

NIST-Hosted Workshop on Collaborative Efforts to Enable Adoption of Rapid Microbial Testing Methods for Advanced Therapy Products

Tuesday, April 25, 2023, 9:00 AM – 5:00 PM (all times are EDT)

AGENDA

(updated 4/24/2023)

OPENING	
9:00 AM – 9:25 AM	Welcome and Opening Remarks <i>Scott Jackson, PhD, Leader, Complex Microbial Systems Group, Biosystems and Biomaterials Division (BBD), Material Measurement Laboratory (MML) at the National Institute of Standards and Technology (NIST)</i> <i>Stephanie Hooker, PhD, Acting Director, MML at NIST</i>
9:25 AM – 10:00 AM	KEYNOTE PRESENTATION A Pathway for Implementing Rapid Microbial Test Method <i>Veera Dheenadhayalan, PhD, Director of Biosafety at AstraZeneca</i>
SESSION 1: Efforts that Support Rapid Microbial Testing Methods for Advanced Therapies <i>Moderator: Kirsten Parratt, BBD, MML, NIST</i>	
10:00 AM – 10:15 AM	USP Evolving Position on Use of Rapid Microbial Methods <i>Huiping Tu, PhD, Senior Principal Scientist at USP</i>
10:15 AM – 10:30 AM	PDA Activities Related to Rapid Microbial Methods <i>Fred Ayers, Advisor – Global Quality Systems at Eli Lilly and Company</i>
10:30 AM – 10:45 AM	Accelerating Adoption of Rapid Microbial Detection Technologies <i>Jennifer Mantle, PhD, Regulatory Committee Coordinator/Technical Project Manager at the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)</i>
10:45 AM – 11:00 AM	BREAK
11:00 AM – 11:15 AM	Advanced Virus Detection Technologies Interest Group (AVDTIG) - Advancing the Adoption of NGS for Adventitious Agent Detection <i>Siemon Ng, PhD, Senior Director of Analytical Development and Quality at Notch Therapeutics</i>
11:15 AM – 11:30 AM	An Overview of the Modern Microbial Methods Collaboration <i>Allison Scott, PhD, Principal Scientist at MicronView LLC</i>
11:30 AM – 11:45 AM	NIST Rapid Microbial Testing Methods (RMTM) Consortium: Activities and Directions <i>Nancy Lin, PhD, Leader, Biomaterials Group, BBD, MML at NIST</i>
11:45 AM – 12:00 PM	Current State of Standards for RMTMs in Advanced Therapies <i>Dawn Henke, PhD, Senior Technical Program Manager, Standards Coordinating Body for Regenerative Medicine (SCB)</i>
LUNCH (on your own) 12:00 PM – 1:30 PM	
SESSION 2: Feedback and Discussion on Rapid Microbial Testing Methods <i>Moderator: Nadratun Chowdhury, BBD, MML, NIST</i>	
1:30 PM – 1:45 PM	Introduction to Breakout Sessions <i>Nadratun Chowdhury, PhD, National Research Council Postdoctoral Fellow, BBD, MML at NIST</i>
1:45 PM – 2:55 PM	Breakout Sessions
2:55 PM – 3:25 PM	Breakout Session Report-out and Discussion

	<i>Breakout Session Moderators, NIST</i>
3:25 PM – 3:45 PM	BREAK
3:45 PM – 4:45 PM	<p>Panel Discussion <i>Moderator: Scott Jackson, NIST</i></p> <p><i>Panelists:</i></p> <ul style="list-style-type: none"> • <i>Guo-Chiuan Hung, PhD, Chemistry, Manufacturing, and Control (CMC) Reviewer at FDA/CBER/Office of Advanced Therapies (OTAT)/Division of Cellular and Gene Therapies (DCGT)/Gene Therapy Branch</i> • <i>Michael Miller, PhD, President at Microbiology Consultants, LLC</i> • <i>Jennifer Robbins, Senior Principal Scientist in Cell Therapy Development at Bristol Myers Squibb</i> • <i>Tricia Vail, Regional Segment Marketing Manager – Applied Research Markets at Sartorius Corporation</i>
CLOSING	
4:45 PM – 5:00 PM	<p>Concluding Remarks <i>Scott Jackson, NIST</i></p>

SLIDES ONLY (No presentation)	
<p>Activities of the MIT Center for Biomedical Innovation Related to Rapid Microbial Methods <i>Stacy Springs, PhD, Executive Director, MIT Center for Biomedical Innovation</i></p>	