# 12th Annual PDA Global Conference on Pharmaceutical Microbiology

**Solving Microbiological Challenges and Sustaining Success through a Culture of Collaboration**

**October 16-18, 2017 | Bethesda North Marriott Hotel & Conference Center | Bethesda, MD**

**As of September 15, 2017**

## Sunday, October 15

- 3:00 p.m. – 7:00 p.m.
  - Registration Open

## Monday, October 16

- 7:00 a.m. – 5:30 p.m.
  - Registration Open
- 7:00 a.m. – 8:30 a.m.
  - Continental Breakfast
- 8:15 a.m. – 8:30 a.m.
  - Welcome and Opening Remarks from Conference Co-Chair
    - **Vinayak B. Pawar, PhD**, Senior Review Microbiologist, CDER, FDA
- 8:30 a.m. – 9:30 a.m.
  - **P1: Opening Plenary Session**
    - **Moderator:** Vinayak B. Pawar, PhD, Senior Review Microbiologist, CDER, FDA
    - **Session Description:** After achieving a dramatic triumph over infection in the 20th century with the introduction of antibacterial chemotherapy, the threat of bacterial diseases has resurfaced with the rise of antibacterial resistance. The Centers for Disease Control and Prevention (CDC) estimate that in the United States, more than two million people are sickened every year with antibiotic-resistant infections, with at least 23,000 dying as a result. The history and contributing factors to the rising trend of antibacterial resistance in the United States will be discussed, as well as recent successes and challenges in the development of novel antibacterial drugs. Efforts to facilitate the development of antibacterial drugs for serious or life-threatening illnesses will be highlighted, including new approaches to the design of clinical trials.
  - **9:00 a.m. – 9:30 a.m.**
    - **The Challenge of Antibacterial Resistance: Learned Lessons and New Directions**
      - **Edward A. Weinstein, MD, PhD**, Medical Officer, CDER, FDA
      - **9:00 a.m. – 9:30 a.m.**
        - **Questions and Answers/Discussion**

## Conference Schedule

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:00 a.m.</td>
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<td><strong>P1: Microbial Control</strong></td>
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<td>10:15 a.m.</td>
<td><strong>Case Study of Environmental Mold Isolation in a Controlled Manufacturing Facility</strong></td>
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| **Case Studies on Microbial Contamination: Benefit of a Cross-Functional Team Investigation**  
Walid El Azab, Ind. Ph., Manager, Technical Services, Life Sciences  
Formulated Chemistries, STERIS Corporation  
11:15 a.m. – 11:45 a.m.  
**Fungal Spore Excursions in Cleanrooms: Case Studies**  
Jim Polarine Jr., MA, Senior Technical Service Manager, STERIS Corporation  
11:45 a.m. – 12:15 p.m.  
Questions and Answers/Discussion | **Contamination Control in Non-Sterile Manufacturing**  
Patricia V. Mills Davis, MSc, Senior Manager, Microbiology Lab, Johnson & Johnson Consumer Inc.  
11:15 a.m. – 11:45 a.m.  
**Taming the Microbial Zoo: FDA’s Perspectives on Non-sterile Drug Products**  
Erika A. Pfeiler, PhD, Microbiologist, CDER, FDA  
11:45 a.m. – 12:15 p.m.  
Questions and Answers/Discussion |

12:15 p.m. – 1:30 p.m.  
**Exhibitor Roundtable Luncheon**  
Exhibitors will be seated at designated tables and will be available for informal discussion with attendees. Exhibit Hall will be closed during this time.

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| **A2: Combination Products**  
Moderator: Vinayak B. Pawar, PhD, Senior Review Microbiologist, CDER, FDA | **B2: Environmental Monitoring**  
Moderator: Marsha Steed (Hardiman), Senior Consultant, Valsource, LLC |
| **Session Description:** The pharmaceutical industry faces many manufacturing challenges as a wide spectrum of regulated treatments are now identified as combination products (e.g., patches, pumps, inhalers, nasal vaccines, targeted nanoparticles, syringes, and other delivery methods). Attendees will hear from the industry representative about combination product delivery system design (e.g., adequate cleanroom, support utilities, and equipment for manufacturing combination components) and manufacturing logistics such as continuous manufacturing applications and flexible facility designs. Regulatory speakers will discuss strategies for demonstrating compliance with cGMP requirement, whether for each of the constituent parts or for the combination product as a whole, with case studies related to current combination product initiatives and updates. | **Session Description:** Environmental monitoring (EM) plays a critical role in our companies for all manufacturing types including non-sterile, low bioburden, medical devices, and aseptic processing. The industry is inundated with guidance about EM for aseptic processing operations, but there is a lack of guidance when it comes to low bioburden processes. This session will include an overview on a new PDA technical report which will give guidance for low bioburden EM. It will cover EM trending advantages when using contamination recovery rates to understand your results. A look into single incubation with rapid technology will also be shown with a case study example. |

