National Institute of Standards and Technology
U.S. Department of Commerce

NIST Rapid Microbial Testing Methods Workshop

"Addressing the Needs for Measurements and Standards for Rapid Testing of Microbial Contaminants in Regenerative Medicine"

Date: Tuesday 19-April-2022
Time: 11:00am-3:30pm (ET)
Location: Cisco WebEx Virtual Meeting
Hosted By: NIST

2022 NIST RMTM Workshop

NIST

The National Institute of Standards and Technology (NIST) was founded in 1901 by Congress to improve U.S. industrial competitiveness by advancing its measurement infrastructure. Now a part of the U.S Department of Commerce, the mission of NIST remains to promote US innovation and industrial competitiveness by offering measurement science, standards, and technology to enhance economic security and improve the quality of life. With a vision to be the world's leader in creating measurement solutions, NIST bolsters three core competencies in measurement science, rigorous traceability, and standards development and use.

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NIST Rapid Microbial Testing Methods Consortium

Bringing together experts across the regenerative medicine field, including stakeholders in industry, academia, and the government, the NIST Rapid Microbial Testing Methods (RMTM) Consortium seeks to address the need for measurement standards for rapid microbial testing of regenerative medicine and advanced therapy products.

CONTENTS

WELCOME

With great pleasure, we welcome you to the 2022 NIST Rapid Microbial Testing Methods Consortium Workshop. Rapid microbial testing methods (RMTMs) have the potential to detect microbial contaminants more quickly in advanced therapy products, as compared to compendial methods that can take weeks. However, RMTMs are not widely adopted in the industry. NIST is hosting this workshop to discuss challenges and standards-based solutions that will help facilitate the use of RMTMs for advanced therapy products and support the activities of the NIST RMTM Consortium.

Workshop Goals Include

- Learning about the state of the field for RMTMs in the advanced therapy sector and prioritizing measurement challenges and standards needs
- Discussing hurdles in the adoption of RMTMs for advanced therapies
- Sharing and obtaining feedback on current activities and future directions of the RMTM Consortium

Expected Outcomes Include

- Shared knowledge of challenges and recent advances in RMTMs
- Increased awareness of the NIST RMTM Consortium and its activities
- Stakeholder feedback to help inform the Consortium Work Plan

Consortium activities to be discussed are the development of methods to quantify microbial cell properties, including total cell count and total genome copy number; application of those methods to microbial whole-cell reference materials; and interlaboratory studies to assess fitness for purpose of the reference materials.

It is an opportune time for all of us as we gather to expand our work's impact and help address the needs of the regenerative medicine community. Thank you all once again for joining us as we work together to inform better practices and advance the implementation of RMTMs for advanced therapy products.

-NIST RMTM Consortium Leadership Team

AGENDA

Tuesday April 19, 2022, 11:00am-3:30pm ET

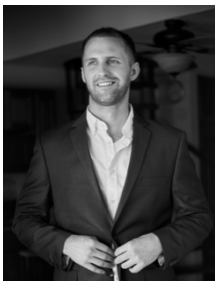
	WELCOME
11:00 AM-11:15 AM	**Opening Remarks and Brief Overview of NIST RMTM Consortium** *Nancy Lin (NIST) and Sheng Lin-Gibson (NIST)*
	Session 1: Barriers and Potential Solutions to Adoption of RMTMs **Moderator: Nancy Lin**
11:15 AM-11:30 AM	**Topic: Regulatory Landscape** *Speaker: Margaret Riley, 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*

SPEAKERS

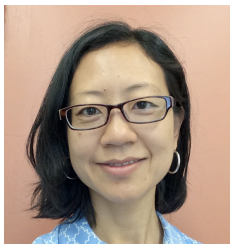
Judith (Judy) Arcidiacono M.S.
U.S. Food and Drug Administration
International Regulatory Expert and Leads for Standards for Regenerative Medicine Therapies
Immediate Office of the Director (IOD)
Office of Tissues and Advanced Therapies (OTAT)

Scott A. Jackson
Leader, Complex Microbial Systems Group
NIST



Jonathan Kallay
Senior Technology and Market Development Manager
Microbial Solutions | Charles River

Anna F. Lau, Ph.D., D(ABMM)
Chief, Sterility Testing Service
Department of Laboratory Medicine
Clinical Center, National Institutes of Health



Sheng Lin-Gibson, Ph.D.
Chief, Biosystems and Biomaterials Group
Material Measurement Laboratory
NIST

Michael J. Miller, Ph.D.
President
Microbiology Consultants, LLC

Felix Montero
Scientific Director of the Healthcare Business
bioMérieux

Alexandra Müller-Scholz, Ph.D.
Manager PCR & Microbiology Applications
Lab Essentials Applications Development
Sartorius

