

PDA Pharmaceutical Microbiology Conference

2025

Agenda

Sunday, 26 October

EDT Daylight Time (UTC -4:00)

14:00 – 19:00	Presenter Ready Room Open
14:00 – 19:00	Registration Open

Monday, 27 October

EDT Daylight Time (UTC -4:00)

07:30 – 08:30	Continental Breakfast
07:30 – 16:00	Presenter Ready Room Open
07:30 – 17:30	Registration Open
P1: Lessons of Recovery and Resilience: Pharma and the Aftermath of the Hurricane Helene Disaster Moderator: Erika A. Pfeiler PhD , Senior Consultant - Microbiology, <i>ValSource, Inc.</i>	
08:30 – 10:30	Opening Remarks from PDA President and Conference Co-Chairs President & CEO: Glenn E. Wright MA, President and CEO, <i>PDA</i> Co-Chair: Lori Daane PhD, Chief Scientific Officer, <i>Bionique Testing Laboratories</i> Co-Chair: Erika A. Pfeiler PhD, Senior Consultant - Microbiology, <i>ValSource, Inc.</i>
	Deep Dive into Crisis Management: Ensuring Quality and Maintaining Operational Excellence Presenter: Christiana Bielinski , Global Head, Quality Compliance, <i>Baxter</i>
	Drug Shortages: Root Causes and Potential Solutions Presenter: CDR Emily T. Thakur RPh, Team Leader, OCD, CDER, DSS, <i>U.S. FDA</i>
	10:00 – 10:30 Q&A
10:30 – 18:30	Exhibit Hall Open
10:30 – 11:15	Networking Break and Poster Presentations in the Exhibit Hall
P2: Breaking Biofilms: Reimagining Biofilm Control from the Inside Out Moderator: Liz Brockson , Aseptic Processing and Sterility Assurance Lead, <i>Takeda Pharmaceuticals</i>	
11:15 – 12:15	Biofilm Busting: The Journey from Bench to Clinic Presenter: Lauren Bakaletz PhD, Professor, <i>The Ohio State University/Abigail Wexner Research Institute at Nationwide Children's Hospital</i>

11:45 – 12:15 **Q&A**

12:15 – 13:45 **Networking Lunch in the Exhibit Hall**

A1: Comparing Apples to Oranges: When Calibration Standards Fail to Keep Pace with Advanced Technologies for Sterility Testing and Environmental Monitoring

Moderator: Anna F. Lau PhD, D(ABMM), Chief, Sterility Testing Service, *National Institutes of Health (NIH)*

Interlaboratory Evaluation of Eight Different Sterility Testing Methods Using a Standardized Sample Set

13:45 – 14:15

- **Presenter:** Jason Kralj PhD, Staff Researcher, *NIST*

A Universal Methodology for Calibrating Biofluorescent Particle Counters Using Real Microorganisms

14:15 – 14:35

- **Presenter:** Svetlana Kiseleva , Chief Product Officer, *Plair SA*

14:35 – 15:15 **Q&A**

B1: Unlocking the Secrets to Environmental Monitoring Trending and Microbial Data Deviations: Harmonized Practices and Advanced Root Cause Analysis

Moderator: Dawn M. Watson , Executive Director, Micro Quality & Sterility Assurance, *Merck & Co., Inc.*

Review of Industry Practices for Environmental Monitoring Trending Highlights the Need for Industry Harmonized Guidance

13:45 – 14:15

- **Presenter:** Christine Caruso , Associate Director, Microbiological Quality & Sterility Assurance, *Merck & Co., Inc.*

The Case of the Missing Root Cause: When Fishbone Diagrams Aren't Enough for Microbial Data Deviations

14:15 – 14:45

- **Presenter:** Amanda Curtis , Microbiology Consultant, *ValSource, Inc.*

14:45 – 15:15 **Q&A**

C1: Bio-Decontamination in Focus: Enhancing Vaporized Hydrogen Peroxide Validation and Control for Aseptic Environments

Moderator: Daniel Bice , Associate Director Microbiologist Quality Compliance, *Teva*

The Hidden Threat in VHP Cycle Validation: Quantifying the Impact of Rogue/Late-Positive Biological Indicators Using Statistical Models and Monte Carlo Simulations

13:45 – 14:15

- **Presenter:** Giacomo Guidi MEng, Aseptic Process Expert & Strategic Marketing, *IMA LIFE*

Applicability of VHP for Contamination Control of Lyophilized Biohazards

14:15 – 14:45

- **Presenter:** Hussein Bachir PhD, Scientist - GMP Compliance, *Franz Ziel GmbH*

