14th Annual PDA Global Conference on Pharmaceutical Microbiology

Magnifying the S.C.O.P.E. of Pharmaceutical Microbiology

October 21-23, 2019 | Bethesda North Marriott Hotel & Conference Center | Rockville, MD

As of August 20, 2019

Sunday, October 20

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

Monday, October 21

7:00 a.m. – 5:30 p.m.
Registration Open

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

8:00 a.m. – 9:45 a.m.
P1: When the SCOPE Gets Personal: Combining the Roles of Scientist and Caregiver
Moderator: Amy McDaniel, PhD, Microbiology Center of Excellence Leader, *Bristol-Myers Squibb*

To kick off the Conference, our first plenary speaker has had the unique perspective of experiencing all five of our topic areas of SCOPE in a very personal way. She has explored and developed the Science, followed the aspects of Compliance, sought out and in some cases created her own Opportunities, produced a specific Product, and Engaged with other scientists, doctors, and regulators in order to save a very special patient, her own husband. This incredible story will set the stage for our Conference and leave our audience of microbiologists inspired to continue their focus on innovating, producing, controlling, and releasing life-saving medicines for patients everywhere.

8:00 a.m. – 8:15 a.m.
Welcome and Opening Remarks from Conference Co-Chair
Amy McDaniel, PhD, Microbiology Center of Excellence Leader, *Bristol-Myers Squibb*

8:15 a.m. – 9:15 a.m.
The Perfect Predator: A Scientist's Race to Save Her Husband from a Deadly Superbug
Steffanie A. Strathdee, MSc, PhD, Harold Simon Professor and Co-Director, IPATH, *UC San Diego* and Author, *The Perfect Predator*

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.
Concurrent Sessions

SCIENCE	SCIENCE
A1: Evolving the SCOPE **Moderator: MaryEllen E. Usarzewicz, MS,** Associate Director, ASO Microbiology, *Bristol-Myers Squibb* *As patient, new product technologies and regulatory expectations evolve we are called upon to explore Science, Compliance, Opportunities, Products, and Engagement in innovative ways in order to demonstrate microbial control. In the cell therapy arena, the use of cell culture media, offers both challenges as well as opportunities regarding a contamination control program. This session will explore the use of cell culture media used in daily manufacturing activities as a potential tool to predict or detect in-process contamination. Additionally, as we strive for increased implementation of Rapid Microbiological*	**B1: Solving Endotoxin Challenges - From Assay to Process Control Strategies** **Moderator: Ed C. Tidswell, PhD, BSc,** Executive Director QA, *Merck & Co., Inc.* *Drug products administered intravenously, intrathecally, or intravitreally must all meet compendial requirements for bacterial endotoxin (BET). The diversity and complexity of current (and future) product formulations and manufacturing processes represent new and evolving challenges in BET assay methodology and manufacturing process controls. This session is purposed to provide expert guidance in this field supported by real-life case studies.*

Methods throughout the industry, using practical approaches in study design is beneficial. This session will discuss a Most Probable Number (MPN) statistical methodology, using quantitative data from a qualitative test in the implementation of rapid sterility testing. Let's use sound science to expand our testing capabilities in order to better serve our patients!	
10:15 a.m. – 10:45 a.m. **Use of Cell Culture Media Microbial Growth Capability as a Potential Tool for the Early Detection of In-Process Contamination** **Rebecca D. Jordan,** QC Microbiology Specialist, *Celgene* 10:45 a.m. – 11:15 a.m. **Demonstrating Comparability of Rapid Microbiological Methods: A Practical Approach Using Most Probable Number** **Stacey N. Ramsey, MS, SM(NRCM),** Senior Scientist, Microbiology, *Alcami Corporation* 11:15 a.m. – 11:45 a.m. **Questions and Answers/Discussion**	10:15 a.m. – 10:45 a.m. **Endotoxin OOS: Investigating the Root Cause** **Crystal M. Booth, MM,** Regional Manager, *PSC Biotech* 10:45 a.m. – 11:15 a.m. **An Endotoxin Control Strategy for the Purification of Antisense Oligonucleotides (ASOs)** **Hien T. Nguyen, MS,** Senior Associate Scientist, *Biogen* 11:15 a.m. – 11:45 a.m. **Questions and Answers/Discussion**

11:45 a.m. – 1:30 p.m.
Grand Opening of Exhibit Hall | Networking Lunch | Poster Presentations | Tech Talks

POSTER PRESENTATIONS
The following posters will be presented during Monday's refreshment breaks.

