2019 PDA Rapid Microbiological Methods Workshop

October 23-24, 2019 | Bethesda North Marriott Hotel & Conference Center | Rockville, MD

as of September 11, 2019

Wednesday, October 23

11:30 a.m. – 5:30 p.m.
Registration Open

1:30 p.m. – 3:30 p.m.
P1: Global Regulatory Overview of Challenges and Opportunities
Moderator: Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*

The implementation of rapid microbiological methods has been gaining momentum across a number of industry sectors. Simultaneously, recent global regulatory policy updates and guidance documents have supported the use of rapid methods. This session will explore current regulatory framework for the validation, submission and utilization of rapid methods. Experts who have worked in this space from the FDA and EMA will share their experiences and provide additional guidance on how to satisfy regulatory expectations.

1:30 p.m. – 1:45 p.m.
Welcome and Opening Remarks from Workshop Co-Chairs
Tony M. Cundell, PhD, Consulting Microbiologist, *Microbiological Consulting, LLC* and
Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*

1:45 p.m. – 2:15 p.m.
CDER & CBER Review Expectation
Erika A. Pfeiler, PhD, Supervisory Microbiologist, CDER, *U.S. FDA*
CDR Simleen Kaur, MSc, Biologist, Team Lead, CBER, *U.S. FDA*
CDR James L. Kenney, DSc, Chief, LMIVTS, CBER, *U.S. FDA*

2:15 p.m. – 2:30 p.m.
Rapid Methods in Pharmaceutical Compounding
Haijing Hu, PhD, Senior Microbiologist, CDER, *U.S. FDA*

2:30 p.m. – 3:00 p.m.
Do the EU GMPs Require the Use of Rapid Microbiological Methods?
Andrew D. Hopkins, BSc, Hon PGDip, Director, Operation Quality QA Audit and Compliance, *AbbVie, Inc.*

3:00 p.m. – 3:30 p.m.
Questions and Answers/Discussion

3:15 p.m. – 7:00 p.m.
Exhibit Area Open

3:30 p.m. – 4:00 p.m.
Refreshment Break in Exhibit Area

4:00 p.m. – 5:45 p.m.
P2: Regulatory Considerations for Validation and Real Time Testing
Moderator: Erika A. Pfeiler, PhD, Supervisory Microbiologist, CDER, *U.S. FDA*

Real-time test results can lead to better decisions regarding the microbiological quality of a product. In some cases, it may provide the only opportunity for testing. In this session, we will explore this burgeoning sub-field of alternative testing methods. This session will also direct participants to useful updates, examples, and resources associated with the updated Ph.Eur. 5.1.6.

4:00 p.m. – 4:25 p.m.
The Evolution of the USP Position on the Use of Rapid Microbial Methods
Tony M. Cundell, PhD, Consulting Microbiologist, *Microbiological Consulting, LLC*

4:25 p.m. – 4:50 p.m.
European Pharmacopoeia Chapter 5.1.6 "Alternative Methods for Control of Microbiological Quality"
Sven M. Deutschmann, PhD, Head of Global ASAT Adventitious Agents Testing & Alternative Microbiological Methods Global Analytical Science & Technology (gASAT) Global QC, *Roche Diagnostics GmbH*

4:50 p.m. – 5:15 p.m.
Development of Rapid Microbiological Methods for the Pharmaceutical Sciences
Yutaka Kikuchi, PhD, Professor, *Chiba Prefectural University of Health Sciences*

5:15 a.m. – 5:45 p.m.
Questions and Answers/Discussion

5:45 p.m. – 7:00 p.m.
Networking Reception in Exhibit Area

Thursday, October 24

7:15 a.m. – 3:30 p.m.
Registration Open

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

8:30 a.m. – 10:00 a.m.
P3: Case Studies: Rapid Microbial Methods
Moderator: Tony M. Cundell, PhD, Consulting Microbiologist, *Microbiological Consulting, LLC*

8:30 a.m. – 9:00 a.m.
Industry Representative Invited

9:00 a.m. – 9:30 a.m.
Validation Process for a Rapid Sterility Testing Method to Determine the Sterility of an Advanced Therapy Medicinal Product (ATMP)
Andrew A. Finnerty, BSc, Grad. Dip, MBA, General Manager, *Centre for Cell Manufacturing Ireland (CCMI) – REMEDI at NUIG Galway Ireland*

