13th Annual PDA Global Conference on Pharmaceutical Microbiology
The Future of Pharmaceutical Microbiology: Small World, Big Opportunities
October 15-17, 2018 | Bethesda North Marriott Hotel & Conference Center | Bethesda, MD

Sunday, October 14
3:00 p.m. – 7:00 p.m.
Registration Open

Monday, October 15
7:00 a.m. – 5:30 p.m.
Registration Open
7:00 a.m. – 8:00 a.m.
Continental Breakfast

8:00 a.m. – 8:15 a.m.
Welcome and Opening Remarks from Conference Co-Chair
Kim Sobien, Principal Sterility Assurance Engineer, PETNET Solutions | A Siemens Company

8:15 a.m. – 8:45 a.m.
Regulatory Challenges to CAR T Commercialization
Yoko Momonoi, Director, Regulatory CMC, Celgene
Kimberly L. Schultz, Biologist, CBER, FDA (Invited)

9:15 a.m. – 9:45 a.m.
Questions and Answers/Discussion

9:45 a.m. – 10:15 a.m.
Refreshment Break

10:15 a.m. – 11:45 a.m.
P2: Current Regulations in EU and US
US Moderator: Julie Barlasov-Brown, MBA, Associate Director Sterile and Microbiology QA, Merck & Co., Inc.

10:30 a.m. – 11:00 a.m.
Inspection Trends and Revision of EU GMP Annex 1
Andrew Hopkins, Expert GDMP Inspector, Medicines and Healthcare Products Regulatory Agency (MHRA)

11:00 a.m. – 11:30 a.m.
Common Inspection Trends
Justin A. Boyd, Investigator, ORA, FDA

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

Imagine using your own body’s cells to cure cancer – the idea has recently been made tangible and has been shown to be successful with new discoveries in the field of immuno-oncology. CAR T (Chimeric Antigen Receptor T-Cell) therapy is a novel cellular therapy that supercharges a patient’s own immune system T-cells and programs them to attack designated cancer cells in the body. Significant challenges with facility design, room classification, manufacturing, testing, and regulatory approval have been brought forth as several of these personalized “living drug” therapies have achieved commercialization. This opening plenary session will explore CAR T product manufacturing challenges from an industry perspective and discuss regulatory challenges for commercialization as well as the use of non-compendial microbiology methods.
### Grand Opening of Exhibit Hall with Lunch and Poster Presentations

**1:30 p.m. – 3:30 p.m.**

**A1: The Trouble with Sterility**
**Moderator: Edward Tidswell, PhD, Executive Director, Microbiology QA, Merck & Co., Inc.**

Sterility is an absolute and binary concept – we categorize therapeutics either sterile or non-sterile. Yet the modality of imparting sterility, sterile manufacturing, and the method of proving sterility remain challenging and possibly one of the greatest potential risks to patient safety. Regulatory expectations, compliance observations, and the cadre of contemporary microbiological tools all used to assure sterility will be discussed to provide a picture of how to avoid trouble with sterility.

**1:30 p.m. – 2:00 p.m.**

**Avoiding Regulatory Trouble with Sterility: Drug Product Sterilization**
**Stephen E. Langille, PhD, Acting Division Director, Division of Microbiology Assessment, CDER, FDA**

**2:00 p.m. – 2:30 p.m.**

**The Problem with Sterility: Aseptic Processing, The Things We Don’t Talk About (Enough)**
**Hal Baseman, Chief Operating Officer, ValSource LLC**

**2:30 p.m. – 3:00 p.m.**

**Industry Representative Invited**

**3:00 p.m. – 3:30 p.m.**

**Questions and Answers/Discussion**

### Refreshment Break and Poster Presentations in Exhibit Hall

**1:30 p.m. – 3:30 p.m.**

**B1: Novel Products, Methods, and Manufacturing Processes**
**Moderator: Irving Ford, Head of CAR-T QC Laboratories, Celgene**

The challenges raised by new products, test methods, and manufacturing processes present great opportunities for innovative approaches in microbiology. The introduction of these new elements is changing the way that we think of microbiology, and forcing the industry and regulators to look at new approaches for process control and product release. This session will explore a novel process, test method, and product to provide unique insights into how the future is quickly becoming the present.