1. **A Rapid Alternative to Culture-Based Mycoplasma Detection**
   Darren J. Bauer, Product Manager, *Thermo Fisher Scientific*
2. **Maintaining a Robust Environmental Monitoring Program Through HACCP Living Risk Assessments**
   Alana Nelson, *Sanofi*
3. **Monocyte Activation Test: Solution to Testing Medical Products and Protecting Patient Safety**
   Shabnam Solati, MS, CEO, *CTL-MAT*
4. **Can Image Analysis be applied to Environmental Monitoring Samples Workflow? A Proof of Concept Study**
   Alberto Poli, Quality Assurance & Regulatory Affairs Manager, *Newlab Engineering SRL*
5. **Impact of Optimizing Processing Variables on the Performance of Lyophilized Prepared Microorganisms**
   Megan K. Cox, MS, Research and Development Associate, *Microbiologics, Inc.*
6. **Simulation of Factor C Activation by Lipopolysaccharide**
   Masakazu Tsuchiya, PhD, Senior Research Scientist, *Charles River Laboratories*
7. **Mold Contamination Challenges**
   Ziva Abraham, PhD, CEO, *Microrite, Inc.*
8. **Best Practices and Innovative Technology Leading the Way to Lean Labs**
   David E. Wadsworth, Global Product Manager, Bio-Detection, *Suez WTS Analytical Instruments, Inc.*
9. **Accurate Identification of Environmental Bacteria by MALDI-TOF Mass Spectrometry using the VITEK® MS Platform**
   Félix A. MONTERO JULIAN, **PhD,** Scientific Director, *Biomerieux*
10. **Capsule contamination analysis using Rapid, Automated Microbiology Detection System**
    Courtney M. Russell, Applications Microbiologist, *Rapid Micro Biosystems*
11. **Utilizing an Organized Data Driven Approach to Investigate, Solve Problems, and Demonstrate Process Control**
    Matthew P. Paquette, MBA, Operational Excellence Manager, *Microbial Solutions / Charles River Laboratories*
12. **Neutralization Efficacy of Culture Media for Surface Monitoring**
    Tim A. Cser, BS, Senior Technology Specialist, *MilliporeSigma*
13. **Practical Applications of Data Integrity and Audit Trail Review**
    Robert A. Lutskus, Associate Director Commercial Operations, *Lonza Informatics*
14. **Evaluation of the Scanstation 100 System for the Automated Incubation and Analysis of Pharmaceutical Environmental Monitoring Samples Using Standard Petri Plates**

Diarmaid O'Riordan, BSc, QC Microbiology Analyst, *Pfizer*

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

COMPLIANCE	OPPORTUNITIES
A2: Microbial Control Challenges **Moderator: Mitch B. Garber, BS, RPh,** Director Sterile & Bio Pharm Product Quality, *GlaxoSmithKline* *Aseptic compliance is an ever-changing target that must be continuously reviewed and improved to maintain patient safety and regulatory compliance. In this session, we will discuss developments, challenges, and expectations of Barrier separation technology for Glove Management Strategy, Visual Airflow (smoke) Studies, and GMP Regulatory Inspector Expectations. These discussions will include examples and case studies from real situations. Come and engage in this exciting dialogue.*	**B2: Sterility Assurance of Cell-Based and Genomic Therapies** **Moderator: Renée S. Blosser, MS,** Microbiologist, CVM, *FDA* *Sterility testing of cell-based and genomic therapies presents unique challenges due to the presence of cells, stability constraints, and small batch size. The development of novel rapid methods and evaluating existing methods provide an opportunity for improved in vitro testing of these therapies to ensure sterility and patient safety while considering the unique profiles of these products. This session will discuss sterility test methods from an industry and regulatory perspective.*
1:30 p.m. – 2:00 p.m. **Rick L. Friedman, MS,** Deputy Director, OMQ, CDER, *U.S. FDA* 2:00 p.m. – 2:30 p.m. **Glove Management Control Strategy Case Study for Aseptic Processing Using Isolator Technology** **Manshi V. Patel,** Associate Director, *Merck & Co., Inc.* 2:30 p.m. – 3:00 p.m. **Characterization of Airflow Patterns, Identification of Barrier System Design Flaws, and Cleanroom/Barrier System Integration Mistakes** **Morgan Polen,** Contamination Control Expert, *Microrite, Inc.* 3:00 p.m. – 3:30 p.m. **Questions and Answers/Discussion**	1:30 p.m. – 2:00 p.m. **Comparative Performance Evaluation of USP, BacT/ALERT Dual-T, and Bactec FX for Contaminant Detection in Cell Products, Viral Vectors, and Radiolabeled PET-Drugs** **James Gebo,** QA Manager, Sterility Testing Service, *National Institutes of Health* 2:00 p.m. – 2:30 p.m. **Case Study on the Selection and Validation of a Rapid Sterility Test for a Novel Cell Therapy Oncology Product** **Michael J. Miller, PhD,** President, *Microbiology Consultants, LLC* 2:30 p.m. – 3:00 p.m. **Randa Melhem, PhD,** Consumer Safety Officer, CBER, *U.S. FDA* 3:00 p.m. – 3:30 p.m. **Questions and Answers/Discussion**

