco (James Agalloco, Squibb)	(James Agalloco, Squibb)
1987	April 9 - 10, San Juan, PR (Fred Nordhauser, Pall)	June 18 - 19, Chicago (Dr. James Harris, Glaxo)	Nov. 18 - 20, Philadelphia (Russell Madsen, Bristol - Myers)	(Dr. James Harris, Glaxo)

Year	Spring	Summer	Annual (Fall)	National Program Cte
1988	March 10 - 11, Washington, D.C. (Regina McCairns, SmithKline & French)	June 9 - 10, Philadelphia (David Flamburg, Vestar)	Oct. 24 - 26, Chicago (Robert Stotz, Upjohn)	(Russell Madsen, Bristol - Myers)
1989	March 9 - 10, NYC (Regina McCairns, SmithKline Beecham)	June 8 - 9, Chicago (Dr. Timothy Leahy, Millipore)	Nov. 2 - 4, Hollywood, FL (Warren Charleton, Burroughs - Wellcome)	(Russell Madsen, Bristol - Myers Squibb)
1990	March 8 - 9, New Brunswick, NJ (Regina McCairns, SmithKline Beecham)	June 7 - 8, Chicago (Dr. Timothy Leahy, Millipore)	Nov. 7 - 9, Philadelphia (James Agalloco, Bristol - Myers Squibb)	(Warren Charleton, Burroughs - Wellcome)
1991	March 7 - 8, New Brunswick, NJ (Dr. Ronald Thiboutot, Bristol-Myers Squibb)	June 6 - 7, Chicago (Dr. Theodore Meltzer, Capitola)	Oct. 23 - 25, Philadelphia (Regina McCairns, SmithKline Beecham and Edward Trappler, Lyophilization Tech.)	(Regina MCCairns, SmithKline Beecham)
1992	March 17 - 20 Philadelphia (James Agalloco, Agalloco & Associates)		Nov. 11 - 13, San Francisco (Martin Henley, Merck & Co.)	(Regina McCairns, SmithKline Beecham)
1993	March 10 - 12, Philadelphia (Dr. Edward Smith, West)		Nov. 1 - 5, Orlando, FL (Dr. John Cronin, Schering Plough)	(Regina McCairns, SmithKline Beecham)
1994	March 8 - 11, Chicago (Dr. Musa Ghannam, Merck)		Nov. 2 - 4, Philadelphia, (Dr. David Butler, Schering Plough Res. Institute)	(Martin Henley, Merck & Co.)
1995	March 15 - 17, San Francisco (Don Elinski, Sterling Winthrop)		Nov. 13 - 15, Boston, MA (Dr. Anthony J. Lucas, Millipore)	

Table 18: Growth During the Decennium 1986-1995

YEAR	Membership Individuals*	Corporate	Assets	Budget / Expenses
1986	1, 915	198	1,487,457	710,581
1987	2, 258	211	1,613,822	926,830
1988	2,755	222	1,727,464	964,225
1989	2, 867	221	1,893,858	886,934
1990	3,367	234	2,289,307	1,000,976
1991	3,500	211	2,609,569	1,066,726
1992	4,500	199	2,731,635	1,442,733
1993	5,638	247	3,249,728	2,714,014
1994	6,496	247	3,812,495	3,684,872
1995	7,703	250	4,130,811	3,756,860

Table 19: Special Meetings of PDA, 1987-1995
(Program Chairman)

1987 May 11-13, Arlington VA (Fred Carleton, Pfizer)
USP/PDA, "International conference on Liquid Borne Particle Inspection and Metrology"

1990 February, Arlington, VA
PDA/IES "International Conference on Particle Detection, Metrology and Control"

August 27-29, Washington, D.C.
PDA/PMA "Sterilization in the 1990s"

Sept. 25-26, Rockville, MD (Doris Conrad, SmithKline Beecham),
PDA/FDA First Annual Joint Conference

1991 Sept. 23-25, Rockville, MD (Daniel Gold, Lederle)
PDA/FDA Second Annual Joint Conference

1992 Feb. 5-6, Arlington, VA (Dr. Randy Hutt, Burroughs Wellcome and Richard Lemons)
PDA/IES "Cleanrooms and Microenvironments"

