pda.org/2019RapidMicro

2019 PDA Rapid Microbiological Methods Workshop

FINAL PROGRAM

CONNECTING PEOPLE SCIENCE AND REGULATION®

OCTOBER 23-24 | ROCKVILLE, MD

EXHIBITION: OCT. 23-24
TRAINING COURSES: OCT. 25
#PDARapidMmicro

GENERAL INFORMATION

REGISTRATION HOURS
Location: Grand Foyer
Wednesday, October 23: 12:00 p.m. – 5:30 p.m.
Thursday, October 24: 7:15 a.m. – 3:30 p.m.

EXHIBIT AREA
Location: Grand Foyer
Wednesday, October 23: 3:15 p.m. – 7:00 p.m.
Thursday, October 24: 9:45 a.m. – 3:45 p.m.

WIFI INFORMATION
Network Name/SSID: PDA2019
Password: Micro19 (not case sensitive)

RECOMMENDED ATTIRE
Business casual attire is recommended for all events. The temperature in the meeting rooms tends to be cool, so a jacket or sweater is advised for your comfort.

BADGES
Attendees are required to wear their Workshop badge as proof of their registration and permits admission to Sessions, Exhibit Area, and the Networking Reception.

VENUE
PDA will conduct all of the sessions and events at the Bethesda North Marriott & Conference Center.

NETWORKING RECEPTION
All registered attendees, are welcome to attend Wednesday evening's Networking Reception.

SPECIAL REQUIREMENTS
For information regarding special needs accommodations, please inquire at the Registration Desk. PDA is committed to make all events accessible to all individuals.

PROGRAM PLANNING COMMITTEE

Program Co-Chairs
Tony Cundell, PhD, *Microbiological Consulting, LLC*
Michael J. Miller, PhD, *Microbiology Consultants, LLC*

Program Committee
Sven M. Deutschmann, PhD, *Roche Diagnostics GmbH*
Irving Ford, MSc, *Celegene, Biotechnology Company*
Erika A. Pfeiler, PhD, *U.S. FDA*