**1:30 p.m. – 2:00 p.m.**

**Process Development and Manufacturing: Current and Future Challenges**
**Vienna Lo, Principal Scientist, Novartis**

**2:00 p.m. – 2:30 p.m.**

**The Monocyte Activation Test (MAT) for Pyrogen Detection**
**Devon Kleindienst, Research Scientist II, Bristol-Myers Squibb**

**2:30 p.m. – 3:00 p.m.**

**Microbiological Considerations for Drug Products Derived from Cannabis and Cannabis Components**
**Marla Stevens-Riley, PhD, Quality Assessment Lead (Acting)/Master Microbiology Reviewer, CDER, FDA**

**3:00 p.m. – 3:30 p.m.**

**Questions and Answers/Discussion**

### 3:30 p.m. – 4:15 p.m.

**4:15 p.m. – 5:45 p.m.**

**B2: Small Mold: Big Problem! Case Studies on Mold in a Manufacturing Facility**
**Moderator: Ebony Arrington, MS, Pfizer Global Supply, Production Operations, Central Support Manager, Pfizer Biotech**

In the wide diversity of the microbial world, mold represents a relatively small portion of the possible overall contaminants. However, the presence of mold within a pharmaceutical manufacturing facility creates the need for heightened awareness and response commensurate with the risk that it poses to the process and ultimately the patient. In this session, two case studies will be presented related to the presence of mold either in the environment or in the process of a pharmaceutical manufacturing facility. The impact and response to the situations will be explored to provide insight into the prevention of future recurrence.

**4:15 p.m. – 5:15 p.m.**

**What’s in Your Equipment?**
**Cheryl Essex, Head of Biologics Microbiological Control, Sanofi**

**4:15 p.m. – 4:45 p.m.**

**Case Study of an Environmental Contamination**
**Brian J. Lloyd, PhD, Project Manager for New Programs, Pfizer Biotechnology**

**4:45 p.m. – 5:15 p.m.**
## Bioburden Intensity: An Integrated Approach to Environmental Monitoring Data Trending

**Austin W. Kuo**, Principal Research Scientist - Sterility Assurance, *Eli Lilly and Company*

5:15 p.m. – 5:45 p.m.

Questions and Answers/Discussion

## Antimicrobial Effectiveness Test Failure: A Case Study for Nasal Spray Product

**Mark P.J. Nabuurs**, BASc Medical Microbiology, *Merck & Co./Merck Sharpe & Dohme*

5:15 p.m. – 5:45 p.m.

Questions and Answers/Discussion

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**Tuesday, October 16**

7:00 a.m. – 4:30 p.m.

Registration Open

7:00 a.m. – 8:15 a.m.

Continental Breakfast

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7:15 a.m. – 8:15 a.m.

Breakfast Roundtable

**Moderator: Julie Barlasov-Brown, MBA**, Associate Director Sterile and Microbiology QA, *Merck & Co., Inc.*

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8:30 a.m. – 10:00 a.m.

**P3: Live Simulcast from Berlin**

9:45 a.m. – 7:00 p.m.

Exhibit Hall Open

10:00 a.m. – 10:45 a.m.

Refreshment Break and Poster Presentations in Exhibit Hall

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10:45 a.m. – 11:15 a.m.