3:30 p.m. – 4:15 p.m.
Refreshment Break | Poster Presentations

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

PRODUCTS	ENGAGEMENT
A3: Keeping Products Safe for Our Patients **Moderator: Christine Sherman, BA,** Global Microbiology, *Takeda* *Providing innovative and safe products is the focus of our industry all around the world. This session will provide that perspective of sterility assurance from two different regulatory bodies, Health Canada and the U.S. FDA. Representatives from Health Canada will discuss a case study for sterility and endotoxin issues for a natural, sterile product used in wound cleaning. Additionally, the session will provide the U.S. FDA view on one of the most critical activities that support sterile products, the media fill.*	**B3: Symbiotic Connections** **Moderator: Irving Ford, MSc,** Head, CAR T QC Laboratories, *Celgene, Biotechnology Company* *Whether partnering with a regulatory body for a new product, existing product, or just to ask a question or interviewing or collaborating with personnel in your respective organization to complete an investigation, engagement is a key aspect in ensuring success. In this session, we will hear from U.S. FDA and industry on how engagement is key to ensuring successful outcomes in establishing/maintaining mutual reliance between industry and regulators as well as in ensuring the involvement of appropriate personnel and data collection to complete a thorough scientifically based investigation.*
4:15 p.m. – 4:45 p.m. **Sterile Natural Health Products for Wound-Cleaning Failed Sterility and Endotoxin Testing** **Karine Lebel,** Microbiologist, *Health Canada*	4:15 p.m. – 4:45 p.m. **Overview of the U.S.-E.U. Mutual Recognition Agreement** **Helen Y. Saccone, PharmD, MSEL,** Senior Advisor, CDER, *U.S. FDA*

Geneviève Dufour, Microbiologist, *Health Canada* 4:45 p.m. – 5:15 p.m. **Regulatory Representative Invited** 5:15 p.m. – 5:45 p.m. **Questions and Answers/Discussion**	4:45 p.m. – 5:15 p.m. **Key Regulatory and Compendia Elements on How to Investigate a Sterility Test Microbiological Data Deviation: Frantic, Facts, and Fiction** **Dennis E. Guilfoyle, MS, PhD,** Senior Director, Microbiology Regulatory Compliance, *Johnson & Johnson* 5:15 p.m. – 5:45 p.m. **Questions and Answers/Discussion**

5:45 p.m. – 7:00 p.m.
Networking Reception | Poster Presentations

Tuesday, October 22

7:00 a.m. – 5:30 p.m.
Registration Open

7:00 a.m. – 8:30 a.m.
Continental Breakfast

7:15 a.m. – 8:15 a.m.
Breakfast Panel Discussion

8:30 a.m. – 10:00 a.m.
P2: Microbiology in Space: Looking Upward and Beyond!
Moderator: MaryEllen E. Usarzewicz, MS, Associate Director, ASO Microbiology, *Bristol-Myers Squibb*