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| **Manufacturing Challenges**  
Susan Neadle, MS, Head, Combination Products Center of Excellence and Senior Director, Design-to-Value and Product Quality Management, Johnson & Johnson Janssen Pharmaceuticals  
2:00 p.m. – 2:30 p.m.  
**Regulatory Challenges and Requirements for Combination Products: Current and Future**  
Melissa B. Burns, MS, Policy Advisor, OC, FDA  
2:30 p.m. – 3:00 p.m.  
**Current Combination Product Initiatives and Updates: Case Studies**  
Steven B. Hertz, MS, Consumer Safety Officer, CDER, FDA  
3:00 p.m. – 3:30 p.m.  
Questions and Answers/Discussion | **Using Contamination Rates for Environmental Monitoring Trending**  
Paula Peacos, MS, Associate Director of Microbiology, Global Pharmaceutical Quality, Bristol-Myers Squibb  
2:00 p.m. – 2:30 p.m.  
**Demonstrating Non-Inferiority for a Rapid, Automated Environmental Monitoring Technology Using a Single-Tiered Incubation Scheme**  
Laure Singer, Senior Associate, Quality Assurance, Pfizer Inc.  
2:30 p.m. – 3:00 p.m.  
**Low Bioburden Environmental Monitoring: PDA Technical Report Development Update**  
3:00 p.m. – 3:30 p.m.  
Questions and Answers/Discussion |

3:30 p.m. – 4:15 p.m.  
**Refreshment Break and Poster Presentations in Exhibit Hall**
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| 4:15 p.m. – 5:45 p.m. | P2: Emerging Leaders  
Moderator: Michael J. Miller, PhD, President, Microbiology Consultants, LLC  
Session Description: Solving problems in the microbiology laboratory often requires collaboration between many individuals and across multiple departments. In addition, laboratory microbiologists often have to work across lines of responsibilities to ensure that projects are completed with involvement from all impacted areas. This session will include three case studies of problem resolution or project implementation with teams of individuals from the front line of the microbiology laboratory. |
| 4:15 p.m. – 4:35 p.m. | Getting Your Product from Fill Line to Clinic (with a Little Help from your Friendly Neighborhood Microbiologist)  
Carly Krystopik, Associate Research Scientist II, Bristol-Myers Squibb |
| 4:35 p.m. – 4:55 p.m. | You Gotta Know When to Hold 'Em: Microbial Challenge Testing and In-use Hold Times for Non-preserved, Sterile, Single-use Products  
Sarah Weiser, MS, Formulation Scientist, Pfizer Inc. |
| 4:55 p.m. – 5:15 p.m. | How Very Sterile This Johnny Is: The Conundrum of Sterility Testing a Terminally-Sterilized Biodegradable Implant  
Melissa Gulmezian-Sefer, PhD, Senior Scientist, SMPD Microbiology, Allergan Inc. |
| 5:15 p.m. – 5:45 p.m. | Questions and Answers/Discussion |
| 5:45 p.m. – 7:00 p.m. | Networking Reception in Exhibit Hall  
Tuesday, October 17  
7:00 a.m. – 4:30 p.m. | Registration Open  
7:00 a.m. – 8:15 a.m. | Continental Breakfast  
7:00 a.m. – 8:00 a.m. | Breakfast Roundtable  
Moderator: Marsha Steed (Hardiman), Senior Consultant, VolSource, LLC  
Session Description: The breakfast round table sessions will capture the conference theme of collaboration by bringing together attendees to address some hot Microbiology topics. Some of these topics may not yet have consensus in the industry so further discussion is warranted. These will be presented in an innovative point/counter-point format, with experts presenting advantages and disadvantages, and risks and benefits of key topics such as: data integrity in the Microbiology lab (multiple analysts reads on plates), incubation schemes for EM, and reaction to microbiological excursions in the critical Grade A environment. The sessions will include small group break out discussions on these and other topics to determine comments and collect feedback for the health authorities.  
Facilitators:  
Amy McDaniel, PhD, Director, Quality Assurance Operations, Pfizer Inc.  
Kim Sobien, Principal Sterility Assurance Engineer, PETNET Solutions | a Siemens Company  
Eric J. Ward, MBA, Quality Assurance Director, Boston Analytical, Inc. |
| 8:15 a.m. – 9:15 a.m. | P3: Patient Perspective  
Moderator: Kim Sobien, Principal Sterility Assurance Engineer, PETNET Solutions, a Siemens Company  
Session Description: As a reminder of the importance of our work as pharmaceutical Microbiologists, we will hear directly from a patient, who is also an industry Microbiologist, who has benefited from the pharmaceutical and medical device products that our companies manufacture. No one ever plans on becoming ill; but when it happens to someone, that patient relies on the quality, safety, efficacy and sterility of the products we manufacture in our jobs to aid in their recovery. This patient perspective talk will remind us why we do what we do for a living and will bring together the patient benefits received as a result of our good work. |
| 8:15 a.m. – 9:00 a.m. | When the Microbiologist Becomes the Patient  
Marsha Steed (Hardiman), Senior Consultant, VolSource, LLC |
| 9:00 a.m. – 4:15 p.m. | Exhibit Hall Open  
9:00 a.m. – 4:15 p.m. | Exhibit Hall Open  
9:15 a.m. – 10:00 a.m. | Refreshment Break, Poster Presentations, and Passport Raffle Drawing in Exhibit Hall |
10:00 a.m.–12:00 p.m.
**A3: Quality Management for the Lab**
Moderator: MaryEllen E. Usarzewicz, MS, Parenteral Manufacturing Support Lead, Analytical & Bioanalytical Operations, Microbiology, Bristol-Myers Squibb

