**NIST RMTM Workshop Agenda**

**19-April-2022, 11:00 AM-3:30 PM ET**

|  |
| --- |
| **WELCOME**  |
| 11:00 AM-11:15 AM | **Opening Remarks and Brief Overview of NIST RMTM Consortium***Nancy Lin (NIST) and Sheng Lin-Gibson (NIST)* |
|  |
| **Session 1: Barriers and Potential Solutions to Adoption of RMTMs****Moderator: Nancy Lin**  |
| 11:15 AM-11:30 AM | **Topic: Regulatory Landscape***Speaker: Margaret Riley, JD, Professor of Law, University of Virginia* *Talk Title: The Regulatory Context for Sterility Standards in Cell-Based Therapies* |
| 11:30 AM-11:50 AM | **Topic: End User Case Study on Implementation of RMTMs***Speaker: Anna Lau, Ph.D., Chief Sterility Testing Services, NIH Clinical Center**Talk Title: Creating GMP in an Academic Research Setting and Clinical Hospital Environment – Challenges and Lessons Learned at the NIH* |
| 11:50 AM-12:10 PM | **Topic: Barriers to Adoption of RMTMs***Speaker: Michael Miller, Ph.D., President, Microbiology Consultants LLC**Talk Title: Rapid Microbiological Methods: A Roadmap for Implementation* |
| 12:10 PM-1:05 PM | **Panel 1: Barriers and Potential Solutions to Adoption of RMTMs***Moderator: Nancy Lin**Panelists: Margaret Riley, Anna Lau, Michael Miller, Sheng Lin-Gibson, and Judith Arcidiacono (FDA)* |
| **BREAK** **1:05 PM-1:15 PM** |
| **Session 2: Technologies and Tools for Rapid Microbial Detection****Moderator: Jason Kralj (NIST)** |
| 1:15 PM-1:25 PM | **Topic: ATP-Based Technologies***Speaker: Jonathan Kallay, Senior Technology and Marketing Manager, Charles River Laboratory* *Talk Title: Celsis ATP Bioluminescence: From Cell Culture to Sterility* |
| 1:25 PM-1:35 PM | **Topic: CO2-Based Technologies***Speaker: Felix Montero, Scientific Director-Health and Personal Care Business,* bioMérieux*Talk Title: TBD* |
| 1:35 PM-1:45 PM | **Topic: Solid Phase Cytometry-Based Technologies***Speaker: Felix Montero, Scientific Director-Health and Personal Care Business,* bioMérieux*Talk Title: Application of Solid Phase Cytometry for rapid microbial testing for advanced therapy products* |
| 1:45 PM-1:55 PM | **Topic: PCR-Based Technologies***Speaker: Alexandra Muller-Scholz, Manager PCR & Microbiology, Sartorius* *Talk Title: Rapid sterility of ATMPs prior treatment - Validation of a qPCR-based test* |
| 1:55 PM-2:05 PM | **Topic: Raman-Based Technologies***Speaker: Oliver Valet, Founder and Managing Director, mibic GmbH & Co. KG**Talk Title: TBD* |
| **BREAK** **2:05 PM-2:15 PM** |
| 2:15 PM-2:35 PM | **Topic: Consortium Directions***Speaker: Scott Jackson, NIST**Talk Title: Current Progress and Activities of the NIST RMTM Consortium* |
| 2:35 PM-3:25 PM | **Panel 2: Technologies and Tools for Rapid Microbial Detection***Moderator: Scott Jackson**Panelists: Jonathan Kallay, Alexandra Muller-Scholz, Felix Montero, Oliver Valet, Kevin Wheeler (AlloSource)* |
| **CLOSING** |
| 3:25 PM-3:30 PM | **Closing Remarks***Scott Jackson and Nancy Lin* |