Feb. 17-19, Basel Switzerland (Peter Bigelow, SmithKline Beecham)
First International Congress on Advanced Technologies, "Advanced Technologies for manufacturing of Aseptic and Terminally Sterilized Pharmaceuticals and Bio-pharmaceuticals"

June 4-5, San Juan, PR (Denise Hall), Pharma-Caribe PDA's first Spanish language conference

Sept. 21-23, Rockville, MD (Fred Gustafson, Abbott)
PDA/FDA Third Annual Joint Conference

Oct. 13-14, New Brunswick, NJ (James Agalloco, Agalloco Assoc., and Phil DeSantis, United Engineers)
"Computer-Integrated Manufacturing"

Oct. 27, Bethesda, MD (Staff) Scientific Forum
"Terminal Sterilization"

1993 Feb. 22-24, Basel, Switzerland (Regina McCairns, SmithKline Beecham and Dr. James Robinson, SmithKline Beecham)
"Validation of Pharmaceuticals and Biopharmaceuticals"

June 9-10, New Brunswick, NJ (Staff) Seminar on the Manufacture and Control of Sterile Bulk Powders

June 16, Bethesda, MD Scientific Forum on Cleaning Validation.

Sept. 10, Bethesda, MD (Staff)
Special Conference, "Impact of the Barr Decision"

Sept. 27-29, Rockville, MD (Doris Conrad, SmithKline Beecham)
Fourth Annual PDA/FDA Joint Conference

1994 Feb. 14-16, Basel, Switzerland (Dr. Lennart Ernerot, Pharmacia)
Third International Conference, "Advanced Pharmaceutical and BioPharmaceutical Development, Manufacturing and Control in Europe and the USA"

March 30, Bethesda, MD (Staff) Forum on Blow/Fill/Seal Technology

June 15, Bethesda, MD (Staff)
Forum on Performance of Environmental Sampling and Setting Alert and Action Levels

September 18-20, Bethesda, MD (Jennie Allewell, Cell Therapeutics)
Fifth Annual PDA/FDA Joint Conference

Nov. 14-16, Tokyo, Japan (Dr. Kunio Kawamura), Takeda Chemical Industries, and Regina McCairns, SmithKline Beecham)
PDA Asian Symposium and Exhibit

1995 January 17-18, Atlanta, GA, (Dr. Carmen Wagner, Lederle Praxis, and Jack Lysfjord, TL Systems)
PDA/ISPE Conference, "Advanced Barrier Technology"

May 9, Bethesda, MD (Staff) Forum on Good Validation Practices

June 7-9, Mexico, D.F.
PDA/AFM (Association Farmaceutica Mexicana)
Pan American Conference

Sept. 18-20, Bethesda, MD (Donald E. Baker, J.D., Fujisawa, USA)
Sixth Annual PDA/FDA Joint Conference, on "Regulatory Compliance in a Changing Environment"

Table 20: Chapter Listing

CAPITAL AREA CHAPTER - Year Formed: 1994

YEAR	PRESIDENT	PRESIDENT-ELECT	SECRETARY	TREASURER
1995	Rande Leibowitz	Bill Stoedter	Kelly Langan	Sylvia Isaacson
1994	Rande Leibowitz*			

*Acting President

DELAWARE VALLEY CHAPTER - Year Formed: 1991

YEAR	PRESIDENT	VICE-PRESIDENT	SECRETARY	TREASURER	CH. LIAISON
1995	Charles Cherundolo	Mark Kaiser	John Earle	Roger Deschenes	Regina McCairns
1994	Charles Cherundolo	James Kehoe	John Earle	Roger Deschenes	Regina McCairns
1993	Charles Cherundolo	James Kehoe	John Earle	Roger Deschenes	Regina McCairns
1992	Charles Cherundolo	James Kehoe	John Earle	Roger Deschenes	Regina McCairns
1991	Charles Cherundolo	James Kehoe	John Earle	Roger Deschenes	Regina McCairns

