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| North Bethesda, MD

MONDAY, OCTOBER 15

7:00 a.m. – 8:00 a.m. | Continental Breakfast **| Grand Foyer**

8:00 a.m. – 9:45 a.m. | P1: The New Frontier of Personalized Medicine: Regulatory Expectations and Microbiological Challenges **| Grand Ballroom A-C**

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 and the use of non-compendial microbiology methods.

EU Moderator: Kerstin Wilken, PhD, PMP, Director, Programs and Education, *PDA Europe*
US Moderator: Kim Sobien, Principal Sterility Assurance Engineer, *PETNET Solutions | A Siemens Company*

8:00 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. | Regulatory Challenges to CAR T Commercialization
Yoko Momonoi, Director, Regulatory CMC, *Celgene*

8:45 a.m. | CAR T Cell Therapies: Regulatory Considerations for Safety Testing
Kimberly LW Schultz, Gene Therapy CMC Reviewer, CBER, *FDA*

9:15 a.m. | Questions and Answers/Discussion

SIMULCAST SESSION

9:45 a.m. – 10:15 a.m. | Refreshment Break **| Grand Foyers**

10:15 a.m. – 11:45 p.m. | P2: Current Regulations in EU and US **| Grand Ballroom A-C**

Current regulatory and inspection trends will be the focus of this very popular session and this year we are fortunate to simulcast presentations from both European and FDA representatives. Renowned MHRA microbiology expert and GMP inspector, Andrew Hopkins, will provide an update on the long-awaited revision to Annex 1, Manufacture of Sterile Medicinal Products. Justin Boyd, an investigator in the Office of Regulatory Affairs with FDA's Team Biologics will present an overview of recent investigational findings and discuss some of the most significant non-compliance issues facing the industry.

EU Moderator: Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*
US Moderator: Julie Barlasov-Brown, MBA, Associate Director Sterile and Microbiology QA, *Merck & Co., Inc.*

10:15 a.m. | Microbiological Implications of the EU GMP Annex 1 Revision
Andrew Hopkins, Expert GDMP Inspector, *Medicines and Healthcare Products Regulatory Agency (MHRA)*

10:45 a.m. | Common Inspection Trends
Justin A. Boyd, Investigator, ORA, *FDA*

11:15 a.m. | Questions and Answers/Discussion

SIMULCAST SESSION

11:45 a.m. – 1:30 p.m. | Grand Opening of the Exhibit Hall with Lunch, Poster Presentations, and Tech Talks **| Grand Ballroom D-H**

TECH TALK SCHEDULE

Stop by booth #415 to see these companies give a short talk and Q&A about a hot topic!

Scheduled Time	Company	Topic	Presenter
11:55 a.m. – 12:05 p.m.	bioMérieux Industry	Streamlined and Sustainable Endotoxin Testing with ENDOZYME® II Go	Tyler Blythe *Business Development Manager for Endotoxin Kits*
12:10 p.m. – 12:20 p.m.	MilliporeSigma	New, Innovative Solutions for Viable Air Sampling in your RABS or Isolator	Tim Cser *Technology Specialist*
12:25 p.m. – 12:35 p.m.	Sartorius	Cell-based Therapies – Rapid QC of Short-shelf Life ATMP	Wayne Miller *Head of Sales Specialists-North America*
12:40 p.m. – 12:50 p.m.	Veltek	Core 2 Scan: RFID based Asset Tracking for Cleanroom Operations	Kevin J. McMurtrie, MBA *Global Business Manager Cleanroom Documentation & Cart Transfer Systems*
12:55 p.m. – 1:05 p.m.	Rapid Micro Biosystems	Growth Direct: Error Reduction, Data Integrity, & Ease of Use	Alison Day *Sr. Manager – Marketing & Customer Understanding*
1:10 p.m. – 12:20 p.m.	Associates of Cape Cod, Inc.	Horseshoe Crab Sustainability Project	Brett Hoffmeister *LAL Production Manager*

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MONDAY, OCTOBER 15, CONTINUED

POSTER PRESENTATIONS

The following posters will be presented during Monday and Tuesday's lunch and refreshment breaks in the Exhibit Hall.

