



## 2020 PDA Rapid Microbiological Methods Workshop *Success Stories for Implementation in the 21st Century*

October 22-23, 2020 | Virtual

as of July 30, 2020

### Thursday, October 22

10:00 a.m. – 11:45 a.m. | **P1: Case Studies on Method Suitability and Validation**  
**Moderator: Erika A. Pfeiler, PhD**, Supervisory Microbiologist, CDER, U.S. FDA

10:00 a.m. – 10:15 a.m. | **Welcome and Opening Remarks**  
**Amy McDaniel**, Bristol Myers Squibb

10:15 a.m. – 10:30 a.m. | **What is Rapid Microbiological Methods and Why is it Important**  
**Michael J. Miller, PhD**, President, *Microbiology Consultants, LLC*

10:30 a.m. – 10:50 a.m. | **Industry Representative Invited**

10:50 a.m. – 11:10 a.m. | **Industry Representative Invited**

11:10 a.m. – 11:30 p.m. | **Industry Representative Invited**

11:30 a.m. – 11:45 a.m. | **Q&A**

11:45 a.m. – 12:30 p.m. | **Exhibit Networking**

12:30 p.m. – 2:00 p.m. | **P2: Expecting the Unexpected: Overcoming the Challenges of Rapid Testing**  
**Moderator: Andrew D. Hopkins, BSc Hon PGDip**, Director, Operation Quality QA Audit and Compliance, *AbbVie, Inc.*

12:30 p.m. – 12:50 p.m. | **Industry Representative Invited**

12:50 p.m. – 1:10 p.m. | **Industry Representative Invited**

1:10 p.m. – 1:30 p.m. | **Regulatory Representative Invited**

1:30 p.m. – 2:00 p.m. | **Q&A**

### Friday, October 23

10:00 a.m. – 11:15 a.m. | **P3: New Technology**  
**Moderator: Michael J. Miller, PhD**, President, *Microbiology Consultants, LLC*

10:00 a.m. – 10:20 a.m. | **Industry Representative Invited**

10:20 a.m. – 10:40 a.m. | **Industry Representative Invited**

10:40 a.m. – 11:00 a.m. | **Cultivation-free ATP RMM System and its Evaluation Based on Method Validation Criteria and Implementation in Pharmaceutical Water System**

**Yoko Nakaim MS**, Manager, *HORIBA Advanced Techno, Co., Ltd.*

11:00 a.m. – 11:15 a.m. | **Q&A**

11:15 a.m. – 11:45 p.m. | **Exhibit Networking**

11:45 a.m. – 1:00 p.m. | **P4: Ask the Experts and Regulators**  
**Moderator: Josh Eaton**, Assistant Director, Scientific Affairs, *PDA*

11:45 a.m. – 12:45 p.m. | **Industry and Regulatory Round Table**

12:45 p.m. – 1:00 p.m. | **Closing Remarks**