METRO CHAPTER - Year Formed: 1991

YEAR	PRESIDENT	PRESIDENT-ELECT	SECRETARY	TREASURER	CH. LIAISON
1995	Laura Bogdanowich	David Bradshaw	Maryann Rech	Dante Serricchio	Leonard Mestrandrea
1994	Laura Bogdanowich	David Bradshaw	Maryann Rech	Dante Serricchio	Leonard Mestrandrea
1993	Laura Bogdanowich	David Bradshaw	Maryann Rech	Dante Serricchio	Leonard Mestrandrea
1992	Leonard Mestrandrea	Laura Bogdanowich	Gloria Monton	Dante Serricchio	James Agalloco
1991	Leonard Mestrandrea	Laura Bogdanowich	Gloria Monton	Dante Serricchio	James Agalloco

MIDWEST CHAPTER - Year Formed: 1989

YEAR	PRESIDENT	VICE-PRESIDENT	SECRETARY	CH. LIAISON
1995	Carol Lampe	Dipak Doshi	Amy Davis	Frank Bing
1994	Carol Lampe	Dipak Doshi	Amy Davis	Frank Bing
1993	Carol Lampe	Dipak Doshi	Amy Davis	Frank Bing
1992	Carol Lampe	Dipak Doshi	Michael Anisfeld	Frank Bing
1991*	Carol Lampe	Shruti Kusumgar	Michael Anisfeld	Frank Bing
1990*	Carol Lampe	Shruti Kusumgar	Michael Anisfeld	Frank Bing
1989*	Carol Lampe	Shruti Kusumgar	Michael Anisfeld	Frank Bing

*For these years, there was also a Treasurer, Michael Sterling.

NEW ENGLAND CHAPTER - Year Formed: 1989

YEAR	PRESIDENT	VICE-PRESIDENT	SECRETARY	TREASURER
1995	Robert Pazzano	James Correia	Michelle Sceppa	Mark Staples
1994	Robert Pazzano	James Correia	Michelle Sceppa	Mark Staples
1993	Robert Pazzano	James Correia	Michelle Sceppa	Mark Staples
1992	Robert Pazzano	Robert Weber	None	James Correia
1991	Robert Pazzano	Robert Weber	Cathy DeWolfe	James Correia
1990	Robert Pazzano and Tim Leahy	Robert Weber		
1989	Robert Pazzano and Tim Leahy			

PUERTO RICO CHAPTER - Year Formed: 1989

YEAR	PRESIDENT	VICE-PRESIDENT	SECRETARY	TREASURER	CH. LIAISON
1995	Brenda Rodriguez de Damiani	Wallace Torres	Zaida Clas	Miriam Varela	Teresita Garrido
1994	Brenda Rodriguez de Damiani	Wallace Torres	Zaida Clas	Miriam Varela	Teresita Garrido
1993	Irene Ortiz	Sergio Silva	None	Miriam Varela	Teresita Garrido
1992	Irene Ortiz	Sergio Silva	Myriam Concepcion	Miriam Varela	Teresita Garrido
1991	Irene Ortiz	Sergio Silva	Myriam Concepcion	Miriam Varela	Teresita Garrido
1990	Hilda Ferrer	Irene Ortiz	Myriam Concepcion	Miriam Varela	Teresita Garrido
1989	Hilda Ferrer	Irene Ortiz	Myriam Concepcion	Miriam Varela	Teresita Garrido

WEST COAST CHAPTER - Year Formed: 1989

YEAR	PRESIDENT	PRESIDENT-ELECT	SECRETARY	TREASURER
1995	Robert Baffi	Kristin Bacigalupi	Barbara Sheng	Steve Carlson
1994	James Fernandez	Robert Baffi	Barbara Sheng	Kristin Bacigalupi
1993	James Fernandez	Robert Baffi	Barbara Sheng	Kristin Bacigalupi
1992	James Fernandez	Robert Baffi	Raul Soikes	Kristin Bacigalupi
1991	Robert Garnick	James Fernandez	Raul Soikes	Mary Davis
1990	Robert Garnick	James Fernandez	Raul Soikes	Robert Baffi
1989	Robert Garnick	John Geigert	John Geigert	Robert Garnick

CANADA CHAPTER - Year Formed: 1992

YEAR	PRESIDENT	VICE-PRESIDENT	SECRETARY	TREASURER
1995	Suzanne Levesque	Shirley Gallaugher	Anna Mallozzi	Yves Archambault
1994	Suzanne Levesque	Shirley Gallaugher	Anna Mallozzi	Yves Archambault
1993	Brian Reid	None	Suzanne Levesque	Yves Archambault
1992	Brian Reid	None	Suzanne Levesque	Peter Dunlop
1991*	Brian Reid	John Parks	Jo-Anna Serafini	Peter Dunlop

*Charter not yet approved by PDA.

