

# Manufacturing USA: Spotlight on Biomanufacturing

January 13, 2017

Institute for Biosciences and Biomedical Research, Rockville, Maryland

## Agenda

9:30 - 9:35	<b>Welcoming Remarks</b>	<i>Willie May, Director Emeritus, NIST</i>
9:35 - 9:40	<b>Manufacturing USA Institute Principles</b>	<i>Phil Singerman, Associate Director for Innovation and Industry Services, NIST</i>
<b>NIIMBL: The National Institute for Innovation in Manufacturing Biopharmaceuticals</b>		<i>Moderator, Kelley Rogers - NIST Federal Technical Program Manager for NIIMBL</i>
9:45 - 10:30	NIIMBL: mission, scope, impact, and organization	<i>Kelvin Lee, NIIMBL Director, Gore Professor of Chemical and Biomolecular Engineering, University of Delaware</i>
10:30- 10:45	Q&A	
<b>Interagency Coordination:</b>		
10:45- 10:55	MATES - the Multiagency Tissue Engineering Subcommittee	<i>Richard McFarland - MATES Chair, US FDA, CBER, OTAT</i>
<b>The Advanced Tissue Biofabrication Manufacturing Innovation Institute (ATB-MII)</b>		<i>Moderator, Kristy Pottol, Federal Program Manager, ATB-MII, USAMMDA</i>
11:00 - 11:45	ARMI: The Advanced Regenerative Medicine Institute: mission, scope, impact, and organization	<i>Tom Bollenbach, ARMI Director</i>
11:45 - 11:55	Q&A	
12:00 - 12:30	Panel Discussion: NIIMBL and ATB-MII	<i>Moderator - John Getz, Deputy Program Manager, ATB-MII, USAMMDA</i>
	<i>Panelists: Tom Bollenbach (ARMI), Kelvin Lee (NIIMBL), Margy Phillips (NIIMBL/NIST), Kirk Pirlo (ATB-MII/USNRL), Kristy Pottol (ATB-MII/USAMMDA), and Kelley Rogers (NIIMBL/NIST)</i>	

### *Speaker and Panelist Biographies*

**Tom Bollenbach** is the Chief Technical Officer for the Advanced Regenerative Medicine Institute (ARMI), awarded under the DoD Advanced Tissue Biofabrication Manufacturing Innovation Institute (ATB-MII) competition. Tom previously served as Vice President of Research and Development at Harvard Apparatus Regenerative Technology, Inc. Tom joined the Harvard Apparatus Regenerative Technology from Organogenesis, where he implemented and completed efficacy and preclinical pharmacology and toxicology programs for bioengineered living skin graft in anticipation of an Investigational New Drug application. He developed wound healing, skin grafting, and oral regeneration models in swine for in vivo evaluation of adult stem cell suspensions, living, bioengineered constructs and biomaterials. He maintained strong cross-functional interactions with Clinical Operations to ensure meaningful translation of swine studies while partnering with business units to provide scientific support for corporate strategies. Tom received his BSc in Biochemistry from the University of Waterloo and PhD in Biochemistry from the University of Notre Dame.

**John Getz** is the Federal Deputy Program Manager for the ATB-MII. He serves as a Product Manager in the Tissue Injury and Regenerative Medicine Project Management Office (TIRM PMO) at the US Army Medical Materiel Development Activity (USAMMDA) on Ft Detrick, MD. The TIRM PMO is responsible for developing and delivering innovative products to restore form, function, and appearance for wounded warriors who have suffered catastrophic injuries. His project efforts span many Defense-related regenerative medicine areas including: extremity injury, prosthetics, assistive technologies, haptics and proprioception, as well as advanced pharmaceutical systems.

John is a certified Defense Acquisition Professional Program Management Level 2. He has worked in project management, medical intelligence, biotechnology product development, business and military operations, and strategic communications for over 12 years and has an extensive background in forensic radiology, advanced injury analysis, weapon, vehicle and personnel protection systems projects for advanced warfighter capabilities. John holds a BSc in Biology with emphasis in chemistry from Millersville University.