50 years ago, American astronauts first set foot on the moon. There was a lot of attention toward microbiology at NASA at this time. In some ways, microbiology hasn't changed much at NASA in these past 50 years, but in other ways huge advances are moving the field forward. In this session, Dr. Sarah Wallace will discuss pre-flight and in-flight microbial monitoring for the International Space Station, including the current requirements and risk posture. Dr. Wallace will provide insight into the Genes in Space-3 investigation aboard the space station. This was the first-time microbes were collected, cultured and identified off the planet. She will then discuss the BEST (Biomolecule Extraction and Sequencing Technology) payload which goes beyond culture and implements a direct swab-to-sequencer method. Highlights will also include a better understanding of the ISS Microbiome, The Molecular Space Age as well as microbial considerations with regard to future NASA programs, including The Gateway and Artemis Programs with Mars on the horizon.

8:30 a.m. – 9:30 a.m.
Spaceflight Microbiology: Beyond the Cultures
Sarah L. Wallace, PhD, Microbiologist, *NASA Johnson Space Center*

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

10:00 a.m. – 10:45 a.m.
Refreshment Break | Passport Drawing | Poster Presentations

POSTER PRESENTATIONS
The following posters will be presented during Tuesday's refreshment breaks.

1. **Common Myths in the Pharmaceutical Industry Related to Contamination Control**
   Jim N. Polarine, MA, Senior Technical Service Manager, *STERIS Corporation*
2. **Use of Enumerated Mycoplasma Controls to Assess Media Quality for Growth Promotion Testing**
   Karla I. Fjeld, PhD, Research and Development Scientist, *Microbiologics, Inc.*
3. **An Innovative Statistical Approach to Validation of Rapid Sterility Testing with the BacT/ALERT Dual-T System**
   Dorien Ruegebrink, BSc, Specialist, *Merck & Co., Inc.*
4. **Endotoxin Detection Using Recombinant Factor C**
   Kevin L. Williams, Senior Scientist R&D, *BioMerieux*
5. **Evaluation and Optimization of MALDI-TOF Mass Spectrometry for Identification of Filamentous Fungi during Environmental Monitoring**

Komal K. Iqbal, Research Assistant I, *Charles River Laboratories*

6. **Review of Current Worldwide Microbiology Testing Methods and Markets in Pharmaceutical Manufacturing**
   Robert Ferguson, MBA, President, *Strategic Consulting Inc.*
7. **Evaluation of TrioBas Mono and Trio for Environmental Monitoring in Sterile Medical Product Manufacturing Clean Rooms**
   Roberto Ligugnana, *Orum International*
8. **Species Differentiation of the Bacillus Cereus Group using the pycA Gene Sequence and an Assessment of its Operational Impact for Pharmaceutical Manufacturers**
   Joseph S. Danner, R&D Research Assistant II, *Charles River Laboratories*
9. **Remediation of Low–Level Mold Recoveries in a Media Formulation Room of a Biologics Manufacturing Facility**
   Wireko Manu-Tawiah, PhD, Scientist Principal, Contamination Control, *Sanofi*
10. **The Monocyte Activation Test: Validation and Analysis**
    Matthias K. Koch, PhD, Senior Scientist RND, *Lonza Walkersville, Inc.*
11. **Detection of Viral Contamination in CHO Culture b Ultra-High Multiplex PCR and Next Generation Sequencing**
    Michael Brewer, Director, Global Principal Consultant, Regulatory, BioProduction, *Thermo Fisher Scientific*
12. **Data Integrity in the Microbiology Laboratory**
    Kimi M. Timberlake, **MBA, PMC,** Operations Software Systems Specialist, *Charles River Laboratories*
13. **Real Time Microbial Detection: True Water System Surveillance for Better Process Control Tool and Risk Reduction**
    Arundhati Samanta, MBA, Global Product Manager, *Mettler-Toledo Thornton*
14. **Comprehensive Evaluation of Compendial USP, BacT/ALERT Dual-T, and BACTEC FX for the Detection of Product Sterility Testing Contaminants**
    Anna Lau, *National Institutes of Health*