1. **Operational Impact of Library Development on The Identification of Organisms in The Family Bacillaceae In Pharmaceutical Manufacturing Using MALDI-TOF Mass Spectrometry Backed Up by Sequencing**
   Christine E. Farrance, PhD, Director of Research and Development, *Charles River Laboratories*
2. **Evaluation of MALDI-TOF Mass Spectrometry for Identification of Mycobacterium Species Found During Environmental Monitoring**
   Warren Crabb, Staff Scientist, *Charles River Laboratories*
3. **Fungal Identification: How Accurate and Robust is Your Characterization Strategy?**
   Bindhu Verghese, PhD, Senior Staff Scientist, *Charles River Laboratories*
4. **The Need for Speed: Validation and Implementation of Rapid Sterility for GMP Testing**
   Krista Spreng, PhD, Scientist, Microbiology Development Services, *Millipore Sigma*
5. **Case Study Using Biofluorescent Particle Counting for Real-Time Environmental Monitoring to Support Improved Product Quality Decisions**
   Philip Villari, MS, Associate Principal Scientist, *Merck & Co., Inc.*
6. **Real Time Microbial Detection: Increases Process Control Providing A Risk Reduction Tool for Monitoring Pharmaceutical Water Systems**
   Kumby Dhliwayo, 7000RMS Applications Specialist, *METTLER TOLEDO Process Analytics*
   Peggy Banarhall, Product Manager, *METTLER TOLEDO Process Analytics*
7. **A Case Study on Implementation of a Real Time Viable Monitoring System in an Aseptic Manufacturing Environment**
   Sandra Saiz-Balbastre, MSc, Biotechnology/Researcher PhD Student, *Reig Jofre Laboratories*
8. **Development and Evaluation of a Rapid and Easy-to-Use Mycoplasma Detection Panel for Use on the FilmArray® System**
   Cynthia L. Phillips, PhD, VP Regulatory and Clinical Affairs, *BioFire Defense, LLC*
9. **Validation of an Automatized Alternative Microbiology Method in the Age of Diverging Guidance**
   David L. Jones, PhD, Director, *Rapid Micro Biosystems*
10. **Case Studies in Contamination Control: Fungal Spores and Deinococcus**
    Jim Polarine Jr., MA, Senior Technical Service Manager, *STERIS Corporation*
11. **How a Contamination Control Program Directly Impacts Product Sterility**
    Joe McCall, SM (NRCM), Technical Service Specialist, *STERIS Life Sciences*
12. **The Linnaeus Conundrum: Is this Disinfectant Effective Against that Cleanroom Isolate?**
    Mark Wiencek, PhD, Lead Microbiologist, *Contec, Inc.*
13. **Harmonized Approach for Cleanroom Hard Surface Disinfectant Efficacy Evaluations**
    Brandy Koslop, *MilliporeSigma, Ecolab Life Sciences*
14. **An Investigation into Particles Found in a Pharmaceutical Ultrapure Water Loop**
    Allison Scott, PhD, Senior Principal Scientist, *Azbil North America Research and Development - BioVigilant*
15. **Operational Excellence in a Pharmaceutical Microbiology Application: Lean Six Sigma Root Cause Analysis and Risk Analysis Approaches**
    Olivia Yee-Chan, Director, Operational Excellence, *Celgene*
16. **Detection of Small Events in Environmental Monitoring Culture Media: How Accurate Is the Visual Inspection?**
    Laurent Leblanc, R&D Healthcare culture media manager, *Biomérieux*
17. **Validation of the Robustness and Ruggedness for the MuScan/Sieve-ID Method**
    Allen Burgenson, Global SME, Testing Solutions, *Lonza Walkersville, Inc.*
18. **Microbiology Testing Requirements for Phase 1 And Phase 2 Clinical Sterile Products.**
    Bhasker A. Rana, PhD, Manager, Microbiology, *Vetter Development Services USA, Inc.*
19. **Validation of Design Features and Method Reducing Risk of False Positive During Bioburden Filtration Testing**
    Claire F. Briglia, Technology Specialist, *EMD Millipore Corp.*
20. **Validation of ENDOZYME II GO - A Time-Saving Endotoxin Assay Based on Recombinant Horseshoe Crab Factor C**
    Kevin l. Williams, Senior Scientist, R&D, *BioMerieux*
21. **Measurement of Endotoxin in Blood-Related Samples**
    Masakazu Tsuchiya, PhD, Senior Research Scientist, *Charles River Laboratories*
22. **Validation of A Cell Line-Based Monocyte Activation Test Method, An In Vitro Pyrogen Test According to USP Validation of Compendial Procedures Guideline**
    Sophie Barrier, R&D Research Scientist, *MilliporeSigma*
23. **Determining Subvisible Particulate Matter in Therapeutic Protein Injections**
    Zachary Beck, Senior Microbiologist, Group Leader, *Eurofins Lancaster Laboratories, Inc.*