**Session Description:** In alignment with the Conference theme, this session will focus on the criticality of collaboration in a regulated microbiology environment. Microbiologists are called upon to participate in excursion investigations and to provide guidance proactively. Ensuring that microbiologists can educate and train colleagues within their organizations and help to assure that their input is understood is crucial. This session will provide information about a risk-based approach to assessing environmental monitoring and critical utilities excursions, insight into the collaborative efforts of FDA investigators working together to assess quality for our patients, as well as a case study on how one organization implemented a shop floor program driving collaboration between microbiology quality control, operations, and quality assurance.

10:00 a.m.–10:30 a.m.
**Aseptic Observation Program: A Shop Floor Program that Engages Quality and Operations to Assure Good Aseptic Technique**
Lisa Sykes-Winstead, MBA, Director of Quality Operations, Sterile Network Lead, Merck & Co./Merck Sharp & Dohme

10:30 a.m.–11:00 a.m.
**Risk-Based Microbial Assessment Tool (R-MAT): A Novel Approach to Assessing Environmental and Critical Utilities Excursions**
Amanda Bishop McFarland, Consultant, ValSource, LLC

11:00 a.m.–11:30 a.m.
**Collaborative Inspections: How Many Teams of U.S. FDA Investigators and Microbiologists Work Together to Evaluate Drug Manufacturing Quality**
U.S. FDA Representative Invited

11:30 a.m.–12:00 p.m.
**Questions and Answers/Discussion**

12:00 p.m.–1:30 p.m.
**Lunch on Your Own. Exhibit Hall Closed** – A listing of local restaurants is available at the PDA Registration Desk.

10:00 a.m.–12:00 p.m.
**B3: Innovation in Pharmaceutical Microbiology**
Moderator: Amy McDaniel, PhD, Director, Quality Assurance Operations, Pfizer Inc.

**Session Description:** This session will focus on innovations for the modern microbiology laboratory, with an emphasis on advancing the science of detecting microorganisms and the manner in which we analyze the data. Participants will learn about the need for online water bioburden systems and how a number of companies have established strategies for validating new water monitoring technologies. The results from PQ comparative studies will also be shared. We will also hear a case study on applying statistical analyses on microbiological data to support claims of equivalence and non-inferiority when comparing alternative methods to compendial methods. The presentation will walk through the statistical models in an easy-to-understand format followed by case studies on how to apply the models using actual data. The session will end with a regulatory overview of the state of rapid sterility testing by one of FDA’s leading experts on alternative microbiological methods. The current need for rapid sterility testing, regulatory enablers and examples of successful validation case studies will be discussed.