**Kelvin H. Lee** is the Director of the Manufacturing USA National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and is the Gore Professor of Chemical and Biomolecular Engineering at the University of Delaware. He previously served as Director of the Delaware Biotechnology Institute. He received a BSE in Chemical Engineering from Princeton and PhD in Chemical Engineering from Caltech. He spent several years in the Biotechnology Institute at the ETH in Zurich, Switzerland and also completed a postdoc in Caltech's Biology Division. Prior to his current appointment, he was on the faculty at Cornell University where he

held the titles of Samuel C. and Nancy M. Fleming Chair Professor, Professor in the School of Chemical and Biomolecular Engineering, Director of the Cornell Institute for Biotechnology, and Director of the New York State Center for Life Science Enterprise.

**Willie E. May** served as the 15th Director of the National Institute of Standards and Technology (NIST) until his retirement in early January 2017. He also served as Under Secretary of Commerce for Standards and Technology, a position created in the America COMPETES Reauthorization Act of 2010. Previously at NIST, he served as Associate Director for Laboratory Programs, where he was responsible for oversight and direction of NIST's seven laboratory programs and served as the principal deputy to the NIST Director. As NIST Director, Willie provided high-level oversight and direction for NIST, to fulfill the agency mission to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology.

Willie led NIST's research and measurement service programs in chemistry-related areas for more than 20 years. His personal research activities were focused in the areas of trace organic analytical chemistry and physico-chemical properties of organic compounds, where his work is described in more than 85-archival publications. Willie received his BS from Knoxville College, and his PhD from the University of Maryland. He has received numerous awards for both his technical leadership and accomplishments and his tireless advocacy promoting diversity in STEM professions.

**Richard McFarland** is the Chair of the Multiagency Tissue Engineering Subcommittee (MATES) within the White House National Science and Technology Council (NSTC) committee on Technology. He is currently the Associate Director for Policy in the Office of Tissues and Advanced Therapies (OTAT – formerly the Office of Cellular, Tissues and Gene Therapies, or OCTGT) in the Center for Biologics Evaluation and Research (CBER), at the U.S. Food and Drug Administration (FDA). In this capacity, he serves as a primary contact for regulatory policy issues, guidance development, and product jurisdiction for the office. Richard has 10 years of experience in the FDA/CBER, 5 primarily as a pharmacology/toxicology reviewer in the former Office of Therapeutics, Research and Review (OTRR) and in the OCTGT. In addition to MATES, Richard has represented CBER on multiple Interagency Committees during his federal service.

Prior to joining CBER, Richard was a faculty member in the Department of Pathology at the University of Texas Southwestern Medical School (UT Southwestern) and an attending physician at Parkland Memorial Hospital. He received a BSc in zoology, a PhD in experimental pathology, and a MD from the University of North Carolina at Chapel Hill. He completed residency training in anatomic and clinical pathology and fellowship training in immunopathology at the University of Texas Southwestern/Parkland Memorial Hospital, Dallas, Texas, USA.

**Margy Phillips** is the Federal Program Manager for the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) Manufacturing USA institute. She is responsible for managing and overseeing the various aspects of the award for NIST and the Federal government. She is a member of NIST's Office of Advanced Manufacturing and works closely with the network of Manufacturing USA institutes. Margy has held a variety of program management positions throughout NIST since 1995, including those in the Advanced Manufacturing National Program Office, the Materials Measurement Laboratory, the Technology Innovation Program, Advanced Technology Program and the Hollings Manufacturing Extension Partnership program.

Her prior experience includes 5 years with Lawrence Associates, Inc. in Dayton, OH, a consulting and technical services firm. Margy managed the firm's technology transfer division, working with DoD laboratories to design and implement technology transfer strategies and activities. Additionally, she served in the U.S. Air Force for 10 years, in a variety of acquisition, program management, contracting and manufacturing related duties. Margy's education includes a BS and MS in Chemistry, an MBA in Acquisition and Contracting, and a JD.