JAPAN CHAPTER - Year Formed: 1991

YEAR	PRESIDENT	VICE-PRESIDENT/ CHAPTER LIAISON	SECRETARY	TREASURER
1995	Kunio Kawamura	Toshiaki Nishihata	Hisao Kyogoku	Morihiro Sudo
1994	Kunio Kawamura	Toshiaki Nishihata	Hisao Kyogoku	Morihiro Sudo
1993*	Toshinobu Aoyama	Kunio Kawamura	T. Sasaki	Hiromi Mitsutake
1992*	Toshinobu Aoyama	Kunio Kawamura	Masayoshi Nishiyama	Hiromi Mitsutake
1991*	Toshinobu Aoyama	Kunio Kawamura	Masayoshi Nishiyama	Hiromi Mitsutake

*For these years, there was a separate office of Chapter Liaison, which was Toshiaki Nishihata

Table 21: Grants Conferred and Administered by the Parenteral Drug Association Foundation for Pharmaceutical Sciences, Inc. 1981-1995

1981 1. John K. R. Robson, M.D.
Medical College of South Carolina, Charleston, SC
$20, 000
"Vitamin Status and Metabolic Control in Cancer."
FUNDED BY: PDA FOUNDATION and W.S. BUCKE GRANT

2. Alan McKenzie, Ph.D.
University of Washington, Seattle, WA
$10, 000
"Freezing and Freeze-Drying of Pharmaceutical Models."
FUNDED BY: PDA

3. Patrick P. DeLuca, Ph.D.
University of Kentucky, Lexington, KY
$10, 000 - 1981
$10, 000 - 1982 (extension of 1981 grant)
"Interaction of Microspheres with Blood Constituents and Effect on Immune Response."
FUNDED BY: PDA

1982 4. James W. McGinity, Ph.D.
University of Texas at Austin, Austin, TX
$10, 000
"Intravenous Fat Emulsions as Drug Delivery Systems."
FUNDED BY: PDA

5. John M. Daly, M.D., F.A.C.S.
Memorial Hospital for Cancer and Allied Diseases, Sloan-Kettering Institute, New York, NY
$10, 000
"Parenteral Nutrition with High Branched-Chain Amino Acids."
FUNDED BY: PDA FOUNDATION and W.S. BUCKE GRANT

1983 6. Moshe Shike, M.D., F.A.C.S., F.R.C.P.
Memorial Hospital for Cancer and Allied Diseases Sloan-Kettering Institute, New York, NY
$10, 000
"Mineral and Bone Metabolism in Patients Receiving Long Term Parenteral Nutrition."
FUNDED BY: PDA FOUNDATION

7. Samual H. Yalkowsky, Ph.D.
University of Arizona, Tucson, AZ
$10, 000
"Formulation of Poorly Soluble Drugs for Parenteral Use."
FUNDED BY: PDA

8. Arnold J. Repta, Ph.D.
University of Kansas, Lawrence, KS
$10, 000
"Prodrugs of Amines for Alteration of Physio-chemical Properties of Drugs for Parenteral Formulation."
FUNDED BY: H.O. WEST FOUNDATION

9. Neil R. Anderson, Ph.D.
Purdue University, Lafayette, IN
$10, 000
"Sterilizing and Depyrogenating Properties of a Plasma Initiated by Laster and Sustained by an Electromagnetic Field."
FUNDED BY: MILLIPORE CORPORATION (Charles P. Schaufus Grant)

1984 10. Theodore D. Sokoloski, Ph.D.
Ohio State University, Columbus, OH
$10, 000
"Drug Entrapment Within Native Albumin Beads." - Part I
FUNDED BY: PDA