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

PRODUCTS	PRODUCTS
A4: Science **Moderator: Kim R. Sobien, MBA,** Principal Sterility Assurance Engineer, *PETNET Solutions | A Siemens Company*	**B4: CAR T Products: Control Strategies and Partnerships** **Moderator: Ebony S. Arrington, MS,** Manager, Production Operations, *Pfizer, Inc.* *The newest products designed to save the lives of critically ill patients require unique production and release strategies ensuring speed and efficiency while maintaining strict microbial control. This challenge has expanded the scope of microbiology on many levels, including the area of partnership with regulatory agencies. This session will highlight contamination control and release strategies for CAR T products as well as FDA case studies related to these novel products.*
10:45 a.m. – 11:15 a.m. **U.S. FDA Efforts to Improve Transparency in Regulatory Decisions Involving Product Quality Microbiology** **John W. Metcalfe, PhD**, Master Microbiology Reviewer, CDER, *U.S. FDA* 11:15 a.m. – 11:45 a.m. **The Effect of Gamma Irradiation Process Interruption on Microbial Resistance of Healthcare Products** **Fatima Hasanain, MA,** Polymer Materials Specialist, *Nordion, A Sotera Health Company* 11:45 a.m. – 12:15 p.m. **Development and Evaluation of a Fully Automated "Laboratory in a Pouch" Mycoplasma Detection Method that Improves the Ease-of-Use and Time-to-Result** **Kenneth P. Tai, PhD,** Quality Control Scientist, *Genentech*	10:45 a.m. – 11:15 a.m. **Contamination Control Testing/Release Strategy for CAR T Products** **Irving Ford, MSc,** Head, CAR T QC Laboratories, *Celgene, Biotechnology Company* 11:15 a.m. – 11:45 a.m. **Regulatory Representative Invited** 11:45 a.m. – 12:15 p.m. **Virtual Reality Training for a CAR T Cell Therapy Production Unit** **Timothy P. Kedzior, MED**, Instructional Design Lead, *Novartis Pharmaceuticals Corporation* 12:15 p.m. – 12:45 p.m. **Questions and Answers/Discussion**

William E. Barry, PhD, Scientist I, *BioFire Defense, LLC* 12:15 p.m. – 12:45 p.m. **Questions and Answers/Discussion**	

12:45 p.m. – 1:45 p.m.
Networking Lunch | Passport Drawing | Poster Presentations | Tech Talks

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

COMPLIANCE	OPPORTUNITIES
A5: Container Closure Integrity Testing **Moderator: Bo Chi, PhD,** Microbiologist, CDER, *U.S. FDA* *Container closure integrity (CCI) breaches in parenteral drug products may result in loss of sterility and product contamination. Therefore, CCI should be maintained throughout the shelf-life of these products. In this session, we will discuss the different types of CCI tests including recent advances and challenges and regulatory expectations. CCI will be illustrated with case studies and the impact of plunger stopper movement of pre-filled syringes on sterility and CCI will be discussed.*	**B5: Microbial Control: Equipment and Facility Design** **Moderator: Leslie A. Furr, MS, SM (NRCM)**, Associate Scientific Liaison, *US Pharmacopeia* *To ensure product quality and safety, it is essential that manufacturing controls take microbiological concepts into account during equipment selection and facility design. In this session, U.S. FDA and industry experts will discuss the importance of selecting the appropriate equipment and demonstrate performance examples of these devices to minimize contamination risk. This discussion will also review the key areas in developing an appropriate microbial control program.*
1:45 p.m. – 2:15 p.m. **Reyes Candau-Chacon, PhD**, Quality Assessment Lead, CDER, *U.S. FDA* 2:15 p.m. – 2:45 p.m. **Container Closure Integrity Testing** **Lauren E. Levac, MS,** Senior Scientist, *PPD* 2:45 p.m. – 3:15 p.m. **The Impact of Syringe Plunger Stopper Movement on Container Closure Integrity: Microbial Incursion Test** **Janet Perez-Brown,** Senior Research Scientist I, *Bristol-Myers Squibb* 3:15 p.m. – 3:45 p.m. **Questions and Answers/Discussion**	1:45 p.m. – 2:15 p.m. **Considerations in the Selection of Sterile Connection Devices for Patient Safety** **James P. Agalloco, BEChE, MSChE, MBA** President, *Agalloco & Associates Inc.* 2:15 p.m. – 2:45 p.m. **How to Audit Sanitary Design of Non-Sterile Product Manufacturing** **Andrew Dick, MS,** Senior Principal QA Microbiologist, *Johnson & Johnson* 2:45 p.m. – 3:15 p.m. **J. Kevin Rice, PhD,** Review Chemist, CVM, *U.S. FDA* 3:15 p.m. – 3:45 p.m. **Questions and Answers/Discussion**

