NIST Workshop: Launch of the Rapid Microbial Testing Methods Consortium
Thursday, September 17, 2020, 1 PM to 5 PM

AGENDA

INTRODUCTORY REMARKS	
1:00 PM – 1:10 PM	**Welcome and Overview RMTM Consortium and Workshop Goals** *NANCY LIN, Leader of the Biomaterials Group, Biosystems and Biomaterials Division (BBD), Material Measurement Laboratory (MML), NIST*
1:10 PM – 1:20 PM	**Overview of NIST Advanced Therapy Program** *SHENG LIN-GIBSON, Chief of the BBD, MML, NIST*
1:20 PM – 1:30 PM	**Overview of NIST Microbial Metrology Program** *SCOTT JACKSON, Leader of the Complex Microbial Systems Group, BBD, MML, NIST*

SESSION 1: CHALLENGES IN SELECTING AND APPLYING A RAPID MICROBIAL TEST Moderator: Jason Kralj, NIST	
1:30 PM – 2:00 PM	**Key Characteristics of Rapid Microbial Test Methods for Cell and Gene Therapies** *SPENCER HOOVER, Independent Consultant*
2:00 PM – 2:20 PM	**FDA Requirements and Recommendations for Sterility Testing of Regenerative Medicine Therapies** *JUDITH ARCIDIACONO, International Regulatory Expert, Standards Liaison, FDA*
2:20 PM – 3:05 PM	**PANEL DISCUSSION: Measurement Challenges and Needs** Moderator: Scott Jackson, NIST ▪ *SPENCER HOOVER, Independent Consultant* ▪ *TOM LEACH, Associate Director, Drug Product Process Engineering and Packaging, AstraZeneca* ▪ *CLAUDIA ZYLBERBERG, CEO, Akron Biotech*

3:05 PM – 3:15 PM	**BREAK**

SESSION 2: ONGOING AND NEW EFFORTS TO ADDRESS CHALLENGES Moderator: Sandra Da Silva, NIST	
3:15 PM – 3:20 PM	**Introduction to Session 2** *NANCY LIN, NIST*
3:20 PM – 3:35 PM	**Progress Toward Documentary Standards to Support Rapid Microbial Testing** *DAWN HENKE, Senior Scientific Program Manager, Standards Coordinating Body*
3:35 PM – 3:55 PM	**Rapid Detection of Bacteria and Fungi in ATMPs Prior Treatment – Validation of a Real-time PCR-based Test** *KAI NESEMANN, Product Manager, Microbiology, Sartorius Lab Instruments GmbH & Co. KG*
3:55 PM – 4:45 PM	**PANEL DISCUSSION: Potential Solutions and Paths for the Consortium** Moderator: Nancy Lin, NIST • *JUDITH ARCIDIACONO, International Regulatory Expert, Standards Liaison, FDA* • *RICHARD HAMMOND, Technology Director, Cambridge Consultants LTD* • *RICHARD MCFARLAND, Chief Regulatory Officer, ARMI|BioFabUSA* • *STACY SPRINGS, Senior Director of Programs; Executive Director Biomanufacturing Initiatives, Massachusetts Institute of Technology's Center for Biomedical Innovation* • *RADHAKRISHNA TIRUMALAI, Principal Scientific Liaison, US Pharmacopeial Convention (USP)*

CONCLUDING REMARKS	
4:45 PM – 5:00 PM	**Summary and Next Steps** *NANCY LIN and SCOTT JACKSON, NIST*