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Online voting is now open for the 2019 PDA Board of Directors and Officers Election!
Use your PDA Member ID and last name to log in at www.pda.org/vote

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MONDAY, OCTOBER 15, CONTINUED

1:30 p.m. – 3:30 p.m. | Concurrent Sessions

A1: The Trouble with Sterility | Grand Ballroom A-C

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.

Moderator: Edward Tidswell, PhD, Executive Director, Microbiology QA, *Merck & Co., Inc.*

1:30 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. | 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. | The Problem with Sterility: Aseptic Processing, The Open Flaw in Using Humans in Your Critical Process
David Keen, Senior Global Microbiology Consultant, *ECOLAB LIFE SCIENCES*

3:00 p.m. | Questions and Answers/Discussion

B1: Novel Products, Methods, and Manufacturing Processes | White Oak

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 how 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.

Moderator: Irving Ford, Head of CAR-T QC Laboratories, *Celgene*

1:30 p.m. | Process Development and Manufacturing: Current and Future Challenges
Vienna Lo, Principal Scientist, *Novartis*

2:00 p.m. | The Monocyte Activation Test (MAT) for Pyrogen Detection
Devon Kleindienst, Research Scientist II, *Bristol-Myers Squibb Company*

2:30 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. | Questions and Answers/Discussion

3:30 p.m. – 4:15 p.m. | Refreshment Break and Poster Presentations in Exhibit Hall | Grand Ballroom D-H

4:15 p.m. – 5:45 p.m. | Concurrent Sessions

A2: Microbial Control | Grand Ballroom A-C

The external environment to a manufacturing process presents a significant source of microorganisms. The potential for microbial ingress from the external environment poses a great challenge for microbial control. This session will focus on controlling a process "from the outside in," through case studies on equipment contributions and use of EM data to protect a process prior to microbial ingress. The goal of the knowledge sharing will be to incorporate elements into your own microbial control strategies and to improve programs for the future.

Moderator: Amy McDaniel, PhD, Microbiologist, CDER, *FDA*

4:15 p.m. | What's in Your Equipment?
Cheryl Essex, Head of Biologics Microbiological Control, *Sanofi*

4:45 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. | Questions and Answers/Discussion

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4:15 p.m. – 5:45 p.m. | Concurrent Sessions, continued

B2: Small Mold: Big Problem! Case Studies on Mold in a Manufacturing Facility | White Oak

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.