14:45 – 15:15 **Q&A**

15:15 – 16:00 **Networking Break and Poster Presentations in the Exhibit Hall**

A2: Conquering Microbial Contamination: Case Studies and Predictive Models in Drug Manufacturing

Moderator: Kurt Jaecques MA, Global Quality Technical Senior Lead, *GSK*

16:00 – 17:30	ProA Paenibacillus Microbial Trend and Resolution: A Case Study 16:00 – 16:30 • Presenter: Andrea Moran , Advisor, <i>Eli Lilly and Company</i>
	A Global Approach for Preventing Microbial Events through a Predictive Model 16:30 – 16:50 • Presenter: Dawn M. Watson , Executive Director, Micro Quality & Sterility Assurance, <i>Merck & Co., Inc.</i>
	16:50 – 17:30 Q&A
B2: Advancing Advanced Therapy Medicinal Products: Navigating Control Strategies and Facility Innovation Moderator: Frederic B. Ayers , Senior Consultant - Microbiology, <i>ValSource, Inc.</i>	
16:00 – 17:30	Challenges of Developing a Contamination Control Strategy for ATMPs: Insider Insights 16:00 – 16:30 • Presenter: Patricia Igneczi , Senior Technical Services Specialist, <i>Contec, Inc.</i>
	ATMP Facilities: Evolving with the Sciences 16:30 – 17:00 • Presenter: Ankur K. Shah PE, Lead Process Engineer, <i>Arcadis</i>
	17:00 – 17:30 Q&A
C2: PDA Technical Report Updates Moderator: Josh Eaton MS , Senior Director, Scientific and Regulatory Affairs, <i>PDA</i>	
16:00 – 17:30	TR 22: Aseptic Process Simulation 16:00 – 16:30 • Presenter: Marcia C. Baroni MBA, VP Quality, Enterprise GxP Compliance & Systems, <i>Emergent BioSolutions</i>
	TR 33: Alternative Microbiological Methods 16:30 – 17:00 • Presenter: Michael J. Miller PhD, President, <i>Microbiology Consultants, LLC</i>
	Q&A with Additional Panelists 17:00 – 17:30 • Panelist: Vanessa A. Figueroa MA, Chief Microbiologist, <i>VVF Science</i> • Panelist: Olivia Venhuizen PhD, Process Development Principal Scientist, <i>Amgen Inc.</i>
17:30 – 18:30	Networking Reception in the Exhibit Hall

Tuesday, 28 October

EDT Daylight Time (UTC -4:00)

08:00 – 17:45	Registration Open
08:00 – 09:00	Continental Breakfast
08:00 – 16:15	Presenter Ready Room Open
P3: The Path to Discovery of the Hepatitis C Virus Moderator: Anna F. Lau PhD, D(ABMM) , Chief, Sterility Testing Service, <i>National Institutes of Health (NIH)</i>	

09:00 – 10:15	Hepatitis C: The End of the Beginning and Possibly the Beginning of the End	
	09:00 – 09:45	• Presenter: Harvey J. Alter MD, Distinguished NIH Scholar, Emeritus, <i>National Institutes of Health (NIH)</i>
	09:45 – 10:15	Q&A
10:15 – 11:00	Networking Break and Poster Presentations in the Exhibit Hall	
10:15 – 16:15	Exhibit Hall Open	
11:00 – 12:30	A3: Microbial Compliance in Focus: Regulatory Trends and Enforcement Insights in Sterile Processing	
	Moderator: Erika A. Pfeiler PhD , Senior Consultant - Microbiology, <i>ValSource, Inc.</i>	
	11:00 – 11:30	Evolving Regulatory Expectations for Microbial Contamination Control in Blow-Fill-Seal (BFS) Technology • Presenter: Julia Marre PhD, Regulatory Affairs, Principal Consultant, <i>NSF</i>
	11:30 – 11:50	Looking at the Past to Plan for the Future: Microbiology Regulatory Inspection and Enforcement Trends in 503B Outsourcing Facilities • Presenter: Abby A. Roth CMQ/OE, Owner/Microbiologist, <i>Pure Microbiology, LLC</i>
	11:50 – 12:30	Q&A
11:00 – 12:30	B3: Progressive Recombinant Endotoxin Test Deployment and Navigating Low Endotoxin Recovery Regulatory Uncertainties	
	Moderator: Jay Bolden , Senior Director, <i>Eli Lilly and Company</i>	
	11:00 – 11:25	Harmonizing Endotoxin Testing: Global Implementation of Recombinant Factor C for Sustainable Endotoxin Testing • Presenter: Evelyn Der RM, SM, CQA, CPGP , Senior Scientist QC, <i>Genentech</i>
	11:25 – 11:50	Regulatory Challenges of Recent Low Endotoxin Recovery Regulatory Queries: Pfizer's Strategy to Evaluate and Implement Global Changes to Meet Evolving Expectations • Presenter: Jody Peraino MS, Principal Scientist, <i>Pfizer</i>
	11:50 – 12:30	Q&A
11:00 – 12:30	C3: From Standards to Solutions: Enhancing Microbial Control with USP's Latest Chapters	
	Moderator: Lori Daane PhD , Chief Scientific Officer, <i>Bionique Testing Laboratories</i>	
	11:00 – 11:30	Overview and In-Depth Discussion of Chapters <1119> and <1119.1> • Presenter: Edward C. Tidswell PhD, Executive Director QA, <i>Merck & Co., Inc.</i>
	11:30 – 12:00	Updates on Rapid Microbiological Methods (RMM) Chapters, Including <1071>, <72>, and <73> • Presenter: Anna F. Lau PhD, D(ABMM), Chief, Sterility Testing Service, <i>National Institutes of Health (NIH)</i>
	12:00 – 12:30	Q&A with Additional Panelists • Panelist: Leslie A. Furr MS, Principal Scientist, <i>USP</i> • Panelist: Huiping Tu PhD, Senior Principal Scientist, <i>USP</i>

