### Wednesday, October 23

11:30 a.m. – 5:30 p.m.

**Registration Open**

<table>
<thead>
<tr>
<th>Time</th>
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<td>1:30 p.m. – 3:30 p.m.</td>
<td><strong>P1: Global Regulatory Overview of Challenges and Opportunities</strong>&lt;br&gt;<strong>Moderator:</strong> Michael Miller, PhD, President, <em>Microbiology Consultants, LLC</em>&lt;br&gt;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.</td>
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<td>1:30 p.m. – 1:45 p.m.</td>
<td><strong>Welcome and Opening Remarks from Workshop Co-Chairs</strong>&lt;br&gt;<em>Tony M. Cundell, PhD,</em> Principal Consultant, <em>Microbiological Consulting, LLC</em> and&lt;br&gt;<em>Michael Miller, PhD,</em> President, <em>Microbiology Consultants, LLC</em></td>
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<td>1:45 p.m. – 2:10 p.m.</td>
<td><strong>Regulatory Update</strong>&lt;br&gt;<em>Erika A. Pfeiler, PhD,</em> Supervisory Microbiologist, CDER, FDA&lt;br&gt;<em>Haijing Hu, PhD,</em> Senior Microbiologist, CDER, FDA&lt;br&gt;<em>Simleen Kaur, PhD,</em> Personnel Management, CBER, FDA&lt;br&gt;<em>CDR James Kenney, PhD,</em> Lab Chief/Regulatory Review Officer, CBER, FDA</td>
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<td>2:10 p.m. – 2:35 p.m.</td>
<td><strong>Andrew Hopkins, AbbVie Inc.</strong></td>
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<td>2:35 p.m. – 3:00 p.m.</td>
<td><strong>Regulatory Representative Invited</strong></td>
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<td>3:00 p.m. – 3:30 p.m.</td>
<td><strong>Questions and Answers/Discussion</strong></td>
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<td>3:15 p.m. – 7:00 p.m.</td>
<td><strong>Exhibit Area Open</strong></td>
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<td>3:30 p.m. – 4:15 p.m.</td>
<td><strong>Refreshment Break in Exhibit Area</strong></td>
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<td>4:15 p.m. – 5:45 p.m.</td>
<td><strong>P2: Regulatory Considerations for Validation and Real Time Testing</strong>&lt;br&gt;<strong>Moderator:</strong> Erika A. Pfeiler, PhD, Supervisory Microbiologist, CDER, FDA&lt;br&gt;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.</td>
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<td>4:15 p.m. – 4:45 p.m.</td>
<td><strong>Application of Aseptic Manufacturing/Testing of Short Life Products</strong>&lt;br&gt;<em>Tony M. Cundell, PhD,</em> Principal Consultant, <em>Microbiological Consulting, LLC</em></td>
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<td>4:45 p.m. – 5:15 p.m.</td>
<td><strong>European Pharmacopoeia Chapter 5.1.6 “Alternative Methods for Control of Microbiological Quality”</strong>&lt;br&gt;<em>Sven M. Deutschmann, PhD,</em> Head of Global ASAT Adventitious Agents Testing &amp; Alternative Microbiological Methods&lt;br&gt;Global Analytical Science &amp; Technology (gASAT) Global QC, <em>Roche Diagnostics GmbH</em></td>
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<td>5:15 a.m. – 5:45 p.m.</td>
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### Thursday, October 24

#### 7:30 a.m. – 5:30 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. – 8:50 a.m.**  
  *Industry Representative Invited*

- **8:50 a.m. – 9:10 a.m.**  
  *Industry Representative Invited*

- **9:10 a.m. – 9:30 a.m.**  
  **Bio-Fluorescent Particle Counters for Investigations: Case Study and Practical Applications**  
  Jeffrey W. Weber, Senior Project Manager, PAT, Global Technology Services, *Pfizer Inc.*

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

#### 9:45 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

- **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:** Jeffrey W. Weber, Senior Project Manager, PAT, Global Technology Services, *Pfizer Inc.*

- **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
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| 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. (Invited)** |
| 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. – 5:15 p.m. | **Panel Discussion**  
**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. |
| 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**  
**Michael Miller,** PhD, President, **Microbiology Consultants, LLC** |