Moderator: Ebony Arrington, MS, Pfizer Global Supply, Production Operations, Central Support Manager, *Pfizer Biotech*

4:15 p.m. | Responding to In-Process Contaminations: A Case Study
Brian J. Lloyd, PhD, Project Manager for New Programs, *Pfizer Biotechnology*

4:45 p.m. | 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. | Questions and Answers/Discussion

5:45 p.m. – 7:00 p.m. | Networking Reception in Exhibit Hall | Grand Ballroom D-H

TUESDAY, OCTOBER 16

7:00 a.m. – 8:30 a.m. | Continental Breakfast | Grand Foyer

7:15 a.m. – 8:15 a.m. | Breakfast Roundtable: Digital Microbiology Laboratories | White Oak

Hosted by the Microbiology/Environmental Monitoring Interest Group

This session will focus on electronic notebooks (ELN), data integrity, and capturing data in the microbiology laboratory. As we move into the future, expectations on data capture and integrity are becoming more of a question. The discussion will focus on how the industry can prepare to meet these expectations as well as what can be done at the laboratory level to provide excellent product quality.

Tessa Patton will provide a presentation on the implementation of ELN at Eurofins Lancaster Laboratories, followed by roundtable discussion about current practices and lessons learned.

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

7:15 a.m. | Electronic Laboratory Notebooks: Bringing cGMP Documentation into the 21st Century
Tessa Patton, Microbiologist/Group Leader, *Eurofins Lancaster Laboratories Inc.*

7:35 a.m. | Roundtable Discussion

8:30 a.m. – 10:00 a.m. | P3: Creative Solutions for Contamination Detection and Control | Grand Ballroom A-C

In this session, we will look at alternative solutions to present contamination detection and control issues. Our two speakers are well-known on both continents for their long experience in pharmaceutical microbiology, investigations and troubleshooting, and their passion for alternative micro methods. Dr. Michael Miller will present an overview of the more recent revision to regulations and guidances to define strategies for short-shelf lives medicines such as cell and gene therapy products. Jeanne Moldenhauer will give a focus on the infamous Burkhoderia cepacia complex and novel methods for eradication of this contamination as well as preventative measures. These two passionate speakers will enrich their presentations with real case studies.

EU Moderator: Olivier Rocher, Head, QC Microbiology and Sterility Assurance, *GSK Vaccines*
US Moderator: Renée Blosser, Master Microbiology Reviewer, CVM, *FDA*

8:30 a.m. | Regulatory Strategies and Case Studies for Rapid Sterility Testing of Gene and Cell Therapy Products
Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*

9:00 a.m. | Case Studies with Burkholderia Cepacia Complex (BCC)
Jeanne Moldenhauer, Vice President, *Excellent Pharma Consulting*

9:30 a.m. | Questions and Answers/Discussion

SIMULCAST SESSION

10:00 a.m. – 10:45 a.m. | Refreshment Break, Passport Drawing, and Poster Presentations in Exhibit Hall | Grand Ballroom D-H

TUESDAY, OCTOBER 16, CONTINUED

10:45 a.m. – 12:15 p.m. | Concurrent Sessions

A3: Environmental Monitoring **| Grand Ballroom A-C**

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 that provide appropriate conditions for manufacture. These programs generate large amounts of data that can make it difficult to determine the best focus of valuable resources. This session will highlight a case study that 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.

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

10:45 a.m. | Leveraging Gown Monitoring Data to Improve Employee Performance
Joe McCall, SM (NRCM), Technical Service Specialist, *STERIS Life Sciences*
Jennifer Longstaff, Manufacturing Manager, Aseptic, *Bausch + Lomb*

11:15 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. | Questions and Answers/Discussion

B3: Biotech Products **| White Oak**

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 experts will present microbial control strategies and case studies in the context of current challenges encountered by the biotech industry.