**(Russell) Kirk Pirlo** is the Federal Chief Technology Officer for the ATB-MII. He is currently a Biological Researcher at the US Naval Research Laboratory (USNRL) where his research is focused on development of novel bioprinting substrates and modular bioreactor systems. Kirk earned a BS in Physics from West Virginia University and a PhD in Bioengineering from Clemson University.

**Kristy Pottol** is the Federal Program Manager for the ATB-MII. Kristy is the Project Manager and Director of the Tissue Injury and Regenerative Medicine Project Management Office (TIRM PMO) at the US Army Medical Materiel Development Activity on Ft Detrick, MD. The TIRM PMO is responsible for developing and delivering innovative products to restore form, function, and appearance for wounded warriors who have suffered catastrophic injuries. The project efforts range across many Defense-related regenerative medicine, prosthetics, and sensory projects spanning skin repair, extremity injury, craniomaxillofacial injury, vascularized composite allotransplantation (hand and face transplants), genitourinary injury, hearing loss, and assistive technologies.

Kristy is a certified Defense Acquisition Professional Program Management Level 3 and Project Management Professional (PMP). She has worked in project management, biotechnology product development, FDA quality systems, business operations, and strategic communications for over 15 years and has an extensive and varied background in product development projects for militarily-relevant medical solutions from vaccines to devices. She spent six years in service, in the US Navy and Army National Guard. She holds an MBA from Regis University, a MSc in

Accounting with an emphasis on Information Systems from the University of North Carolina at Wilmington, and a BS in Physics with an emphasis in biophysics from East Carolina University.

**Kelley Rogers** is the Federal Technical Program Manager for the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) Manufacturing USA institute. Kelley is currently on detail in the Office of Advanced Manufacturing Office at NIST, and a Technical Program Director for Biosciences within the Material Measurement Laboratory (MML). Kelley worked previously in the pharmaceutical industry as a principal investigator for Antimicrobials R&D. She received a PhD from Yale University, Department of Molecular Biophysics and Biochemistry, and a BA from Hendrix College. As a researcher, Kelley focused on eubacterial protein synthesis machinery and cell signaling pathways in model eukaryotic systems.

**Phil Singerman** is the Associate Director for Innovation and Industry Services at the National Institute of Standards and Technology (NIST). In this capacity he is responsible for the NIST suite of external partnership programs, including the Hollings Manufacturing Extension Partnership, the Baldrige Performance Excellence Program, the Office of Advanced Manufacturing, NIST technology transfer, economic analysis, and small business innovation research awards. Phil serves as the U. S. Co-Chair of the Israel–U.S. Binational Industrial Research and Development (BIRD) Foundation and on the U.S. – India Science & Technology Endowment Board (STEB) and the Stakeholders Council of the Advanced Functional Fabrics of America (AFFOA). Prior to joining NIST, he was a Senior Vice President at B&D Consulting, a DC-based firm providing strategic advice and technical assistance on federal economic development programs to nonprofit organizations, local governments, and universities. Previously he was a managing director of a \$120 million seed stage venture fund that invested in biotechnology.

Phil has more than 35 years of experience in technology based economic development; he was the first chief executive of two of the best known and longest lasting private-public partnerships: the Ben Franklin Technology Center of Southeastern Pennsylvania and the Maryland Technology Development Corporation. During the Clinton Administration he served as U.S. Assistant Secretary of Commerce for Economic Development. Phil has participated on scores of local, state, and national advisory boards and associations, including the State Science and Technology Institute, the Technology Council of Maryland, the International Economic Development Council (IEDC), National Governors Association Advisory Committee on Entrepreneurial Policy, and the National Science Foundation Small Business Advisory Committee. He was the 2011 recipient of IEDC's Federal Leadership in Economic Development Award. Phil received his BA from Oberlin College and holds a PhD from Yale University. He has taught at Yale College, Barnard College (Columbia University), and the Fels Institute of Government (University of Pennsylvania). After graduating from college he served as a Peace Corps Volunteer in Colombia, South America, working in rural community development.