Margaret Riley, JD
Professor of Law
University of Virginia

Oliver Valet
Founder and Managing Director
mibic GmbH & Co. KG

Kevin Wheeler
Microbiology Scientist
AlloSource

BIOGRAPHIES

Judy Arcidiacono

Judy is the Lead for the Standards Development Program for Regenerative Medicine Therapies (RMT). She leads FDA's participation in ISO TC 276 and serves as a liaison to ASTM F04 Committee on Tissue Engineered Medical Products (TEMPs). She works closely with the National Institute for Standards and Technology (NIST) and the Standards Coordinating Body (SCB) to foster the development of standards that support innovation and product development in the RMT field.

In her position as an International Regulatory Expert, Judy is responsible for representing FDA/CBER/OTAT points of view in developing international regulatory policies and the development standards for regenerative medicine therapies. She serves as the secretariat for the International Pharmaceutical Regulators Forum (IPRP) Cell Therapy Working Group and Gene Therapy Working Group. She is also the co-chair of the Centers for Regulatory Excellence for Advanced Therapies at the APEC Regulatory Harmonization Center Steering Committee.

Judy has been at FDA for almost 32 years. For the first 18 years, she worked in the Division of Cell and Gene Therapy as a research/reviewer. In this role, she researched the human immunological response to xenotransplantation products and reviewed clinical trial applications for NK cell and T cell therapies and xenotransplantation products. Currently, Judy is the lead for policy development for xenotransplantation products.

Scott Jackson

Dr. Scott Jackson joined The National Institute of Standards and Technology (NIST) in May of 2014. At NIST, Dr. Jackson is currently the leader of the Complex Microbial Systems Group in the Biosystems and Biomaterials Division. In this current role, Dr. Jackson is leading international efforts to improve microbiome and metagenomic measurements by organizing inter-lab studies, developing reference materials and reference methods.

Prior to joining NIST in 2014, Dr. Jackson spent 11 years as a principal investigator at FDA where he developed advanced genomic tools for characterizing the global genomic diversity of enteric pathogens, with applications in food safety, bioforensics and public health.

Dr. Jackson completed his PhD research in biochemistry and biophysics at The University of Maryland and Johns Hopkins University where he focused on the evolution of mobile genetic elements. Dr. Jackson performed his undergraduate studies in Chemistry and Geology at the University of South Carolina.

Jonathan Kallay

Jonathan (Jon) Kallay is a Senior Technical & Market Development Manager working remotely for the Microbial Solutions product lines. He is a subject matter expert on microbiological investigations for manufacturing facilities that make regulated products. Jon provides practical laboratory experience to help clients identify the optimal path forward for their labs. Jon received his Bachelor's degree in biochemistry from Denison University before earning a post-graduate diploma in pharmaceutical microbiology from the University of Manchester.

Anna Lau

Dr. Lau earned her PhD from the University of Sydney, Australia, where her research focused on the development of novel diagnostic platforms for invasive fungal diseases. In 2011, she joined the NIH to complete a fellowship in Clinical Microbiology in the Department of Laboratory Medicine. Following her fellowship, she joined the Clinical Microbiology Service as a Staff Scientist where she co-directed the Bacteriology, Specimen Processing, Parasitology, and Molecular Epidemiology sections. In 2018, Dr. Lau was promoted to Chief of the newly created Sterility Testing Service to support the NIH-wide cGMP aseptic processing and manufacturing of cellular therapy and drug pharmaceuticals for NIH clinical protocols.

Dr. Lau's translational research has focused on the development of rapid diagnostic platforms using molecular-based techniques and mass spectrometry. Her current research involves advancing testing platforms used in the biopharmaceutical setting whilst also meeting the Food and Drug Administration requirements for quality and patient safety. Her work is reflected in nearly 50 publications and book chapters, and she has been recognized with numerous awards to include eight NIH Clinical Center CEO and Director's awards, and the Forbes 30 Under 30 Award for Healthcare Science.

Dr. Lau serves on the Editorial board for the Journal of Clinical Microbiology; is a member of the American Society for Microbiology, the Parenteral Drug Association and the United States Pharmacopeia; and she chairs the NIH Environmental Monitoring Advisory Committee for cGMP. Dr. Lau is board certified through the American Board of Medical Microbiology.