11. J. Richard Thompson, Pharm D.
The Moses H. Cone Memorial Hospital, Greensboro, NC
$10, 000
"The Relationship of Serum Morphine Concentration to Analgesia in Cancer Patients Receiving Continuous Intravenous Morphine Infusion."
FUNDED BY: PDA

12. John T. Pinto, Ph.D.
Sloan-Kettering Institute, New York, NY
$10, 000
"Selective Adriamycin-Induced Inhabition of Favin Metabolism in Rat Heart: Implications for Adequate Vitamin B2 Supplementation During Chemotherapy."
FUNDED BY: PDA FOUNDATION

13. J. Howard Rytting, Ph.D.
University of Kansas, Lawrence, KS
$10, 000
"Effects of Temperature and Pressure on the Stability of Blood Platelet Preparations."
FUNDED BY: MILLIPORE CORPORATION (Charles P. Schaufus Grant)

14. Milap C. Nahata, Pharm.D.
Ohio State University, Columbus, OH
$5, 000
"Evaluation of Methods for the Administration of Parenteral Medications."
FUNDED BY: H.O. WEST FOUNDATION

1985 15. Joseph T. Rubino, Ph.D.
University of North Carolina, Chapel Hill, NC
$15, 000
"Estimation of Liquid Vehicle Composition from Physicochemical Parameters."
FUNDED BY: PDA

16. James D. Bryers, Ph.D.
Duke University, Durham, NC
$10, 000 (cash)
$10, 000 (equipment)
"Biofilm Formation Effects on the Operation and Scale-Up of Cell Recycle Fermentation Systems."
FUNDED BY: MILLIPORE CORPORATION (Charles P. Schaufus Grant)

17. Theodore D. Sokoloski, Ph.D.
Ohio State University, Columbus, OH
$15, 000
"Drug Entrapment Within Native Albumin Beads." - Part II
FUNDED BY: PDA

18. Rex O. Brown, Pharm.D.
University of Tennessee, Memphis, TN
$15, 000
"Prospective Randomized Study of Albumin Supplementation in Hypoalbuminemic Patients Receiving Total Parenteral Nutrition: Effects on Hospital Morbidity."
FUNDED BY: PDA FOUNDATION

19. Richard S. Rivlin, M.D.
New York Cornell Medical, Rockefeller University, Sloan-Kettering Cancer Institute
$100, 000 (Three Year Grant)
Fellowship for Career in Parenteral Nutrition Relating to Cancer Chemotherapy
FUNDED BY: PDA FOUNDATION and H.O. WEST FOUNDATION

20. Ho-Leung Fung, Ph.D.
State University of New York, Buffalo, NY
$15, 000
"Optimization of Organic Solvents in Intramuscular Injection Vehicles."
FUNDED BY: PDA

21. Theodore D. Sokoloski, Ph.D.
Ohio State University, Columbus, OH
$15, 000
"Drug Entrapment Within Natural Polymeric Systems: Albumin and Fibrin."
FUNDED BY: PDA

22. Nicholas G. Lordi, Ph.D.
Rutgers University, New Brunswick, NJ
$15, 000
"Quantitative and Mechanistic Measurements of Container / Closure Integrity."
FUNDED BY: PDA FOUNDATION

23. Louis Ace, Ph.D.
Northeast Louisiana University, Monroe, LA
$15, 000
"Selective Ocular Drug Delivery Using Liposomes."
FUNDED BY: PDA FOUNDATION

24. Michael W. Townsend
University of Kentucky, Lexington, KY
$10, 000 (cash)
$10, 000 (equipment)
"The Effects of Freezing and Drying on Immunoglobulin Conformation."
FUNDED BY: MILLIPORE CORPORATION (Charles P. Schaufus Grant)

1987 25. David R. Luke, Pharm.D.
University of Houston, Houston, TX
$15, 000
"Efficacy and Toxicity of Cyclosporine Delivered in Liposomes."
FUNDED BY: PDA FOUNDATION (Research Grant)

26. Kenneth Avis, D.Sc.
University of Tennessee, Memphis, TN
$10, 000 (cash)
$10, 000 (equipment)
"The Role of Endotoxin in Dry Heat Sterilization Validation: Kinetics of Lipid A Inactivation to Elucidate Mechanisms of Endotoxin Destruction."
FUNDED BY: MILLIPORE CORPORATION (Charles P. Schaufus Grant)