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

10:45 a.m. | Microbiology and Biologic Manufacturing are Interdependent!
Jean Stuckey, Senior Principal Microbiologist, *Patheon Biologics, LLC, part of Thermo Fisher Scientific*

11:15 a.m. | Current Challenges for Biotech Products
Reyes Candau-Chacon, PhD, Quality Assessment Lead, Division of Microbiology Assessment, Branch IV, CDER, *FDA*

11:45 a.m. | Questions and Answers/Discussion

12:15 p.m. – 1:45 p.m. | Networking Luncheon, Passport Drawing, and Poster Presentations in Exhibit Hall **| Grand Ballroom D-H**

TECH TALK SCHEDULE

Stop by booth #415 to see these companies give a short talk and Q&A about a hot topic!

Scheduled Time	Company	Topic	Presenter
12:25 p.m. – 12:35 p.m.	Lonza	Pushing the Boundaries in Automation First Glimpse of Next-Generation Solution for Endotoxin Detection – PyroTec™ Pro	Josiah Hosie *Product Strategist*
12:40 p.m. – 12:50 p.m.	Quality Executive Partners	Operating a Microbiology Lab in Virtual Reality	Vanessa Figueroa *Executive Director, Microbiology*
12:55 p.m. – 1:05 p.m.	Charles River Labs	A Complete Data Integrity Strategy for the Modern Laboratory	Matthew Paquette *Product Specialist*

Do you have a regulatory question for our panel of experts?

Fill out a question card and drop it in the collection box located at the registration desk to hear it during Wednesday's Ask the Regulators discussion.

TUESDAY, OCTOBER 16, CONTINUED

1:45 p.m. – 3:15 p.m. | Concurrent Sessions

A4: Risk Identification, Assessment, and Mitigation | Grand Ballroom A-C

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.

Moderator: Yeissa M. Chabrier-Roselló, PhD, Microbiology Reviewer, CDER, *FDA*

1:15 p.m. | Specific Problems and Advice Associated with Writing Microbiological Risk Assessment Reports
Dennis E. Guilfoyle, PhD, Senior Director, Microbiology Regulatory Compliance, *Johnson & Johnson*

1:45 p.m. | Case Study on Quality Risk Management
Mitchell B. Garber, RPh, Director of Sterile and Biopharm Product Quality, *GlaxoSmithKline*

2:15 p.m. | Risk Reduction in a Novel Aseptic Manufacturing Process
Jessica G. Chiaruttini, PhD, Microbiologist, CDER, *FDA*

2:45 p.m. | Questions and Answers/Discussion

B4: Predictably Irrational Microbiology | White Oak

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.

Moderator: MaryEllen E. Usarzewicz, MS, Parenteral Manufacturing Support Lead, Analytical & Bioanalytical Operations, Microbiology, *Bristol-Myers Squibb*

1:15 p.m. | Sterility Test Recoveries and Process Simulation Design
Kenneth Boone, Associate Director, Sterile & Microbiology Quality Assurance, *Merck & Co., Inc.*

1:45 p.m. | Principles to Consider for Setting Appropriate Bioburden Sample Hold Times
Gretchen Brunner, Scientist, QC Science and Technology, *Sanofi*
Mark J. Kapeckas, Biologics Corporate Quality Global Program Manager, *Sanofi Biologics*

2:15 p.m. | Disinfectant Efficacy: Expect the Unexpected
Jeffrey W. Heiser, Director, Microbiology, *Boston Analytical*

2:45 p.m. | Questions and Answers/Discussion

3:15 p.m. – 4:00 p.m. | Refreshment Break, Passport Drawing, and Poster Presentations in Exhibit Hall | Grand Ballroom D-H

Do you have a regulatory question for our panel of experts?
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TUESDAY, OCTOBER 16, CONTINUED

4:00 p.m. – 5:30 p.m. | P4: Future Leaders | Grand Ballroom A-C

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 firsthand 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.

