

Cover



30 Protective Packaging Choices Challenge Packaging Engineers

As more and more companies release drug products requiring temperature management during distribution the role of the distribution packaging engineer has become quite challenging. From controlled room temperature products to those requiring sub zero conditions, there can be an intimidating amount of solutions available.

Cover Art Illustrated by Katja Yount

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34 A Look into the Future of Parenteral Manufacturing: Part 1

The *2010 Parenterals Conference* gave an overview on existing issues and potential solutions as well as future trends. While it is impossible to give a details of everything that was presented, the following review offers some highlights that might convey the spirit and value of the event.



38 Speakers at Biennial Training Conference Rate a 4 out of 5

GMP and regulatory compliance trainers from locations around the world came together this October in Baltimore, Md. where the theme of the conference was *Compliance Training and Performance in a Changing Environment*.



39 PDA's 5th Annual Microbiology Conference Hits Blogosphere

As part of his site, rapidmicromethods.com, Dr. Michael Miller blogs about various topics of interest. This year, he covered *PDA's 5th Annual Pharmaceutical Microbiology Conference*, and has graciously allowed us to share some of his posts in the PDA Letter.

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28 U.S. FDA, Industry Meet to Share Notes on Virus Control

Virus contamination is not a common occurrence in the tightly controlled world of vaccine and therapeutic biotech manufacturing. Yet the issue was suddenly thrust into the spotlight in 2009 and 2010, as two high-profile cases of product/process contamination made headlines.

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Contribute to Upcoming *PDA Letters*

We are always looking for articles on the latest regulatory developments, science and technology trends, and other topics important to our community. For the May issue, we are looking for articles on supply chain, for June, internal investigations, and for the July/August issue, aseptic processing. If you want to contribute, contact **Emily Hough** at hough@pda.org.

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24 The Power of Knowledge

Knowledge is already one of the most precious commodities in the pharmaceutical industry. According to the *Oxford English Dictionary*, knowledge is defined as “expertise, and skills acquired by a person through experience or education; the theoretical or practical understanding of a subject.” The competition to get the most knowledgeable people has already started and companies are spending a lot of time and money to find, attract and hire subject matter experts. This seems to be in conflict with the recent layoffs in the pharmaceutical industry. But both are parts of a picture to get more efficient and to reach operational excellence.

Cover Art by Henrik Jonsson

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28 A Look into the Future of Parenteral Manufacturing: Part 2

The first to give a flavor of where the industry comes from, what has been achieved, what is still an issue and where it is heading was **Tor Gråberg**, Chief Pharmaceutical Inspector, Medical Products Agency, Sweden. Gråberg elaborated on globalization and harmonization needs and projects, big versus small pharma positions and potentials, information and trust building, role and implications of contract manufacturing and environmental impact.

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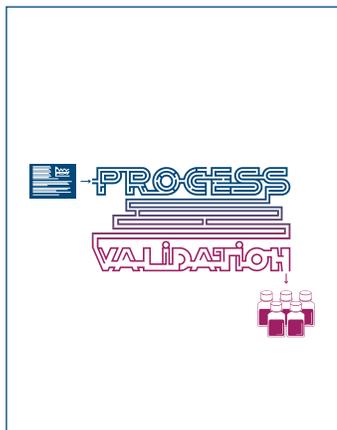
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18 Process Validation: Industry Comments Impact Six Aspects of FDA PV Guidance

Since the new U.S. FDA *Guidance for Industry on Process Validation: General Principles and Practices* was published as a draft in Nov 2008, the pharmaceutical industry has asked many questions and voiced concern about implementation challenges. FDA refined the document based on the comments that were received from industry.