1988 27. Roland Bodmeier, Ph.D.
University of Texas, Austin, TX
$15, 000
"Preparation and Evaluation of Biodegradable Poly (dl-lactide) Microparticles."
FUNDED BY: PDA FOUNDATION (Research Grant)

28. Michael Jay, Ph.D.
University of Kentucky, Lexington, KY
$10, 000 (cash)
$10, 000 (equipment)
In-Process Stability Measurements of Lyophilized Peptide Preparations by Perturbed Angular Correlation."
FUNDED BY: MILIPORE CORPORATION (Charles P. Schaufus Grant)

29. Daniel Kahne, Ph.D.
Princeton University, Princeton, NJ
$15, 000
"Glycosylation of Unreactive Substrates."
FUNDED BY: PDA FOUNDATION (Research Grant)

30. Joseph T. Rubino, Ph.D.
University of North Carolina, Chapel Hill, NC
$15, 000
"Studies on the Physical and Chemical Stability of Parenteral Emulsion and Emulsifiers."
FUNDED BY: PDA FOUNDATION (Research Grant)

M. Hyat Alkan, Ph.D.
1989 31. University of Illinois, Chicago
$15, 000
"Mixed Micelles as Proliposomes for the Parenteral Delivery of Poorly Soluble Drugs."
FUNDED BY: PDA FOUNDATION (Research Grant)

32. Thomas P. Johnston, Ph.D.
University of Illinois, Chicago
$15, 000
"Sustained Parenteral Administration of Biological Response Modifiers for Immunotherapy of Human Malignancies."
FUNDED BY: PDA FOUNDATION (Research Grant)

33. James D. Bryers, Ph.D.
Duke University, Durham, NC
$10, 000 (cash)
$10, 000 (equipment)
"Effect of Cell Separation and Recycle on Cell Activity and Protein Productivity."
FUNDED BY: MILLIPORE CORPORATION (Charles P. Schaufus Grant)

34. Richard S. Rivlin, M.D.
New York Cornell Medical, Rockefeller University, Sloan-Kettering Cancer Institute
$17, 000 (extension of 1985 grant)
Fellowship for Career in Parenteral Nutrition Relating to Cancer Chemotherapy
FUNDED BY: PDA FOUNDATION and THE H.O. WEST FOUNDATION

1990 35. Ronald T. Borchardt, Ph.D.
University of Kansas, Lawrence, KS
$15, 000/yr. – 3 yr.
"Aspartyl-Isoaspartyl Interconversion: Potential Stability Problem in Parenteral Dosage Forms."
FUNDED BY: PDA FOUNDATION, SCHERING-PLOUGH CORPORATION and SYNTEX CORP. (Grant in Biotechnology)

36. Scott L. Diamond, Ph.D.
State University of New York, Buffalo, NY
$10, 000 (cash)
$10, 000 (equipment) - 1 yr.
"Protein Synthesis by Mammalian Cells in Hydrodynamic Environments."
FUNDED BY: MILLIPORE CORPORATION (Charles P. Schaufus Grant)

37. Victor C. Yang, Ph.D.
University of Michigan, Ann Arbor, MI
$15, 000
"A Novel, Long-acting Parenteral Drug Delivery System."
FUNDED BY: GLAXO, INC., DR. JOHN N. KAPOOR and PDA FOUNDATION (Research Grant)

38. Kenneth E. Avis, D.Sc.
University of Tennessee, Memphis, TN
$15, 000
"Study of Liposomes as a Drug Delivery Vehicle for a Model Protein (Lactate Dehydrogenase) Formulated for Freeze-Drying."
FUNDED BY: THE PALL CORPORATION, THE PDA FOUNDATION and THE WARNER-LAMBERT FOUNDATION (Research Grant)

39. Daniel Kahne, Ph.D.
Princeton University, Princeton, NJ
$15, 000 (extension of 1988 grant)
"Glycosylation of Unreactive Substances."
FUNDED BY: PDA FOUNDATION (Research Grant)