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

9:30 a.m. – 3:45 p.m.
Exhibit Area Open

10:00 a.m. – 10:45 a.m.
Refreshment Break in Exhibit Area

10:45 a.m. – 12:15 p.m.
P4: Finish Product Testing of Sterile and Non-Sterile Products
Moderator: Irving Ford, MSc, Head of CAR-T QC Laboratories, *Celgene, Biotechnology Company*

Due to increasing demands for expedited product shipments, lean manufacturing processes, and cost reduction efforts, the need for rapid methods for final product testing has become a necessity for expedited testing and product release. This need can be met with rapid microbiology methods. In this session, rapid microbiology methods that have been successfully validated and implemented for both sterile and non-sterile final product testing will be explored.

10:45 a.m. – 11:15 a.m.
Validation and Successful Implementation of ScanRDI, a Rapid Microbiology Method for Testing the Sterility of Filterable Drug Products, for the Release of Sterile Compounded Preparations
Anthony T. Grilli, MS, Owner, *FOCUS Laboratories / Atlas Analytical Inc.*

11:15 a.m. – 11:45 a.m.
Real-Time PCR detection of Burkholderia cepacia in Pharmaceutical Products Contaminated with Low Levels of Bacterial Contamination
Luis E. Jimenez, Sr., PhD, Associate Professor, *Bergen Community College*

11:45 a.m. – 12:15 p.m.
Questions and Answers/Discussion

12:15 p.m. – 1:30 p.m.
Networking Lunch

1:30 p.m. – 3:00 p.m.
P5: Implementation of Rapid Methods for In-Process and Finished Product Testing
Moderator: Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*

The use of rapid methods for in-process and finished product testing has a number of advantages over conventional testing, including faster times to result that can facilitate GMP decisions related to microbiological control. This session will explore the routine use of rapid Mycoplasma and automated, growth-based technologies and provide a framework for regulatory acceptance and approval for these alternative methods.

1:30 p.m. – 1:50 p.m.
Rapid Mycoplasma Development and Validation Strategy to Obtain Regulatory Approval for MACI® Product Release Testing
John Duguid, *Vericel Corporation*

1:50 p.m. – 2:10 p.m.
Automated Colony Counting at Biogen: Technology Selection to Implementation
Bill M. Carpenter, MS, Senior Manager, QC Microbiology, *Biogen, Inc.*

2:10 p.m. – 2:30 p.m.
Validation and Global Implementation of PCR-based Alternative Mycoplasma-Detection Assays
Sven M. Deutschmann, PhD, Head of Global ASAT Adventitious Agents Testing & Alternative Microbiological Methods Global Analytical Science & Technology (gASAT) Global QC, *Roche Diagnostics GmbH*

2:30 p.m. – 3:00 p.m.
Questions and Answers/Discussion

3:00 p.m. – 3:45 p.m.
Refreshment Break in Exhibit Area

3:45 p.m. – 5:30 p.m.
P6: Ask the Experts and Regulators
Moderator: Irving Ford, MSc, Head of CAR-T QC Laboratories, *Celgene, Biotechnology Company*

Have you ever wondered which method is correct for your application and/or will your chosen method be met with resistance from regulators? Then, the session is for you! Come and engage in an exciting panel discussion with key industry experts and representatives from various global regulatory agencies as we probe into the fascinating world of rapid microbiology methods and the many perceived and/or factual opportunities/challenges that they bring. You are guaranteed to leave with an enhanced and renewed vigor for evaluating and implementing rapid microbiology methods.

3:45 p.m. – 5:15 p.m.
Panel Discussion
Tony M. Cundell, PhD, Consulting Microbiologist, *Microbiological Consulting, LLC*
Sven M. Deutschmann, PhD, Head of Global ASAT Adventitious Agents Testing & Alternative Microbiological Methods Global Analytical Science & Technology (gASAT) Global QC, *Roche Diagnostics GmbH*
Andrew D. Hopkins, BSc, Hon PGDip, Director, Operation Quality QA Audit and Compliance, *AbbVie, Inc.*
Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*
Erika A. Pfeiler, PhD, Supervisory Microbiologist, CDER, *U.S. FDA*

5:15 p.m. – 5:30 p.m.
Closing Remarks and Final Wrap-up from Workshop Co-Chairs
Tony M. Cundell, PhD, Consulting Microbiologist, *Microbiological Consulting, LLC* and
Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*