12:30 – 14:00	Networking Lunch in the Exhibit Hall
C4: Advancing Microbial Control: Efficacy, Validation, and Risk-Based Approaches in Pharmaceutical Cleaning Moderator: Daniel Bice , Associate Director Microbiologist Quality Compliance, <i>Teva</i>	
14:00 – 15:30	The Future of Disinfection Efficacy Testing: Aligning Validation to Regulatory Landscapes 14:00 – 14:30 Presenter: David J. Collins , Principal Global Technical Consultant, <i>Ecolab Life Sciences</i>
	Microbial Control for Nonsterile Manufacturing Equipment Product-Contact Surfaces 14:30 – 14:50 Presenter: Antonio F. Ortiz MS, Technical Services Manager, <i>STERIS Corporation</i>
	14:50 – 15:30 Q&A
B4: Digital Integrity and Intelligent Automation: Microbial Quality in the Modern Age Moderator: Julia Marre PhD, Regulatory Affairs, Principal Consultant, <i>NSF</i>	
14:00 – 15:30	Mastering Data Integrity in the Digital Age: A Risk-Based Path to GxP Excellence 14:00 – 14:30 Presenter: Peniel Ortega PMP, Managing Director, <i>PharmAllies</i>
	Suitability Evaluation of an AI-Driven Automated System for Colony Counting in Environmental Monitoring and Bioburden Testing 14:30 – 14:50 Presenter: Camilla Giardini , Project Manager, <i>Copan Newlab</i>
	14:50 – 15:30 Q&A
A4: Global Strategies for Validating and Implementing Alternative Microbiological Methods: Insights and Lessons Learned Moderator: Lori Daane PhD, Chief Scientific Officer, <i>Bionique Testing Laboratories</i>	
14:00 – 15:30	Global Implementation of Novel Microbial Technology Across BMS Enterprise 14:00 – 14:30 Presenter: Aimee L. Cunningham PhD, MPH, Associate Director, <i>Bristol Myers Squibb</i>
	A Global Approach to New Technology Introduction and Validation: Automated Colony Counting 14:30 – 15:00 Presenter: Phil Duncanson PhD, Senior Director, <i>AstraZeneca</i>
	15:00 – 15:30 Q&A
15:30 – 16:15	Networking Break, Poster Presentations, and Passport Drawing in the Exhibit Hall
B5: Contamination Control Strategies in Action: Real-World Tools and Mindsets That Deliver Results Moderator: Liz Brockson , Aseptic Processing and Sterility Assurance Lead, <i>Takeda Pharmaceuticals</i>	
16:15 – 17:45	The CCS Advantage: Elevating Patient Safety Through an Infinite Mindset 16:15 – 16:45 Presenter: Frederic B. Ayers , Senior Consultant - Microbiology, <i>ValSource, Inc.</i>
	No More Guesswork: Practical Tools for a Better CCS 16:45 – 17:15 Presenter: Vanessa A. Figueroa MA, Chief Microbiologist, <i>VVF Science</i>