40. Richard S. Rivlin, M.D.
Memorial Sloan-Kettering Cancer Institute, New York, NY
$5, 000 (extension of 1985 grant)
FUNDED BY: H.O. WEST FOUNDATION (Fellowship Grant)

1991 41. Gunther Hochhaus, Ph.D.
University of Florida, Gainesville, Fla.
$15, 000/yr. - 3 yr.
"New Method for the Analysis of Tyrosine Containing Peptides - Application to Stability Studies."
FUNDED BY: PDA FOUNDATION and SCHERING-PLOUGH CORPORATION (Grant in Biotechnology)

42. Nair Rodriguez-Hornedo, Ph.D.
The University of Michigan, Ann Arbor, Michigan
$10, 000/yr. in cash for 3 years and $10, 000/yr. in Millipore equipment for 3 years.
"Formulation and Process of the Selective Crystallization of Buffer Components During Freezing."
FUNDED BY: MILIPORE CORPORATION (Charles P. Schaufus Grant in Parenteral Processing)

43. Karen D. Caldwell, Ph.D.
The University of Utah, Salt Lake City, Utah
$15, 000/yr - 1 yr. grant
"Structural Studies of Fat Emulsions by Sedimentation Field-Flow Fractionation."
FUNDED BY: GLAXO, INC., JOHN N. KAPOOR, Ph.D. and PALL CORPORATION
(Foundation Research Grant)

44. Yongyut Rojanasakut, Ph.D.
West Virginia University, Morgantown, West Virginia
$15, 000/yr. - 1 yr.
"Ocular Peptide Absorption: Control of Tight Junction Permeability and Charge Selectivity."
FUNDED BY: PDA FOUNDATION and WARNER-LAMBERT COMPANY
(Foundation Research Grant)

45. Richard S. Rivlin, M.D.
Memorial Sloan-Kettering Cancer Institute, New York, New York
$10, 000 (extension of 1985 grant)
FUNDED BY: H.O. WEST FOUNDATION (Fellowship Grant)

1992 46. Bradley D. Anderson, Ph.D.
The University of Utah, Salt Lake City, Utah
$15, 000/yr. - 3 yr.
"The Role of Intramolecular Nucleophilic Catalysis and the Effects of Self-Association on the Deamidation of Human Insulin at Low pH."
FUNDED BY: SCHERING-PLOUGH CORPORATION, JOHN N. KAPOOR, Ph.D., and THE NINA "DALE" DEMUTH FUND (Grant in Biotechnology)

47. Paul M. Bummer, Ph.D.
The University of Kentucky, Lexington, Kentucky
$15, 000/yr. - 1 yr.
"Studies on the Mechanism of Gas Aqueous Interface-induced Aggregation in Protein Solutions."
FUNDED BY: GLAXO, INC., PALL CORPORATION and THE PDA FOUNDATION (Foundation Research Grant)

48. Diane J. Burgess, Ph.D.
The University of Connecticut, Storrs, Connecticut
$15, 000/yr. - 1 yr.
"Development of Technology to Determine Sterility of Capsular Drug Delivery Systems"
FUNDED BY: THE PDA FOUNDATION and WARNER-LAMBERT COMPANY, PARKE-DAVIS DIVISION (Foundation Research Grant)

49. Richard S. Rivlin, M.D.
Memorial Sloan-Kettering Cancer Institute, NewYork, New York
$5, 000 (extension of 1985 grant)
FUNDED BY: PDA FOUNDATION for PHARMACEUTICAL SCIENCES, INC., in memory of ANDREW J. SCHMITZ, Jr.)

1993 50. J. Keith Guillory, Ph.D.
University of Iowa, Iowa City, Iowa
$15, 000/yr. - 1 yr.
"Lyophilization and Stability Studies of Peptides and Related Compounds."
FUNDED BY: PDA FOUNDATION, THE KAPOOR CHARITABLE FOUNDATION and SCHERING-PLOUGH CORPORATION.
(Grant in Biotechnology)

51. Steven L. Nail, Ph.D.
Purdue University, West Lafayette, Indiana
$15, 000/yr. - 1 yr.
"The Effect of Surface Interaction Antigen and Vaccine Adjuvant on Immune Response in an animal Model."
FUNDED BY: PDA FOUNDATION, GLAXO, INC., and PALL CORPORATION.
(Research Grant)