Cover Art Illustrated by Katja Yount

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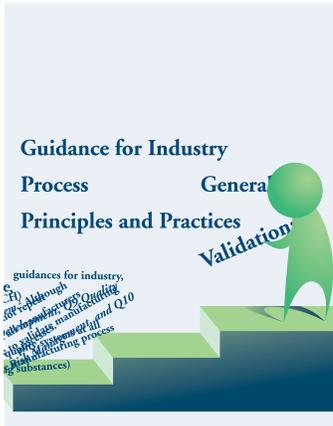
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22 Process Validation: FDA has Guidance, Industry has Questions

The U.S. FDA's final Guidance for Industry on Process Validation: General Principles and Practices (a revision of the 1987 guideline) is sure to raise a lot of questions as industry works to implement new principles.

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22 Eight Solutions for Controlling Supply Chain Risk

The pharmaceutical supply chain is particularly at risk in the zones outside of the direct control of manufacturers: ingredient supply and final product distribution. In this issue of the *PDA Letter*, we present articles that offer a number of solutions to lower risks throughout the chain.

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24 Multi-Pronged Strategy Needed to Combat Counterfeiters

Globalization is impacting most industries, and the pharmaceutical industry is no exception. On the positive side, it has enabled our industry to enter markets all over the world and provide life-giving medicines to millions of patients. With the benefits of globalization, however, come significant challenges and responsibilities.



26 Achieving Visibility On-Demand

There are no easy answers to the question of how to reduce risks in the pharmaceutical supply chain, particularly with respect to ingredients purchased from an expanding and complex international market. In recent years, PDA has worked with industry and regulators to sponsor meetings, an industry consortium has formed, new regulations/guidances have passed and/or are being considered, yet it seems there continues to be more questions than answers.



32 IPEC Contributions Mitigate Risk in Excipient Supply Chain

The supply chain for drug components has become an area of strong focus for drug manufacturers and regulators around the world in recent years, due to several unfortunate events that affected the health of hundreds of patients around the world. These events revealed once more that patient safety cannot only depend on the drug itself and its manufacturing conditions, but on each step of the supply chain, from the starting material to the end-user.

34 New Product Tracking Systems Soon Required

Working to ensure that safe and effective drugs are available to consumers, industry and regulators are looking to authenticate and identify achievable features of a track and trace system.

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26 Implementing Regulatory Intelligence – An Organizational Program Management Approach

Regulatory Intelligence (RI) is a key enabler for any company to be able to reach an optimized and harmonized state of global compliance.

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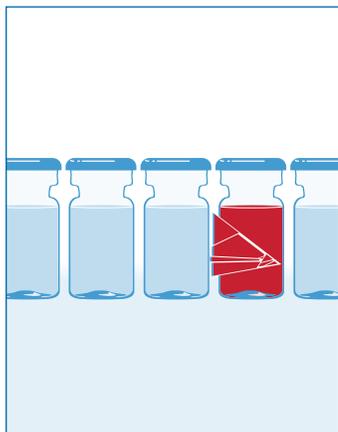
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36 Amgen Strengthens CAPA/Quality Systems in Wake of Glass Failures

The mark of a strong quality system is one that evolves when things go wrong. Amgen's recent experience with glass breakages shows that the company is committed to having the best possible system for monitoring and improving quality.

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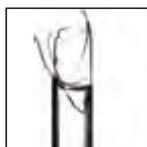
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30 The Value of Plant Isolates in Pharma Quality

Increasingly, pharmaceutical companies are including their own isolates in the battery of microorganisms that they use for media growth promotion testing and validation studies. These “plant isolates” are wild-type strains isolated during environmental monitoring, sterility and bioburden testing, and routine testing for contamination or spoilage. In so doing, these companies seek best microbiology practice, but it remains somewhat controversial.



38 Delamination Propensity of Pharmaceutical Glass Containers by Accelerated Testing with Different Extraction Media

The issue of delamination is a serious one as it can cause glass particles to appear in vials, a problem that has forced a number of drug product recalls in recent years. To combat this, pharmaceutical and biopharmaceutical manufacturers need to understand the underlying reasons for glass delamination.