**A3: Environmental Monitoring**

**Moderator: Christine Sherman**, Director, Global Microbiology and Aseptic Network, *Takeda*

*To assure control of manufacturing facilities, environmental monitoring (EM) programs are critical to evaluate the effectiveness of disinfection programs, operator’s aseptic practices, and the engineering controls in place which provide appropriate conditions for manufacture. These programs generate large amounts of data which can make it difficult to determine the best focus of valuable resources. This session will highlight a case study which provides guidance and tools to evaluate personnel gowning data to assess trends and risks. The second case study evaluated the impact of facility changes on sterility assurance and how to determine the most efficient and effective EM performance qualification after modification of the facility.*

10:45 a.m. – 11:15 a.m.

**Leveraging Gown Monitoring Data to Improve Employee Performance**

**Joe McCall, SM (NRCM)**, Technical Service Specialist, *STERIS Life Sciences and Jennifer Longstaff*, Manufacturing Manager, Aseptic, *Bausch + Lomb*

11:15 a.m. – 11:45 a.m.

**A Case Study of Environmental Monitoring Performance Qualification (EMPQ) Risk Analysis**

**Frederic B. Ayers**, Consultant Scientist, *Eli Lilly and Company*

11:45 a.m. – 12:15 p.m.

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10:45 a.m. – 11:15 a.m.

**B3: Biotech Products**

**Moderator: Bo Chi**, Microbiologist, CDER, *FDA*

*Microbial control and sterility assurance during manufacture of biotech products are critical to ensure product quality and patient safety. In this session, FDA and industry will present microbial control strategies and case studies in the context of current challenges encountered by the biotech industry.*
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<th>Time</th>
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<td>12:15 p.m. – 1:15 p.m.</td>
<td>Questions and Answers/Discussion</td>
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<td>1:15 p.m. – 3:15 p.m.</td>
<td>Exhibitor Roundtable Luncheon</td>
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<td>Exhibitors will be seated at designated tables and will be available for informal discussion with attendees. Exhibit Hall will be closed during this time.</td>
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<td>1:15 p.m. – 3:15 p.m.</td>
<td>A4: Risk Identification, Assessment, and Mitigation</td>
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<td>Moderator: Yeissa M. Chabrier-Roselló, PhD, Microbiology Reviewer, CDER, FDA</td>
<td>A microbiological risk assessment is the scientifically-based process to estimate the likelihood of exposure to a microbial hazard and the resulting impact from this exposure. While the overall tools for quality risk management have been well described (ICH Q9), the practical applications for microbiology continue to present opportunities. This session will present three unique case studies on microbiological risk identification, assessment, and mitigation. It will include real-life perspectives on reactive microbiological risk assessment reports, improvements in aseptic processing to prevent microbial contamination, and manufacturing situations where the shelf life of the product influences the need to build risk reduction into the overall manufacturing processing. This session will emphasize the importance of design with a risk in mind for manufacturing operations upstream and downstream of the final drug product.</td>
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<td>1:15 p.m. – 3:15 p.m.</td>
<td>B4: Predictably Irrational Microbiology</td>
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<td>Moderator: MaryEllen E. Usarzewicz, MS, Parenteral Manufacturing Support Lead, Analytical &amp; Bioanalytical Operations, Microbiology, Bristol-Myers Squibb</td>
<td>Despite best efforts at performing testing in a consistent, predictable fashion, the nature of microbiology is such that the living organisms sometimes do not provide rational results. Predictability also includes the repetitive nature of performing an action in the same way, even if the action (or test) does not seem rational. This session will focus on the predictably irrational nature of microbiology (from the perspective of both testing and results), including case studies on disinfectant efficacy evaluation and recovery of an anaerobic microorganisms from an aerobic aseptic process simulation.</td>
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<td>1:15 p.m. – 1:45 p.m.</td>
<td>Specific Problems and Advice Associated with Writing Microbiological Risk Assessment Reports for Pharmaceutical/OTC/Medical Device Raw Material/Component/Finished Product Contamination</td>
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<td>Kenneth Boone, Associate Director, Sterile &amp; Microbiology Quality Assurance, Merck &amp; Co., Inc.</td>
<td>Sterility Test Recoveries and Process Simulation Design</td>
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<td>1:45 p.m. – 2:15 p.m.</td>
<td>Case Study on Quality Risk Management</td>
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<td>Kenneth Boone, Associate Director, Sterile &amp; Microbiology Quality Assurance, Merck &amp; Co., Inc.</td>
<td>Principles to Consider for Setting Appropriate Bioburden Sample Hold Times</td>
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<td>2:15 p.m. – 2:45 p.m.</td>
<td>Risk Reduction in a Novel Aseptic Manufacturing Process</td>
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<td>Gustavo J. Chiaruttini, PhD, Microbiologist, CDER, FDA</td>
<td>Disinfectant Efficacy: Expect the Unexpected</td>
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<td>2:45 p.m. – 3:15 p.m.</td>
<td>Questions and Answers/Discussion</td>
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<td>3:15 p.m. – 4:00 p.m.</td>
<td>Refreshment Break and Poster Presentations in Exhibit Hall</td>
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<td>4:00 p.m. – 5:30 p.m.</td>
<td>P4: Future Leaders</td>
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<td>Moderator: Kim Sobien, Principal Sterility Assurance Engineer, PETNET Solutions</td>
<td>Solving regulatory and process problems in the small world of microbiology can seem overwhelming in the grand scheme of product control and quality. Yet sharing of these challenges by the leaders who have experienced them first hand will ensure future success. This session will include four exciting case studies of problem resolution, project implementation, or deficiency awareness from the front lines of the microbiology laboratory or product review division.</td>
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<td>4:00 p.m. – 4:15 p.m.</td>
<td>Free Range Facility Parenting: Challenges in Establishing Contamination Control, Environmental Monitoring, and Microbiological Testing Strategies for CAR T Therapies</td>
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Wednesday, October 17