Sheng Lin-Gibson

Dr. Sheng Lin-Gibson is the Chief of the NIST Biosystems and Biomaterials Division. She oversees a multidisciplinary research portfolio that includes regenerative medicine and advanced therapies, precision medicine, synthetic biology, and complex microbial systems. She leads and coordinates the development of global standards for emerging biotechnology, many of which support regenerative medicine and advanced therapy. She has coauthored over 80 peer-reviewed publications, serves on many Interagency

Working Groups as well as numerous expert review panels and advisory boards. She has received two Department of Commerce Gold Medals.

Michael Miller

Dr. Michael J. Miller is an internationally recognized microbiologist and subject matter expert in pharmaceutical microbiology, contamination control and the validation and implementation of rapid microbiological methods (RMM). He is currently the President of Microbiology Consultants, LLC (http://microbiologyconsultants.com) and owner of http://rapidmicromethods.com, an educational website dedicated to the advancement of rapid microbiological methods within a variety of healthcare, pharmaceutical, consumer and related industry sectors.

For more than 30 years, he has held numerous R&D, manufacturing, quality, business development and executive leadership roles at Johnson & Johnson, Eli Lilly and Company and Bausch & Lomb. In his current role, Dr. Miller consults with multinational companies in providing technical, quality, regulatory and training solutions in support of rapid methods, sterile and non-sterile pharmaceutical manufacturing, contamination control and remediation, environmental monitoring, sterilization and laboratory operations.

Dr. Miller has authored more than 100 technical publications and presentations and is the editor of PDA's Encyclopedia of Rapid Microbiological Methods. He currently serves on the editorial and scientific review boards for American Pharmaceutical Review, European Pharmaceutical Review and the PDA Journal of Science and Technology. Dr, Miller serves as the chairperson for the revision.

Felix Montero

Felix is a Scientific Director of the Healthcare Business of bioMérieux. Felix has over 25 years of experience in industrial and clinical diagnostics and previously served as the Chemunex R&D Director in bioMérieux. Félix graduated from the Autonomous Metropolitan University in Mexico as Industrial Biochemistry Engineer and obtained a PhD in Immunology from the Aix Marseille II University in France. Felix is a member of different scientific organizations (PDA, ISAC) and served as an expert in a panel for the Development of Compendial Rapid Sterility Tests for the USP. Félix has been and continues to be extensively involved in the implementation and acceptance of rapid and alternative microbiological methods. He has authored more than 40 scientific publications in basic and applied immunology/microbiology and is an inventor on more than 6 patents on immune therapeutic approaches. He is a prominent speaker at congresses and conferences and a regular contributor to bioMérieux scientific whitepapers. Félix have extensive technical experience includes development of in vitro diagnostic and research use reagents and applications, cell and tissue culture systems, microbiology, alternative and rapid microbiological methods, sterility testing, mycoplasma detection, compendia methods, methods for blood bank testing, cell and gene therapy process.

Alexander Muller Scholz

Alexandra holds a Masters degree in Biotechnology from the Technical University of Braunschweig (Germany, 2010) and a PhD in Live Science from the University of Hannover (Germany, 2014). Before her start in the current role as Manager PCR & Microbiology Applications, she began her career at Sartorius as PhD Student and later as scientist in the Microbiology Product Development Department within LPS being responsible for PCR related projects.

Margaret Riley

Margaret Foster Riley, Dorothy Danforth Compton Professor at the Miller Center, is professor of law at UVA Law School, professor of public health sciences at the UVA School of Medicine, and professor of public policy at the University's Frank Batten School of Leadership and Public Policy. A scholar working in the intersection of law, regulation, policy, and ethics in the Life Sciences, Riley has written and presented extensively about health care law, biomedical research, genetics, food and drug regulation, reproductive technologies, human and animal biotechnology, and public health. She is currently a member of the NIH NExTRAC, a FACA committee that advises the NIH Director on issues concerning emerging biotechnologies. Riley has advised numerous state and federal agencies, including the Food and Drug Administration; the Environment Protection Agency; the Department of Defense; committees of the National Institutes of Health, the National Science Foundation, and the National Academies of Science, Engineering and Medicine; the Virginia Department of Health; and the Virginia Bar.

Oliver Valet [Placeholder]

Kevin Wheeler

Kevin currently is a Scientist in Quality and Research Microbiology at AlloSource. Kevin holds a Master of Science in Biology with special emphasis on microbial ecology and a Bachelor of Arts in Biology. He also is a National Registry Certified Microbiologist and Certified tissue bank specialist.

