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**
08:30 – 10:30	**P1: Lessons of Recovery and Resilience: Pharma and the Aftermath of the Hurricane Helene Disaster** **Moderator: Erika A. Pfeiler PhD**, Senior Consultant - Microbiology, *ValSource, Inc.* 08:30 – 09:00: **Opening Remarks from Conference Co-Chairs** • **Co-Chair: Lori Daane PhD**, Chief Scientific Officer, *Bionique Testing Laboratories* • **Co-Chair: Erika A. Pfeiler PhD**, Senior Consultant - Microbiology, *ValSource, Inc.* 09:00 – 09:30: **Deep Dive into Crisis Management: Ensuring Quality and Maintaining Operational Excellence** • **Presenter: Christiana Bielinski** , Global Head, Quality Compliance, *Baxter* 09:30 – 10:00: **Drug Shortages: Root Causes and Potential Solutions** • **Presenter: CDR Emily T. Thakur RPh**, Team Leader, OCD, CDER, DSS, *U.S. FDA* 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**
11:15 – 12:15	**P2: Breaking Biofilms: Reimagining Biofilm Control from the Inside Out** **Moderator: Liz Brockson** , Aseptic Processing and Sterility Assurance Lead, *Takeda Pharmaceuticals* 11:15 – 11:45: **Biofilm Busting: The Journey from Bench to Clinic** • **Presenter: Lauren Bakaletz PhD**, Professor, *The Ohio State University/Abigail Wexner Research Institute at Nationwide Children's Hospital*

	11:45 – 12:15	**Q&A**
12:15 – 13:45	**Networking Lunch in the Exhibit Hall**	
13:45 – 15:15	**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)*	
	13:45 – 14:15	**Interlaboratory Evaluation of Eight Different Sterility Testing Methods Using a Standardized Sample Set** • **Presenter: Jason Kralj PhD**, Staff Researcher, *NIST*
	14:15 – 14:35	**A Universal Methodology for Calibrating Biofluorescent Particle Counters Using Real Microorganisms** • **Presenter: Svetlana Kiseleva** , Chief Product Officer, *Plair SA*
	14:35 – 15:15	**Q&A**
13:45 – 15:15	**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.*	
	13:45 – 14:15	**Review of Industry Practices for Environmental Monitoring Trending Highlights the Need for Industry Harmonized Guidance** • **Presenter: Christine Caruso** , Associate Director, Microbiological Quality & Sterility Assurance, *Merck & Co., Inc.*
	14:15 – 14:45	**The Case of the Missing Root Cause: When Fishbone Diagrams Aren't Enough for Microbial Data Deviations** • **Presenter: Amanda Curtis** , Microbiology Consultant, *ValSource, Inc.*
	14:45 – 15:15	**Q&A**
13:45 – 15:15	**C1: Bio-Decontamination in Focus: Enhancing Vaporized Hydrogen Peroxide Validation and Control for Aseptic Environments** **Moderator: Daniel Bice** , Associate Director Microbiologist Quality Compliance, *Teva*	
	13:45 – 14:15	**The Hidden Threat in VHP Cycle Validation: Quantifying the Impact of Rogue/Late-Positive Biological Indicators Using Statistical Models and Monte Carlo Simulations** • **Presenter: Giacomo Guidi MEng**, Aseptic Process Expert & Strategic Marketing, *IMA LIFE*
	14:15 – 14:45	**Applicability of VHP for Contamination Control of Lyophilized Biohazards** • **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*	
		ProA Paenibacillus Microbial Trend and Resolution: A Case Study

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

09:00 – 10:15	09:00 – 09:45	• **Presenter: Harvey J. Alter MD**, Distinguished NIH Scholar, Emeritus, *National Institutes of Health (NIH)*
	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, *ValSource, Inc.*	
	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, *NSF*
	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, *Pure Microbiology, LLC*
	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, *Eli Lilly and Company*	
	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, *Genentech*
	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, *Pfizer*
	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, *Bionique Testing Laboratories*	
	11:00 – 11:30	**Overview and In-Depth Discussion of Chapters <1119> and <1119.1>** • **Presenter: Edward C. Tidswell PhD**, Executive Director QA, *Merck & Co., Inc.*
	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, *National Institutes of Health (NIH)*
	12:00 – 12:30	**Q&A with Additional Panelists** • **Panelist: Leslie A. Furr MS**, Principal Scientist, *USP* • **Panelist: Huiping Tu PhD**, Senior Principal Scientist, *USP*

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

	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, *NSF*	
	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, *Wacker Biotech US*
	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, *Bionique Testing Laboratories*
	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, *GSK*	
	16:15 – 16:45	**Sterilization Validation and Indirect Product Contacting Parts** • **Presenter: Renee V. Buthe** , Technical Services Manager, *STERIS Corporation*
	16:45 – 17:15	**Understanding the Dynamics of Particle and Microbial Transport in Isolators** • **Presenter: Noel M. Long** , Senior Sterility Assurance Adviser, *Cytiva*
	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, *ValSource, Inc.*	
	07:45 – 08:05	**Panel Introductions**
	08:05 – 09:00	**Panel Discussion and Q&A** • **Panelist: Ziva Abraham PhD**, CEO, *Microrite, Inc.* • **Panelist: Lori Daane PhD**, Chief Scientific Officer, *Bionique Testing Laboratories* • **Panelist: Irving Ford MSc**, , *Quality Leader* • **Panelist: Mitch B. Garber RPh**, President, *MG Aseptic and Quality Assurance Consulting* • **Panelist: Marc Glogovsky MS**, Business Unit Manager - Microbiology, *ValSource, Inc.*
	P4: Beyond Blame: A Systems Approach to Understanding and Preventing Human Error **Moderator: Frederic B. Ayers** , Senior Consultant - Microbiology, *ValSource, Inc.*	

09:15 – 10:30	09:15 – 10:00	**A Systems Approach to Addressing Human Error** • **Presenter: Patrice D. Tremoulet MS, PhD**, Director of Human Factors Engineering, *ECRI*
	10:00 – 10:30	**Q&A**
10:30 – 11:00	**Networking Break**	
11:00 – 12:30	**P5: Ask the Regulators**	
	11:00 – 11:10	**Panel Introduction**
	11:10 – 12:25	**Panel Discussion and Q&A** • **Panelist: Simone E. Pitts MS**, National Expert, Pharmaceutical, OII, *U.S. FDA* • **Panelist: Simleen Kaur MSc**, Biologist, Team Lead, OCBQ, CBER, *U.S. FDA* • **Panelist: Simone E. Pitts MS**, National Expert, Pharmaceutical, OII, *U.S. FDA*
	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, *ValSource, Inc.*
08:30 – 16:00	**Effective Sterility Assurance in Aseptic Processing Training Course (PDA 542)** **Instructor: Mark C. Hallworth** , Senior GMP Scientist, *Particle Measuring Systems* **Instructor: Ugonna Omeronye** Global GMP Pharma Advisory Specialist *Particle Measuring Systems*
08:30 – 16:00	**Elements of GxP Training and Personnel Qualification Program Essentials Workshop (PDA 201)** **Instructor: Christian Torstensson MS**, Principal, Learning Consultant, *The Atlantec Group*
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, *MilliporeSigma*
09:00 – 16:45	**PDA Pyrogens Workshop 2025 (Day 2 of 2 - Separate Registration Required)**