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 June 24, 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: The Perfect Predator
Moderator: Amy McDaniel, PhD, Microbiology Center of Excellence Leader, *Bristol-Myers Squibb*

Epidemiologist Steffanie Strathdee and her husband, psychologist Tom Patterson, were vacationing in Egypt when Tom came down with a stomach bug. Steffanie dosed Tom with an antibiotic and expected the discomfort to pass. Instead, his condition turned critical.

Local doctors at an Egyptian clinic, an emergency medevac team and then a German hospital failed to cure him. By the time Tom reached the world-class medical center at UC San Diego, where both he and Steffanie worked, bloodwork revealed why modern medicine was failing: Tom was fighting one of the most dangerous, antibiotic-resistant bacteria in the world.

Frantic, Steffanie combed through research old and new and came across phage theory: the idea that the right virus, aka "the perfect predator," can kill even the most lethal bacteria. Phage treatment had fallen out of favor almost 100 years ago, after antibiotic use went mainstream. Now, with time running out, Steffanie appealed to phage researchers all over the world for help… and together they achieved a major medical breakthrough.

The Perfect Predator is a nail-biting account of how Steffanie resurrected a forgotten cure—allying with the FDA, researchers from Texas A&M, and a clandestine Navy biomedical center—to design a treatment and save her husband before it was too late. The Perfect Predator is a story of love and against-all-odds survival, detailing how Steffanie helped uncover the science behind a powerful new weapon in the global superbug crisis.

8:00 a.m. – 8:15 a.m.
Welcome and Opening Remarks from Conference Co-Chair

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: Science **Moderator: MaryEllen E. Usarzewicz, MS,** Associate Director, ASO Microbiology, *Bristol-Myers Squibb*	**B1: Science** **Moderator: Ed C. Tidswell, PhD, BSc,** Executive Director QA, *Merck*
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 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 Nguyen,** 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 with Lunch, Poster Presentations, and Tech Talks

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 Blosser, MS,** Master Microbiology Reviewer, 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. **Regulatory Representative Invited** 2:00 p.m. – 2:30 p.m. **Glove Management Control Strategy of Aseptic Processing Using Barrier Separation Technology** **Manshi 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. **Regulatory Representative Invited** 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

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 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 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 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* **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**	4:15 p.m. – 4:45 p.m. **Regulatory Representative Invited** 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 Guilfoyle,** Sr. 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 and Poster Presentations in Exhibit Hall

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: Genes in Space-3 Project
Moderator: MaryEllen E. Usarzewicz, MS, Associate Director, ASO Microbiology, *Bristol-Myers Squibb*

In this session, Dr. Sarah Wallace will provide her unique perspective as the Principal Investigator for the Genes in Space-3 Project aboard the International Space Station.

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

9:45 a.m. – 7:00 p.m.
Exhibit Hall Open

10:00 a.m. – 10:45 a.m.
Refreshment Break, Passport Drawing, and Poster Presentations in Exhibit Hall

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

SCIENCE	PRODUCTS
A4: Science **Moderator: Kim R. Sobien, MBA,** Principal Sterility Assurance Engineer, *PETNET Solutions | A Siemens Company*	**B4: Products** **Moderator: Ebony S. Arrington, MS,** Manager, Production Operations, *Pfizer, Inc.*
10:45 a.m. – 11:15 a.m. **Regulatory Representative Invited** 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. **Questions and Answers/Discussion**	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. **Questions and Answers/Discussion**

12:15 p.m. – 1:15 p.m.
Networking Lunch, Passport Drawing, Poster Presentations, and Tech Talks in Exhibit Hall

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

COMPLIANCE	OPPORTUNITIES
A5: Container Closure Integrity Testing **Moderator: Bo Chi, PhD,** Microbiologist, CDER, *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, 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.*
1:15 p.m. – 1:45 p.m. **Reyes Candau-Chacon, PhD**, Quality Assessment Lead (Acting), Division of Microbiology Assessment, Branch IV, CDER, *FDA* 1:45 p.m. – 2:15 p.m. **Container Closure Integrity Testing** **Lauren E. Levac, MS,** Senior Scientist, *PPD* 2:15 p.m. – 2:45 p.m. **The Impact of Syringe Plunger Stopper Movement on Container Closure Integrity: Microbial Incursion Test** **Janet Perez-Brown,** Associate Research Scientist II, *Bristol-Myers Squibb* 2:45 p.m. – 3:15 p.m. **Questions and Answers/Discussion**	1:15 p.m. – 1:45 p.m. **Considerations in the Selection of Sterile Connection Devices for Patient Safety** **James P. Agalloco, BEChE, MSChE, MBA** President, *Agalloco & Associates Inc.* 1:45 p.m. – 2:15 p.m. **How to Audit Sanitary Design of Non-Sterile Product Manufacturing** **Andrew Dick, MS,** Senior Principal QA Microbiologist, *Johnson & Johnson* 2:15 p.m. – 2:45 p.m. **Regulatory Representative Invited** 2:45 p.m. – 3:15 p.m. **Questions and Answers/Discussion**

3:15 p.m. – 4:00 p.m.
Refreshment Break, Passport Drawing, and Poster Presentations in Exhibit Hall

4:00 p.m. – 5:30 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.

4:00 p.m. – 5:30 p.m.
Experienced Managers
Joyce Hansen, Vice President, *Johnson & Johnson Sterility Assurance*
Anil Sawant, Senior Vice President, Global Quality Compliance, *Merck*

Future Leaders Who Have Stayed or Become Managers
Lindsey L. Colvin, Associate Director, *Merck*
Ayako Hasegawa, Principal Scientist, *Allergan*

Independent Contributors
Jay Bolden, Senior Consultant 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: Never Home Alone
Moderator: Amy McDaniel, PhD, Microbiology Center of Excellence Leader, *Bristol-Myers Squibb*

Join Dr. Rob Dunn is this session where he will talk participants through the natural history of the wilderness in their homes, from the microbes in their showers to the crickets in their basements.

8:30 a.m. – 9:30 a.m.
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, *FDA* and **John W. Metcalfe, PhD**, Quality Assessment Lead, Division of Microbiology Assessment, Office of Process and Facilities/Office of Pharmaceutical Quality, CDER, *FDA*

10:30 a.m. – 12:00 p.m.
Panel Discussion
John T. Arigo, PhD, Division Director, CDER, *FDA*
Patricia F. Hughes, PhD, Acting Branch Chief, Division of Microbiology Assessment, CDER, *FDA*

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