10:00 a.m.–10:30 a.m.
**Towards a New Paradigm for Compendial Sterility Testing**
Anthony M. Cundell, PhD, Consulting Microbiologist, Microbiological Consulting, LLC

10:30 a.m.–11:00 a.m.
**Case Studies on Selecting Statistical Approaches for the Validation of Alternative and Rapid Microbiological Methods**
Michael J. Miller, PhD, President, Microbiology Consultants, LLC

11:00 a.m.–11:30 a.m.
**Rapid Sterility Tests**
Bryan S. Riley, PhD, Branch Chief (Acting), Division of Microbiology Assessment Branch II, CDER, FDA

11:30 a.m.–12:00 p.m.
**Questions and Answers/Discussion**
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| 1:30 p.m. – 3:30 p.m. | **A4: Biotechnology**  
Moderator: Walid El Azab, Ind. Ph., Manager, Technical Services, Life Sciences Formulated Chemistries, STERIS Corporation  
**Session Description:** Recent regulatory updates and technological and manufacturing developments are significantly influencing the biopharmaceutical industry. The biopharmaceutical industry is facing pressure to continuously challenge and improve their manufacturing processes to achieve regulatory compliance and high quality product. In addition, it is also expected to implement new technology to improve microbial control and faster response to avoid drug shortage. The goal of this session is to share different industry perspectives on how introduction of new technology, robust aseptic training, effective root cause investigation, and microbial control will support lean processes, faster lead-time, improved return on investment, and regulatory compliance. |
| 1:30 p.m. – 2:00 p.m. | **It Takes Two to Take Control (Microbial Control, That Is)!**  
Ruth Varden, MSc, Director, Quality, Alexion Pharmaceuticals, Inc.  
Jane Wyatt, MSc, Director, Quality Control Ireland, Alexion Pharmaceuticals, Inc.  
2:00 p.m. – 2:30 p.m.  
**The Use of Environmental Monitoring Recovery Rates in Support of Bulk Biologic Manufacturing**  
Jeanne Mateffy, Director Quality Services, Microbiology, Amgen Inc.  
2:30 p.m. – 3:00 p.m.  
**A Risk-Based Approach for an Aseptic Manipulation and Intervention Program**  
Frederic B. Ayers, Consultant Scientist – Sterility Assurance Technology, Eli Lilly and Company  
3:00 p.m. – 3:30 p.m.  
**Questions and Answers/Discussion** |
| 3:30 p.m. – 4:15 p.m. | **Refreshment Break, Poster Presentations, and Passport Raffle Drawing in Exhibit Hall** |
| 4:15 p.m. – 6:00 p.m. | **P4: FDA Update on Human Drug Compounding: Regulatory Policy and Drug Quality**  
Moderator: John W. Metcalfe, PhD, Quality Assessment Lead, Division of Microbiology Assessment, Office of Process and Facilities/Office of Pharmaceutical Quality, CDER, FDA  
**Session Description:** During this session, FDA will provide an update on the Agency’s regulation and oversight of human drug compounding since passage of the 2013 Drug Quality and Security Act (DQSA), which established a new category of drug compounders called outsourcing facilities. FDA speakers will provide an overview of the Agency’s compounding oversight program and describe relevant policies. Participants will learn about FDA’s inspctional program for outsourcing facilities; quality standards, including current good manufacturing practice requirements and insanitary conditions, applicable to outsourcing facilities; and guidance documents and regulations that pertain to outsourcing facilities. The session is targeted to participants from all segments of the pharmaceutical industry, and is especially applicable to those working in the newly established outsourcing facility arena. |
| 4:15 p.m. – 4:35 p.m. | **Overview of FDA’s Compounding Program**  
Julie Dohm, PhD, JD, Agency Lead on Compounding and Senior Scientific Advisor for Compounding, CDER, FDA  
4:35 p.m. – 4:55 p.m.  
**FDA Policies Relevant to Compounding Quality**  
Sara Rothman, MPH, Senior Policy Advisor, Office of Unapproved Drugs and Labeling Compliance, Office of Compliance, CDER, FDA  
4:55 p.m. – 5:15 p.m.  
**FDA Inspections of Outsourcing Facilities**  
Justine Tomasso, MBS, Consumer Safety Officer, Pharmaceutical Quality Programs Branch, Division of Pharmaceutical Quality Programs/Office of Pharmaceutical Quality Operations, ORA, FDA  
5:15 p.m. – 5:45 p.m.  
**Understanding CGMP Requirements and Insanitary Conditions**  
Ian F. Deveau, PhD, Chief, Global Compliance Branch 1, Division of Drug Quality I, Office of Manufacturing Quality, Office of Compliance, CDER, FDA  
5:45 p.m. – 6:00 p.m.  
**Questions and Answers/Discussion** |
Wednesday, October 18

7:00 a.m. – 12:30 p.m.
Registration Open

7:00 a.m. – 8:15 a.m.
Continental Breakfast

7:00 a.m. – 8:00 a.m.
Breakfast Roundtable Report Out
Moderator: Marsha Steed (Hardiman), Senior Consultant, Valsource, LLC

Session Description: This roundtable will include a report out and full audience discussions on the results of day 1 findings from the various small groups. Collaboration will help make us all more informed on how to tackle these issues back in our own companies.

