

**Regulatory Science to Advance Precision Medicine Forum**  
**A Meeting by University of Rochester, PhRMA Foundation, and University of Virginia**

**Wednesday, September 27, 2017**  
**9:00am – 3:30pm**

**PhRMA Foundation**  
**950 F Street NW**  
**Washington, DC 20004**

**Agenda**

- 9:00 am Continental Breakfast
- 9:30 am Welcome (*Eileen Cannon and Bill Chin, PhRMA Foundation*)
- 9:35 am Review of Meeting Objectives (*Joan Adamo and Scott Steele, University of Rochester*)
- 9:45 am 3D Printing of Medical Products: Presentation(s) and discussion
- Emerging Science (*John Fisher, University of Maryland*)
  - Considerations to Inform Regulatory Decision-Making (*Richard McFarland, ARMI*)
- 10:45 am Omics for Precision Medicine: Presentation(s) and discussion
- Emerging Science (*Shashikant Kulkarni, Baylor College of Medicine*)
  - Considerations to Inform Regulatory Decision-Making (*Michael Pacanowski, Soma Ghosh and Zivana Tezak, CDER / CDRH FDA*)
- 11:45 am Discussion and Charge to the Breakout Groups (*Scott Steele, University of Rochester*)
- 12:00 pm Working Lunch: Breakout Group Sessions
- 1:45 pm Break
- 2:00 pm Reports from the Breakout Groups and Discussion
- 3D Printing
  - Omics for Precision Medicine
- 3:00 pm Review Progress and Identify Next Steps (*Robert Meyer, University of Virginia*)
- 3:30 pm Adjourn



## **Regulatory Science to Advance Precision Medicine Forum Participants:**

[Joan Adamo](#), Director, Regulatory Support Services and Assistant Professor, Biomedical Engineering, Clinical and Translational Science Institute, University of Rochester Medical Center

[Robert Bienvenu II](#), Adjunct Assistant Professor, Daniel K. Inouye Graduate School of Nursing, Uniformed Services University

[Khaled Bourj](#), Office of the Chief Scientist, FDA

[Jennifer Brown](#), Director, Clinical Research Quality, Spectrum, Stanford Center for Clinical & Translational Research & Education

[Bruce Burnett](#), Director of Regulatory Affairs and Quality, Duke Translational Medicine Institute, Duke University; Office of Research Support and Compliance, Office of the Director, NIH

[Eileen Cannon](#), President, PhRMA Foundation

[Christine Colvis](#), Director, Drug Development Partnership Programs, National Center for Advancing Translational Sciences, NIH

[Owen Fields](#), Vice President, Inflammation and Immunology – Regulatory, Worldwide Safety & Regulatory, Pfizer Inc.

[John Fisher](#), Director, Center for Engineering Complex Tissues and Chair, Fischell Department of Biomedical Engineering, University of Maryland

[Soma Ghosh](#), Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA

[John Gigantino](#), Director, Global Regulatory Affairs, Sanofi

[Mathangi Gopalakrishnan](#), Research Assistant Professor, Center for Translational Medicine, University of Maryland

[Warren Grayson](#), Associate Professor, Department of Biomedical Engineering, Johns Hopkins University

[Heather Hatcher](#), Clinical and Translational Science Institute, Wake Forest Baptist Medical Center

[Scott Hollister](#), Professor, Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology and Emory University

[Rosemarie Hunziker](#), Tissue Engineering/Regenerative Medicine Program Director, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health

[Christina Jones](#), Research Chemist, Organic Chemical Measurement Science Group, NIST

[Karl Kieburtz](#), Professor, Neurology, University of Rochester Medical Center

[Shashikant Kulkarni](#), Professor & Vice Chairman for Research, Department of Molecular and Human Genetics, Baylor College of Medicine; Chief Scientific Officer and Senior Vice President, Baylor Genetics

[Michael Liebman](#), Founder, IPQ Analytics, Adjunct Professor of Pharmacology and Physiology, Drexel College of Medicine

[Sheng Lin-Gibson](#), Leader, Biomaterials Group, Biosystems and Biomaterials Division, NIST

[Mark Lowenthal](#), Research Chemist, Bioanalytical Science Group, NIST

[Don McClain](#), Director, Clinical and Translational Science Institute and Professor of Medicine, Endocrinology and Metabolism, Wake Forest Baptist Medical Center

[Richard McFarland](#), Chief Regulatory Officer, Advanced Regenerative Manufacturing Institute/ BioFabUSA

[Sean Mellican](#), Takeda Pharmaceuticals, Inc.

[Robert Meyer](#), Director, Virginia Center for Translational and Regulatory Sciences and Associate Professor, Public Health Sciences, University of Virginia

[Andrika Morant](#), Clinical Translational Science Center, Weill Cornell Medicine

[Michael Pacanowski](#), Office of Clinical Pharmacology, CDER, FDA

[Daryl Pritchard](#), Vice President, Science Policy, Personalized Medicine Coalition

[Henry Rodriguez](#), Director, Office of Cancer Clinical Proteomics Research, National Cancer Institute, NIH

[Kelley Rogers](#), Federal Technical Program Manager, NIIMBL, NIST

[Noel Southall](#), Leader, Informatics, National Center for Advancing Translational Sciences, NIH

[Scott Steele](#), Director, Regulatory Science Programs and Associate Professor, Public Health Sciences, Clinical and Translational Science Institute, University of Rochester Medical Center

[Zivana Tezak](#), Office of In Vitro Diagnostics and Radiological Health, CDRH, FDA

[Bruce Wilcox](#), SVP, Research & Development, Applied Proteomics, Inc.

[Jeanne Wright](#), Clinical Research Project Manager, Michigan Institute for Clinical and Health Research, University of Michigan at Ann Arbor

[Carolyn Yong](#), Team Leader, Device and Combination Products, Cell Therapies Branch, Office of Tissues and Advanced Therapies, CBER, FDA

[Yuan-Shan Zhu](#), Clinical and Translational Science Center & Weill Department of Medicine, Weill Cornell Medicine



*The project is supported by the University of Rochester CTSA award number UL1 TR002001 from the National Center for Advancing Translational Sciences of the National Institutes of Health. The content does not necessarily represent the official views of the National Institutes of Health.*