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

4:00 p.m. | Free Range Facility Parenting: Challenges in Establishing Contamination Control, Environmental Monitoring, and Microbiological Testing Strategies for CAR T Therapies
Joseph R. Sondej, Associate Director, QC Microbiology, *Celgene*

4:15 p.m. | It's A Small World After All: Microbial Biogeography of a Manufacturing Facility
Emily Elizabeth Castelloe, Rotational Development Program Associate, *Pfizer Inc.*

4:30 p.m. | Facility Fitness: Tracking Steps to Sterility Assurance
Joshua Schmitz, Principal Engineer Sterility Assurance, *Advanced Sterilization Products (ASP), Johnson & Johnson*

4:45 p.m. | Common Deficiencies for Drug Substance Manufacturing
María José López Barragán, PhD, Microbiologist, CDER, *FDA*

5:00 p.m. | Questions and Answers/Discussion

6:00 p.m. – 9:00 p.m. | PDA EM Incubation Conditions Task Force *(Invitation Only)* **| Forest Glen**

WEDNESDAY, OCTOBER 17

7:00 a.m. – 8:30 a.m. | Continental Breakfast | Grand Foyer

7:15 a.m. – 8:15 a.m. | Breakfast Roundtable: Environmental Monitoring Incubation Conditions | White Oak

Hosted by the Microbiology/Environmental Monitoring Interest Group

This session will concentrate on environmental monitoring samples around incubation conditions. There are several approaches in the industry on how samples should be incubated, including latest trends of single temperature incubation. To address these considerations, the PDA sanctioned a task force to evaluate single temperature incubation and provide industry with guidance.

This session will begin with a short presentation by Scott Weiss on initiation of this PDA Task Force, followed by roundtable discussions about current practices, filing information, and regulatory expectations.

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

7:15 a.m. | Effectiveness of One Media/One Incubation Condition for Functional Environmental Monitoring Program
Scott Weiss, Director Industrial Microbiology - Sterility Assurance, *Johnson & Johnson*

7:35 a.m. | Roundtable Discussion

8:30 a.m. – 10:00 a.m. | P5: USP Updates | Grand Ballroom A-C

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.

Moderator: Radhakrishna S. Tirumalai, PhD, Principal Scientific Liaison, *US Pharmacopeial Convention*

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

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

9:10 a.m. | The Boil Test: Estimating Microbial Resistance to Sterilization
Edward Tidswell, PhD, Executive Director, Microbiology QA, *Merck & Co., Inc.*

9:30 a.m. | Questions and Answers/Discussion

10:00 a.m. – 10:30 a.m. | Refreshment Break | Grand Foyer

WEDNESDAY, OCTOBER 17, CONTINUED

10:30 a.m. – 12:15 p.m. | P6: Ask the Regulators **| Grand Ballroom A-C**

During this interactive session, FDA will provide insight into questions posed by audience participants. The session is targeted to participants from all segments of the pharmaceutical industry and will provide valuable perspectives from agency experts from reviewers of compounding, sterility assurance, aseptic processing, and terminal sterilization of small molecules. In addition, biotechnology professionals can seek input from agency experts on biosimilars and new molecules manufactured using biotechnology processes. Finally, expert field inspectors will provide their perspectives on inspection-related questions. Don't miss this unique opportunity to interact with regulators in an open forum focused exclusively on your microbiology concerns!

Moderators: Amy McDaniel, PhD, Microbiologist, CDER, *FDA* and **John W. Metcalfe, PhD,** Quality Assessment Lead, CDER, *FDA*

10:30 a.m. | Panel Discussion

Justin A. Boyd, Investigator, ORA, *FDA*
Patricia F. Hughes, PhD, Branch Chief, CDER, *FDA*
Stephen E. Langille, PhD, Acting Division Director, Division of Microbiology Assessment, CDER, *FDA*
Anthony F. Lorenzo, Lead Consumer Safety Officer, CBER, *FDA*
Kimberly LW Schultz, Gene Therapy CMC Reviewer, CBER, *FDA*

Submit your questions in advance by dropping them at registration on Mon. or Tue.!

12:00 p.m. | Closing Remarks from Conference Co-Chair

Amy McDaniel, PhD, Microbiologist, CDER, *FDA*