PDA Staff
Annette Bacchus
Josh Eaton

SCHEDULE-AT-A-GLANCE

WEDNESDAY, OCTOBER 23

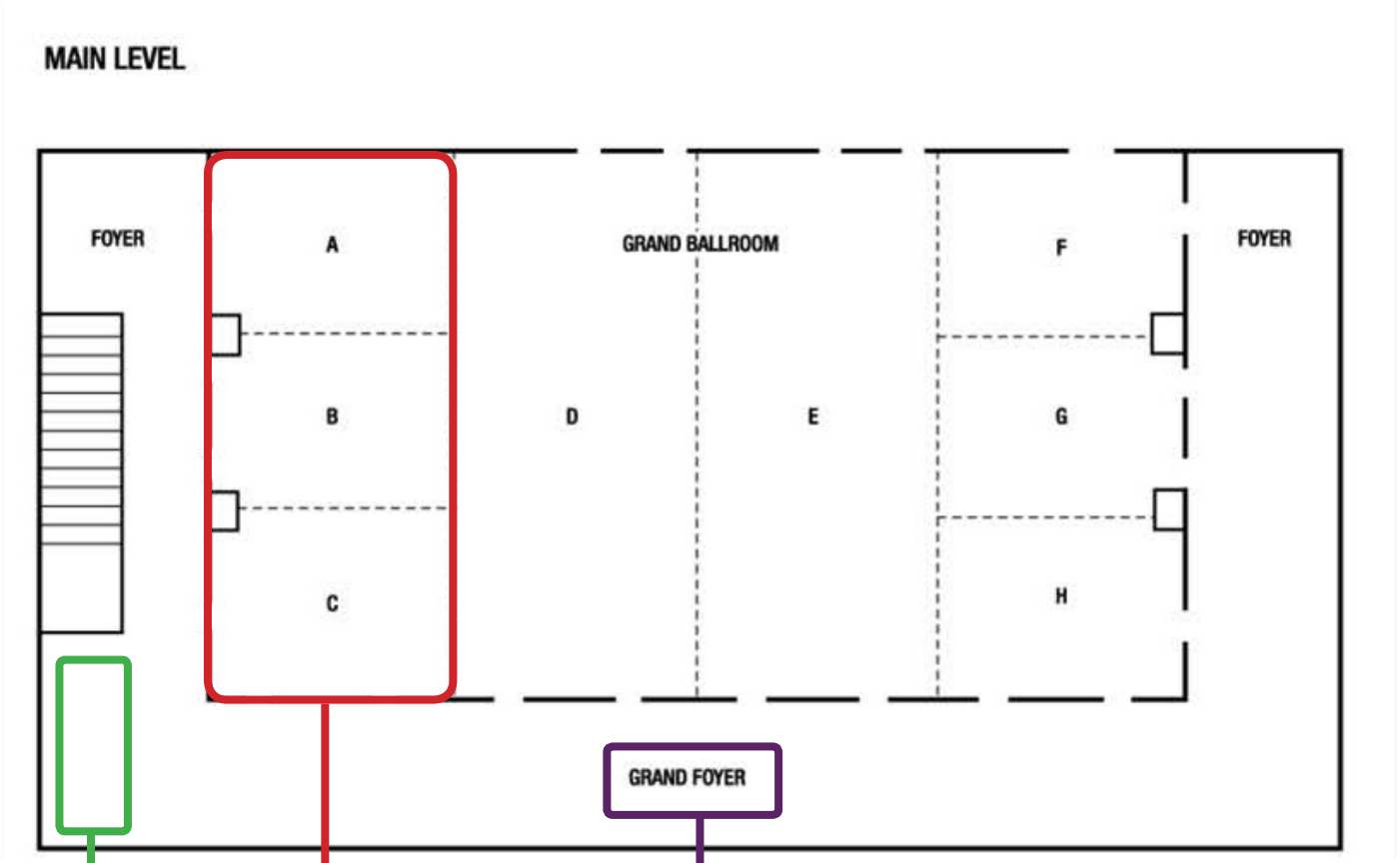
1:30 p.m. – 3:30 p.m. ..... **P1: Global Regulatory Overview of Challenges and Opportunities**
3:30 p.m. – 4:00 p.m. ..... **Refreshment Break**
4:00 p.m. – 5:45 p.m. ..... **P2: Regulatory Considerations for Validation and Real-Time Testing**
5:45 p.m. – 7:00 p.m. ..... **Networking Reception**

THURSDAY, OCTOBER 24

7:30 a.m. – 8:30 a.m. ..... **Continental Breakfast**
8:30 a.m. – 10:00 a.m. ..... **P3: Rapid Microbial Methods Appropriate for Air and Water Monitoring and Cellular Therapy Sterility Testing**
10:00 a.m. – 10:45 a.m. ..... **Refreshment Break**
10:45 a.m. – 12:15 p.m. ..... **P4: Finish Product Testing of Sterile and Non-Sterile Products**
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**
3:00 p.m. – 3:45 p.m. ..... **Refreshment Break**
3:45 p.m. – 5:30 p.m. ..... **P6: Ask the Experts and Regulators**
5:30 p.m. **Adjournment**

***Session locations can be found within the agenda**

CONFERENCE FLOOR PLAN



GRAND FOYER
Registration

GRAND BALLROOM A-C
Plenary Sessions

GRAND FOYER
Continental Breakfast
Refreshment Breaks
Exhibit Area
Networking Reception

CONFERENCE FLOOR PLAN

WEDNESDAY, OCTOBER 23

1:30 p.m. – 3:30 p.m. ..... **P1: Global Regulatory Overview of Challenges and Opportunities**
Location: Grand Ballroom A-C

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 U.S. FDA and EMA will share their experiences and provide additional guidance on how to satisfy regulatory expectations.