52. Elizabeth M. Topp, Ph.D.
University of Kansas, Lawrence, Kansas
$15, 000/yr. - 1 yr.
"Transport of Peptides and Proteins in a Model Basement Membrane."
FUNDED BY: WARNER-LAMBERT COMPANY, PARKE-DAVIS DIV., and PDA FUNDATION.
(Research Grant)

1994 53. Bhogi B. Sheth, Ph.D.
University of Tennessee, College of Pharmacy, Memphis, TN.
$10, 000/yr. - 3 yrs. plus $10, 000/yr. for Millipore Equipment.
"Particle Size Reduction and Lyophilization of Parenteral Emulsions."
FUNDED BY: MILLIPORE CORPORATION
(Charles P. Schaufus Grant in Parenteral Processing.)

54. James Stewart, Ph.D.
University of Georgia, College of Pharmacy, Athens, GA
$15, 000/yr. - 3 yrs.
"HPLC/FT - IR: A New Approach to the Analysis of Peptides/Proteins and its Application in Stability Studies."
FUNDED BY: P.D.A. FOUNDATION FOR PHARMACEUTICAL SCIENCES, INC., SCHERING-PLOUGH CORPORATION and STEPHEN M. OLIN, Ph.D.
(Grant in Biotechnology)

55. Thomas P. Johnston, Ph.D.
University of Illinois at Chicago, College of Pharmacy - 1 yr. (Incomplete)
"Inhibition of Surface Adsorption of Protein Drugs Using Solvent Additives."
FUNDED BY: P.D.A. FOUNDATION, GLAXO, INC. and PALL CORPORATION.
(Research Grant)

56. Stephen L. Nail, Ph.D.
Purdue University, College of Pharmacy, West Lafayette, In.
$15, 000/yr. - 1 yr.
"Measurements of Viscoelastic Properties to Predict Stability of Freeze Dried Protein Formulations."
FUNDED BY: WARNER-LAMBERT COMPANY, PARKE-DAVIS DIVISION and THE KAPOOR CHARITABLE TRUST.
(Research Grant)

1995 57. Janet L. Wolfe, Ph.D.
University of Tennessee, College of Pharmacy, Memphis, TN.
$15, 000/yr. - 3 yrs.
"The Inhibition of Aggregation of Interleukin -2by Protein Disulfide Isomerase."
FUNDED BY: P.D.A. FOUNDATION FOR PHARMACEUTICAL SCIENCES, INC. and SCHERING-PLOUGH CORP.

58. Diane J. Burgess, Ph.D.
University of Connecticut, College of Pharmacy, Storrs, Ct.
$15, 000 - 1 yr.
"Development of Stable Controlled Release Parenteral Emulsion Systems."
FUNDED BY: WARNER-LAMBERT COMPANY, PARKE-DAVIS DIVISION.
The Kapoor Charitable Foundation and the P.D.A. Foundation

59. Valentino J. Stella, Ph.D.
The University of Kansas, College of Pharmacy, Lawrence, KS
$15, 000/yr. - 1 yr.
"Evaluation of Sulfobutyl Ether B-Cyclodextrins as Solubilizing/Stabilizing Freeze-Dried Excipients."
FUNDED BY: P.D.A. FOUNDATION, GLAXO, INC., and PALL CORPORATION.

Postscript

At the 1996 PDA Annual Meeting celebrating PDA's fiftieth anniversary, Ken Avis was presented with a Board of Director's Special Recognition for Lifetime Achievement, in recognition of his contributions over the years to PDA and the pharmaceutical industry. The course on preparation of parenteral medications that he directed for 24 years served as an inspiration for PDA's Training and Research Institute, and PDA has named a laboratory in our new Institute in Ken's honor. He passed away in Memphis, Tennessee January 28, 1999.

Fred Carleton, after a full professional life of serving the pharmaceutical industry and PDA, is enjoying retirement in Boynton Beach, Florida.

The Parenteral Drug Association is now known as *PDA - An International Association for Pharmaceutical Science and Technology*, and looks forward with great anticipation to "The Second Fifty Years."

Edmund M. Fry
Bethesda, Maryland, USA
February 1999

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