### 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, Principal Consultant, *Microbiological Consulting, LLC*  
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, FDA  
Simleen Kaur, PhD, Personnel Management, CBER, FDA  
CDR James Kenney, PhD, Lab Chief/Regulatory Review Officer, CBER, FDA  

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

| 2:30 p.m. – 3:00 p.m. | Andrew Hopkins, *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, 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, Principal Consultant, *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* |
Development of rapid microbiological methods for the pharmaceutical sciences (provide examples vs reading bullet points)
Yutaka Kikuchi, PhD, National Institute of Health Sciences

Questions and Answers/Discussion

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, Principal Consultant, 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 Finnerty, General Manager, Centre for Cell Manufacturing Ireland (CCMI)

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

9:30 a.m. – 4:00 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, 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
Tony Grilli, Atlas

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.
Lunch on your own
### 1:30 p.m. – 3:00 p.m.
**P5: In-Process Testing**
**Moderator:** Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*

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 Carpenter,** 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, 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, Principal Consultant, *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 Hopkins,** Manager, *AbbVie, Inc.*
**Michael J. Miller,** PhD, President, *Microbiology Consultants, LLC*
**Erika A. Pfeiler,** PhD, Supervisory Microbiologist, CDER, FDA

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