	17:15 – 17:45	Q&A
16:15 – 17:45	A5: Live Bugs and Fast Facts: Microbial Quality for Modern Biologics Moderator: Julia Marre PhD , Regulatory Affairs, Principal Consultant, <i>NSF</i>	
	16:15 – 16:40	Quality Frameworks for Injectable Live Microbial Products (LMP): What the LMP Field Can Learn from ATMPs Presenter: Moira M. Schuler PhD, Global CMC Manager, <i>Wacker Biotech US</i>
	16:40 – 17:05	Strategy and Case Studies for Demonstrating Product-Specific Suitability of a Rapid Hybrid Testing Approach for Mycoplasma Detection Presenter: Kevin Susice MS, Project-Based Scientist, <i>Bionique Testing Laboratories</i>
	17:05 – 17:45	Q&A
16:15 – 17:45	C5: Sterilization Challenges and Environmental Monitoring: Navigating EU Annex 1 Compliance Moderator: Kurt Jaecques MA , Global Quality Technical Senior Lead, <i>GSK</i>	
	16:15 – 16:45	Sterilization Validation and Indirect Product Contacting Parts Presenter: Renee V. Buthe , Technical Services Manager, <i>STERIS Corporation</i>
	16:45 – 17:15	Understanding the Dynamics of Particle and Microbial Transport in Isolators Presenter: Noel M. Long , Senior Sterility Assurance Adviser, <i>Cytiva</i>
	17:15 – 17:45	Q&A

Wednesday, 29 October

EDT Daylight Time (UTC -4:00)

07:30 – 09:00	Continental Breakfast
07:30 – 12:30	Registration Open
07:45 – 09:00	From Classroom to Cleanroom: Navigating a Career in Pharmaceutical Microbiology Moderator: Frederic B. Ayers , Senior Consultant - Microbiology, <i>ValSource, Inc.</i>
	07:45 – 08:05 Panel Introductions
	Panel Discussion and Q&A Panelist: Ziva Abraham PhD, CEO, <i>Microrite, Inc.</i> Panelist: Lori Daane PhD, Chief Scientific Officer, <i>Bionique Testing Laboratories</i>
	08:05 – 09:00 Panelist: Irving Ford MSc , , <i>Quality Leader</i> Panelist: Mitch B. Garber RPh, President, <i>MG Aseptic and Quality Assurance Consulting</i> Panelist: Marc Glogovsky MS, Business Unit Manager - Microbiology, <i>ValSource, Inc.</i>
P4: Beyond Blame: A Systems Approach to Understanding and Preventing Human Error	

Moderator: Frederic B. Ayers , Senior Consultant - Microbiology, <i>ValSource, Inc.</i>	
09:15 – 10:30	A Systems Approach to Addressing Human Error 09:15 – 10:00 Presenter: Patrice D. Tremoulet MS, PhD, Director of Human Factors Engineering, <i>ECRI</i>
	10:00 – 10:30 Q&A
10:30 – 11:00	Networking Break
P5: Ask the Regulators Moderator: Erika A. Pfeiler PhD , Senior Consultant - Microbiology, <i>ValSource, Inc.</i>	
11:00 – 12:30	11:00 – 11:10 Panel Introduction
	Panel Discussion and Q&A 11:10 – 12:25 Panelist: Donald B. Ertel MS, MT (ASCP), Branch Chief / Program Manager, OCBQ, CBER, <i>U.S. FDA</i> Panelist: Simleen Kaur MSc, Biologist, Team Lead, OCBQ, CBER, <i>U.S. FDA</i> Panelist: Simone E. Pitts MS, National Expert, Pharmaceutical, OII, <i>U.S. FDA</i>
	12:25 – 12:30 Closing Remarks from the PDA Pharmaceutical Microbiology Conference 2026 Co-Chairs
14:00 – 18:30	PDA Pyrogens Workshop 2025 (Day 1 of 2 - Separate Registration Required)

Thursday, 30 October

EDT Daylight Time (UTC -4:00)

08:00 – 16:45	Registration Open PDA Pyrogens Workshop
08:30 – 16:00	Contamination Control Strategy Essentials Workshop (PDA 293) Instructor: Frederic B. Ayers , Senior Consultant - Microbiology, <i>ValSource, Inc.</i>
	Effective Sterility Assurance in Aseptic Processing Training Course (PDA 542) Instructor: Mark C. Hallworth , Senior GMP Scientist, <i>Particle Measuring Systems</i> Instructor: Susan B. Cleary EMBA Director Product Development <i>Novatek</i>
08:30 – 16:00	Elements of GxP Training and Personnel Qualification Program Essentials Workshop (PDA 201) Instructor: Christian Torstensson MS , Principal, Learning Consultant, <i>The Atlantec Group</i>
08:30 – 16:00	Environmental Monitoring Methods and Investigations Training Course – Looking for the Needle in the Haystack (PDA 618) Instructor: Tim A. Cser , Senior Technology Specialist, <i>MilliporeSigma</i>
09:00 – 16:45	PDA Pyrogens Workshop 2025 (Day 2 of 2 - Separate Registration Required)