Facilitators:
Amy McDaniel, PhD, Director, Quality Assurance Operations, Pfizer Inc.
Kim Sobien, Principal Sterility Assurance Engineer, PETNET Solutions | A Siemens Company
Eric J. Ward, MBA, Quality Assurance Director, Boston Analytical, Inc.

8:15 a.m. – 9:30 a.m.
P5: USP Updates
Moderator: Radhakrishna Tirumalai, Principal Scientific Liaison, US Pharmacopeial Convention

Session Description: Compatible with its overall mission, the role of the U.S. Pharmacopeial Convention (USP) in microbiology and sterility assurance is to develop public standards pertaining to microbiology that, along with other requirements, ensure the consistent quality of products. This session will provide an overview on current and proposed activities of the USP General Chapters-Microbiology Expert Committee, with emphasis on revisions to existing chapters and new chapter proposals.

8:15 a.m. – 8:40 a.m.
Current Activities of the USP Microbiology Expert Committee
David Hussong, PhD, Microbiology and Regulatory Consultant, ValSource, LLC

8:40 a.m. – 9:05 a.m.
Proposed Revisions to USP <1211> and <1222>
Edward Tidswell, PhD, Executive Director, Sterile Quality Assurance, Merck & Co./Merck Sharp & Dohme

9:05 a.m. – 9:30 a.m.
Questions and Answers/Discussion

9:40 a.m. – 10:40 a.m.
P6: The Mutual Reliance Initiative: A New Path for Pharmaceutical Inspections in Europe and Beyond
Moderator: CAPT Sharon K. Thoma, PharmD, National Expert of Pharmaceuticals, United States Public Health Service, ORA, FDA

Session Description: Mutual Reliance Initiative is a new path for Mutual Recognition Agreements between two or more countries to recognize a specific process or procedure of the other country. The intent is to create an expanded inspectorate, one where investigators and inspectors from FDA and trusted partners, such as those in the European Union and beyond, would work together, rely on each other’s inspections, avoid duplicating inspections, and conduct more inspections in areas where the increase in drug manufacturing has greatly increased. The benefit of Mutual Recognition is in strengthening the use of each other’s drug inspection expertise and resources which will result in greater efficiencies for both regulatory systems and provide a more practical means to oversee the large number of drug manufacturing facilities outside of the U.S. and EU.

9:40 a.m. – 10:10 a.m.
FDA’s 2017 Mutual Reliance Initiative
Susan F. Laska, Senior Advisor for Medical Products, ORA, FDA

10:10 a.m. – 10:40 a.m.
Questions and Answers/Discussion

10:40 a.m. – 11:00 a.m.
Refreshment Break

11:00 a.m. – 12:30 p.m.
P7: Ask the Regulators
Moderators: Kim Sobien, Principal Sterility Assurance Engineer, PETNET Solutions, a Siemens Company and John W. Metcalfe, PhD, Quality Assessment Lead, Division of Microbiology Assessment, Office of Process and Facilities/Office of Pharmaceutical Quality, CDER, FDA

Session Description: In the Ask the Regulators session, attendees can interact directly with members of regulatory agencies to pose questions and get answers about pressing microbiology issues. This session will provide attendees with a unique opportunity to engage several regulatory speakers in further discussions regarding regulations, trends, solutions and best demonstrated practices.

Panelists
U.S. FDA ORA Representative Invited
U.S. FDA CDRH Representative Invited
Julie Dohm, PhD, JD, Agency Lead on Compounding and Senior Scientific Advisor for Compounding, CDER, FDA
Lynne A. Ensor, PhD, Director, Division of Microbiology Assessment, CDER, FDA
Laurie P. Norwood, Deputy Director, Office of Compliance and Biologics Quality, CBER, FDA
12:30 p.m.

Closing Remarks from the Conference Co-Chair

Kim Sobien, Principal Sterility Assurance Engineer, PETNET Solutions | A Siemens Company