44 Root Cause an Elusive End for Micro Investigations

While there are some guidance documents available (e.g., the United States Pharmacopeia and the Aseptic Guidelines for products marketed in the United States and the Orange Guide for the UK), it is truly through years of experience that one knows how to properly handle investigations into non-conforming microbiological results. This article will focus on sterility testing failures, environmental monitoring non-conformance results and media fill failures.

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20 Reduce Your Deviations: Implement a Quality Near Hit Program

What if you can preempt quality and compliance problems by training employees to be aware of potential deviations that occur throughout their day and, going further, document them and take proactive corrective measures? Sound a little bit like a Quality version of *Minority Report*? Well, this is exactly what we have done at Grifols Clayton site (formerly Talecris), and the results are noteworthy.

Cover Art Illustrated by Katja Yount

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Drug manufacturers go to great lengths to assure the sterility of their pharmaceutical and biological/vaccine products that are administered intravenously/ intramuscularly (IV/IM), but cannot account for the additional manipulations performed by healthcare professionals on the sterile product in preparation for administration to the patient.



30 **Solutions for Longer Shelf Life and Cost Savings Explored**

What would it mean to your company if you could find a way to drive down costs and keep drug products fresher longer?

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18 Personalized Medicines: The Next Big Thing in Healthcare

There are always benefits to going the extra mile or two in anything you do, and now pharmaceutical manufacturers who want to pursue the enhanced approach to licensing filings, including fully supported design space, will benefit from increased flexibility to enact post-approval changes.

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12 With ICH Q11, More Development Means Less Filings

There are always benefits to going the extra mile or two in anything you do, and now pharmaceutical manufacturers who want to pursue the enhanced approach to licensing filings, including fully supported design space, will benefit from increased flexibility to enact post-approval changes.

17 PDA Israel Chapter Calls for Additional Work on Q11

On July 26, 2011, despite it being the height and heat of the summer, the PDA Israel Chapter attracted 120 people to a discussion meeting on the draft ICH guidance, Q11: Development and Manufacture of Drug Substance.



24 Evaluating the Use of RFID in the Pharmaceutical Industry

As an industry we need to evaluate RFID (radio-frequency identification) technology in our supply chains.



30 Device Usability: Getting It Right from the Start

Recently there has been a huge increase in interest within the pharmaceutical and drug delivery community around "human factors" (HF), or usability.

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36 PDA/FDA Serves as Platform for Agency to Announce Initiatives, Industry to Comment

The third and last day of the *2011 PDA/FDA Joint Regulatory Conference* held in Washington, D.C. included traditional sessions wherein officials from the U.S. FDA provided updates on compliance matters and FDA Center initiatives.

40 Reasons for Missing the Mark of First Cycle Approvals

Regulators have between four to ten months to determine whether a new drug product or major manufacturing change is safe, efficacious and acceptable for approval.

42 Practical Recall Lessons Given at PDA/FDA

No matter how hard companies work and spend on ensuring product quality, recalls happen, so companies are advised to have plans in place to manage product recalls.

46 FDA PIC/S Its Friends

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Get Involved with the *PDA Letter!*

Volunteer for the *PDA Letter* Editorial Committee

The *PDA Letter* Editorial Committee is looking for active PDA members to provide ideas and to comment on articles for the *PDA Letter*. For more information about this two-year volunteer commitment, please contact **Emily Hough** at hough@pda.org by December 15.

Authors Wanted!

The *PDA Letter* is looking for authors for the following topics:

Issue	Topic	Articles Due
March	1) Manufacturing Innovation: Achieving Excellence in Sterile and Emerging Biopharmaceutical Technology 2) Forecast for Targeted Drug Delivery Systems	January 20
April	Quality and Regulatory Legislation	February 3
May	Biofilm and Bioburden Management	March 2
June	Rapid Screening Methods: Review of Screening Methods and Regulatory Perspectives	April 2
July/August	Sterile Processing	May 14
September	FDA Organizational Changes	July 2
October	1) Biosimilars; Generics 2) Targeted Therapies	August 3
November/December	Reports from the <i>PDA/FDA Joint Regulatory Conference</i>	September 10

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