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

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

7:15 a.m. – 8:15 a.m.
Breakfast Roundtable
Moderator: Julie Barlasov-Brown, MBA, Associate Director Sterile and Microbiology QA, Merck & Co., Inc.

8:30 a.m. – 10:00 a.m.
PS: USP Updates
Moderator: Radhakrishna S. Tirumalai, PhD, Principal Scientific Liaison, US Pharmacopeial Convention

Compatible with its overall mission, the role of 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; discussion of a proposed new chapter proposal on a test for absence of B.cepacia complex; and, discussion of bioburden resistance in materials being terminally sterilized and a simple method to determine this.

8:30 a.m. – 8:50 a.m.
Current Activities of the USP Microbiology Expert Committee
David Hussong, PhD, Chief Technical Officer, Eagle

8:50 a.m. – 9:10 a.m.
Burkholderia Cepacia – Prominent Recalls, Screening Methods, and Controls
Tony Cundell, PhD, Principal Consultant, Microbiological Consulting, LLC

9:10 a.m. – 9:30 a.m.
Estimating Microbial Resistance to Sterilization: The Boil Test
James Agalloco, President, Agalloco & Associates Inc.

9:30 a.m. – 10:00 a.m.
Questions and Answers/Discussion

10:00 a.m. – 10:30 a.m.
Refreshment Break

10:30 a.m. – 12:00 p.m.
P6: Ask the Regulators
Moderator: Amy McDaniel, PhD, Microbiologist, CDER, FDA and John W. Metcalfe, PhD, Quality Assessment Lead, CDER, FDA

Panel Discussion
Justin A. Boyd, Investigator, ORA, FDA
Patricia F. Hughes Troost, PhD, Acting Branch Chief, Division of Microbiology Assessment, CDER, FDA (Invited)
Stephen E. Langille, PhD, Acting Division Director, Division of Microbiology Assessment, CDER, FDA
Laurie P. Norwood, Deputy Director, Division of Manufacturing Product Quality, OCBQ, CBER, FDA
Closing Remarks from the Conference Co-Chair

Amy McDaniel, PhD, Microbiologist, CDER, FDA