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

1:45 p.m. **U.S. FDA CDER and CBER Review Expectations**
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. **Alternative Microbiological Methods Used at Compounding Facilities**
Haijing Hu, PhD, Senior Microbiologist, CDER, *U.S. FDA*

2:30 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. **Q&A Panel**

3:30 p.m. – 4:00 p.m. ..... **Refreshment Break in Exhibit Area**
Location: Grand Foyer

DO YOU HAVE A QUESTION FOR OUR PANEL OF EXPERTS?
Fill out a question card and drop it in the collection box located at the registration desk to hear it during Thursday's Ask the Experts and Regulators Session.

WEDNESDAY, OCTOBER 23

4:00 p.m. – 5:45 p.m. ..... **P2: Regulatory Considerations for Validation and Real-Time Testing**
Location: Grand Ballroom A-C

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. **The Evolution Position of the USP on Rapid Microbial Methods**
Tony Cundell, PhD, Principal Consultant, *Microbiological Consulting, LLC*

4:25 p.m. **European Pharmacopoeia Chapter 5.1.6 "Alternative Methods for Control of Microbiological Quality"**
Sven M. Deutschmann, PhD, Head of Global Analytical Science & Technology, *Roche Diagnostics GmbH*

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

5:15 p.m. **Q&A Panel**

5:45 p.m. – 7:00 p.m. ..... **Networking Reception in Exhibit Area**
Location: Grand Foyer

THURSDAY, OCTOBER 24

7:30 a.m. – 8:30 a.m. ..... **Continental Breakfast**
Location: Grand Foyer

8:30 a.m. – 10:00 a.m. ..... **P3: Rapid Microbial Methods Appropriate for Air and Water Monitoring and Cellular Therapy Sterility Testing**
Location: Grand Ballroom A-C

Moderator: Tony Cundell, PhD, Principal Consultant, *Microbiological Consulting, LLC*

Two case histories are presented how two different organizations approached the selection, validation, regulatory approval, and implementation of the RMM to: 1) improve in-process control in their facility and 2) expedited the detection of microbial contamination in cell cultures. The speakers will highlight lessons learnt during this process.

8:30 a.m. **Bioflorescent Particle Counter-Based Real-Time Feedback and Control Processing Conditions**
Frederic B. Ayers, Research Scientist, *Eli Lilly and Company*

9:00 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. **Q&A Panel**

10:00 a.m. – 10:45 a.m. ..... **Refreshment Break in Exhibit Area**
Location: Grand Foyer

10:45 a.m. – 12:15 p.m. ..... **P4: Finish Product Testing of Sterile and Non-Sterile Products**
Location: Grand Ballroom A-C

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. **Validation of ScanRDI for Release of Compounded Pharmaceutical Products**
Anthony T. Grilli, MS, Owner, *FOCUS Laboratories / Atlas Analytical Inc.*

11:15 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. **Q&A Panel**

12:15 p.m. – 1:30 p.m. ..... **Networking Lunch**
Location: White Oak

THURSDAY, OCTOBER 24

1:30 p.m. – 3:00 p.m. ..... **P5: Implementation of Rapid Methods for In-Process and Finished Product Testing**

Location: Grand Ballroom A-C

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. **Rapid Mycoplasma Development and Validation Strategy to Obtain Regulatory Approval for MACI® Product Release Testing**
John Duguid, Senior Director, Research & Development, *Verical Corporation*

1:50 p.m. **Automated Colony Counting at Biogen: TRP Microbiology Current State of Implementation and Vision**
Bill M. Carpenter, MS, Senior Manager, QC Microbiology, *Biogen*

2:10 p.m. **Validation and Global Implementation of PCR-Based Alternative Mycoplasma-Detection Assays**
Sven M. Deutschmann, PhD, Head of Global Analytical Science & Technology, *Roche Diagnostics GmbH*

2:30 p.m. **Q&A Panel**

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

Location: Grand Foyer

3:45 p.m. – 5:30 p.m. ..... **P6: Ask the Experts and Regulators**

Location: Grand Ballroom A-C

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. **Panel Discussion**
Tony Cundell, PhD, Principal Consultant, *Microbiological Consulting, LLC* and
Sven M. Deutschmann, PhD, Head of Global Analytical Science & Technology, *Roche Diagnostics GmbH*
Andrew D. Hopkins, BSc, Hon PGDip, Director, Operation Quality QA Audit and Compliance, *AbbVie, Inc.*
CDR James L. Kenney, DSc, Chief, LMIVTS, CBER, *U.S. FDA*
Michael J. Miller, PhD, President, *Microbiology Consultants, LLC*
Erika A. Pfeiler, PhD, Supervisory Microbiologist, CDER, *U.S. FDA*

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

NOTES

2019 PDA Rapid Microbiological Methods Workshop

EXHIBIT GUIDE:

ASSOCIATES OF CAPE COD, INC.