3:45 p.m. – 4:30 p.m.
Refreshment Break | Passport Drawing | Poster Presentations

4:30 p.m. – 6:00 p.m.
P3: Circle of Leaders: Future Leaders and Experienced Leaders
Moderators: Irving Ford, MSc, Head, CAR T QC Laboratories, *Celgene, Biotechnology Company* and **Mitch B. Garber, BS, RPh,** Director Sterile & Bio Pharm Product Quality, *GlaxoSmithKline*

As microorganisms must continually adapt to their environment to survive and proliferate, so must a microbiologist/scientist during his/her career. The science of microbiology continues to evolve which presents many different career opportunities for a microbiologist/scientist. The session will highlight the career journeys of experienced leaders as well as up and coming leaders in the science of microbiology and pharmaceutical industry. Come and engage in this exciting dialogue and you too may be surprised at the many opportunities that exist for your career path.

4:30 p.m. – 6:00 p.m.
Experienced Managers
Joyce Hansen, Vice President, *Johnson & Johnson Sterility Assurance*
Anil Sawant, MSc, PhD, Senior Vice President, Global Quality Compliance, *Merck & Co., Inc.*

Future Leaders Who Have Stayed or Become Managers
Lindsey L. Colvin, Associate Director, *Merck & Co., Inc.*
Ayako Hasegawa, PhD, Associate Director, *Allergan*

Independent Contributors
Jay S. Bolden, Senior Consultant Quality-Biologist, *Eli Lilly and Company*
Hilary A. Chan, MS, Principal QC Scientist, *Takeda*

Wednesday, October 23

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

7:00 a.m. – 8:30 a.m.
Continental Breakfast

7:15 a.m. – 8:15 a.m.
Breakfast Panel Discussion

8:30 a.m. – 10:00 a.m.
P4: When the SCOPE Expands: Drawing Conclusions on Microbial Diversity in our Homes and Beyond
Moderator: Amy McDaniel, PhD, Microbiology Center of Excellence Leader, *Bristol-Myers Squibb*

Working together as a community of microbiologists is critical in advancing the science of microbiology in the pharmaceutical industry. In a unique application of this philosophy of working together, our final plenary speaker engaged citizen scientists from around the world to efficiently collect samples globally, adding to his understanding of the diversity of microorganisms in our own homes. This presentation has implications to the diversity of microorganisms in our manufacturing facilities around the world, since we bring our flora from our homes into the places in which we work. Understanding the nature and interactions of microorganisms on our bodies and even in areas such as shower heads (with potential applications to safety showers in manufacturing facilities), can lead to better risk assessment and appropriate levels of control in low bioburden and aseptic manufacturing facilities.

8:30 a.m. – 9:30 a.m.
Never Home Alone: The History and Future of Our Life Indoors
Rob Dunn, PhD, Professor, Applied Ecology, *NC State University* and Author, *Never Home Alone*

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.
P5: Ask the Regulators Panel Discussion
Moderator: Yeissa Chabrier-Rosello, PhD, Microbiologist, CDER, *U.S. FDA* and **John W. Metcalfe, PhD**, Master Microbiology Reviewer, CDER, *U.S. FDA*

During this interactive session, U.S. 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 on the topics of Science, Compliance, Opportunities, Products and Engagement. FDA reviewers of sterility assurance, aseptic processing, and terminal sterilization for small molecules, as well as reviewers of biotechnology applications will provide their perspective on audience questions. Expert compliance personnel 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!

10:30 a.m. – 12:00 p.m.
Panel Discussion
John T. Arigo, PhD, Branch Chief, CDER, *U.S. FDA*
Rick L. Friedman, MS, Deputy Director, OMQ, CDER, *U.S. FDA*
Patricia F. Hughes, PhD, Acting Branch Chief, Division of Microbiology Assessment, CDER, *U.S. FDA*
Anthony F. Lorenzo, Lead Consumer Safety Officer, CBER, *U.S. FDA*

12:00 p.m.
Closing Remarks from the Conference Co-Chair
Yeissa Chabrier-Rosello, PhD, Microbiologist, CDER, *U.S. FDA*