PLANNING COMMITTEE

NIST

Tara Eskandari, M.S., B.S.
Biosystems and Biomaterials Division-HQ

Scott Jackson, PhD
Complex Microbial Systems Group

Shaswat Koirala, M.S., B.S.
Biosystems and Biomaterials Division-HQ

Jason Kralj, PhD
Complex Microbial Systems

Nancy Lin, PhD
Group Leader, Biomaterials Group

Stephanie Servetas, PhD
Complex Microbial Systems Group

Standards Coordinating Body for Regenerative Medicine (SCB)

Dawn Henke, PhD
Senior Technical Program Manager

Melody Sanders, PhD
Scientific Program Manager

Acknowledgements

We would like to express our gratitude to all speakers and panelists for their contributions to this event.

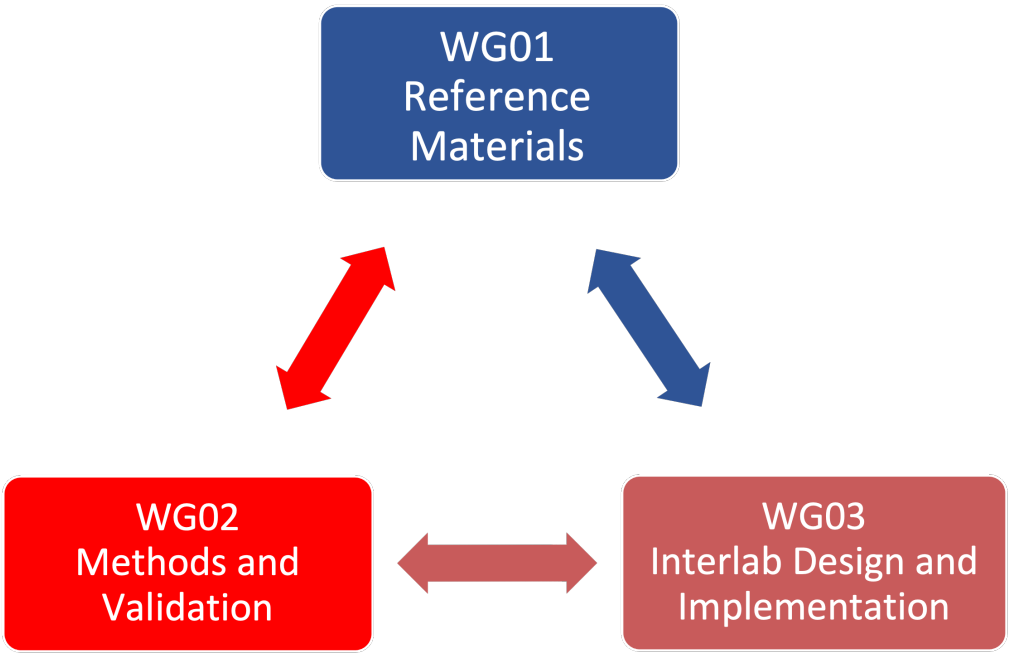
ADDITIONAL INFORMATION & RESOURCES

Consortium Ongoing Efforts and Future Directions

- Identify and/or design fit for purpose microbial cell reference materials and develop methods to characterize cell properties beyond colony forming units.
- Develop guidance on the use of reference materials in the qualification and/or validation of rapid microbial testing methods for advanced therapy products.
- Design interlaboratory studies based on candidate reference materials to evaluate materials and support the development of best practices and standard methods.

Overview of Consortium Organization

The RMTM Consortium Consists of Three Working Groups



WG01 MISSION: The mission of the Reference Material Working Group (WG01) is to identify and facilitate the development, characterization, and qualification of reference materials (RMs) to support the wide adoption of new and existing Rapid Microbiology Test Methods (RMTMs) within the Advanced Therapy Industry.

WG02 MISSION: The mission of the Methods and Validation Schemes Working Group (WG02) is to develop a framework for the validation of methods to support the wide adoption of new and existing Rapid Microbiology Test Methods (RMTMs) by the Advanced Therapy Industry.

WG03 MISSION: The Interlaboratory Study Design and Implementation Working Group (WG03) mission is to design and implement interlaboratory studies to assess the analytical performance of various RMTMs while also evaluating the performance and fitness for purpose of candidate reference materials.

HOW TO GET INVOLVED

Become A Member

- Complete the Letter of Interest Form
- Participants will sign a Cooperative Research and Development Agreement (CRADA); Federal Agencies may join under Letter Agreement
- No cost to join the Consortium

Member Benefits

- Access to a neutral forum to address pre-competitive needs
- Participation in the development of reference materials, methods, and protocols, and interlaboratory studies
- Access to tools developed by the Consortium ahead of public release
- Institutional representation on Consortium steering committee

For More Information

CONTACT

Nancy Lin
Email: nancy.lin@nist.gov

Scott Jackson
Email: scott.jackson@nist.gov