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Associates of Cape Cod, Inc. (ACC) is a global biopharmaceutical company specializing in endotoxin and glucan detection. ACC was the first company licensed by the FDA to manufacture LAL for use as a quality control test for endotoxin in the pharmaceutical and medical device industry. ACC also operates a contract testing service.

ATLAS ANALYTICAL

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Atlas Analytical is an FDA registered laboratory offering cGMP analytical support to life science industries. Whether biotech, large pharma, or compounding pharmacy, Atlas Analytical's microbiology, chemistry and stability testing capabilities meet its client's needs with compliance, rapid turnaround time and excellent customer service.

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As the partner of choice for managing microbial quality control, the Charles River purposely-built Microbial Solutions portfolio of Endosafe® endotoxin testing, Accugenix® microbial identification and Celsis® microbial detection solutions, provides clients with the critical, decision-driving data necessary to help bring products to market safely and efficiently.
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MIDI Labs, Inc. is an FDA-registered, ISO 17025 certified, cGMP-compliant service laboratory that provides rapid, accurate, and cost effective bacterial, yeast, and fungal identification. For our pharmaceutical, probiotic, and nutraceutical customers, we provide three ultimate technologies: DNA Sequencing, MALDI-TOF, and fatty acid analysis. For additional information, please contact info@midilabs.com.

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Rapid Micro Biosystems delivers the Growth Direct™ System, an automated, non-destructive rapid detection and enumeration technology-based on the compendial method for microbial quality control in pharmaceutical manufacturing. The system automates and accelerates detection and enumeration in the areas of environmental monitoring and bioburden testing, eliminating manual steps and analysis.

2019 PDA Quality Week

Mastering Risk Management for Organizational Success

Register by Oct. 25 and save up to $600!

HIGHLIGHTS OF THE WEEK

Tuesday, Dec. 10
Get the latest industry and regulatory perspectives on ICH Q9

Friday, Dec. 13
In this compliance update, regulatory experts will share their thoughts on the regulators' use of QRM

Make plans to attend the inaugural *2019 PDA Quality Week*!

THREE EVENTS. ONE GOAL.

Gain the skills you need to implement and optimize a quality risk management (QRM) program in your organization – directly from global industry and regulatory experts!

- ***Risk Management in the Regulatory Landscape Conference*** **| December 9-10**
  Discover the current QRM global regulatory expectations and how regulatory agencies are using risk-based decisions to determine inspection frequencies and provide oversight.
- ***Building a Foundation and Culture for Quality Risk Management Integration Workshop*** **| December 11**
  Real-world case studies from organizations that have established QRM programs and find out how to create a strong quality culture as a prerequisite for a successful QRM program.
- ***Optimizing Quality Risk Management Conference*** **| December 12-13**
  See how risk-based approaches can foster success in your organization and optimize the overall lifecycle management of a product, as envisioned by ICH Q12.

With three events from which to choose, there is something for everyone!

Register for two events and save 10% or register for all three events and save 15%!

To learn more and register, visit *pda.org/2019QualityWeek*

DECEMBER 9-13 | WASHINGTON, DC

EXHIBITION: **DEC. 9-11**
RISK MANAGEMENT IN THE REGULATORY LANDSCAPE CONFERENCE: **DEC. 9-10**
BUILDING A FOUNDATION AND CULTURE FOR QUALITY RISK MANAGEMENT INTEGRATION WORKSHOP: **DEC. 11**
OPTIMIZING QUALITY RISK MANAGEMENT CONFERENCE: **DEC. 12-13**
#PDAQualityWeek

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