NATIONAL MATERIALS AND MANUFACTURING BOARD

Roundtable on Biomedical Engineering Materials and Applications

The National Academies' Keck Center Room 101
March 25-26, 2018

Medical Product Development: Changes, Challenges, Strategies, Relationships Among Stakeholders

AGENDA

Sunday, March 25, 2018

6:00 pm — Committee Dinner
Carmine's Italian Restaurant, 425 7th St NW, Washington, DC 20004
After-dinner talk – Art Coury - *Corporate Research Collaborations: Lessons from a "Journeyman" Technology*

Monday, March 26, 2018

7:30 am — Breakfast available

8:00 am — Welcome – Art Coury and Becky Bergman, BEMA Co-chairs

8:10 am — *Assessing Opportunities and Business Relationships to Optimize Development Strategies – A Buy Side View*
Anjali Kumar, Shire Pharmaceuticals

9:00 am — *Pioneering as a Unique Approach to Life Science Innovation*
Jason Park, Flagship Pioneering

9:50 am — *Break*

10:05 am — *CDRH: No Longer the Big Bad Wolf*
Terry Woods, FDA

10:30 am — *CDRH's Breakthrough Devices Program: A Regulatory Path to Expedite Medical Device Development and Review*
Maureen Dreher, FDA

11:00 pm — *Academia - Industry – Investor Commercialization Pathways: Changes and Perspective*
Arikha Moses, Galatea Surgical; Joachim Kohn, Rutgers University

11:50 pm — *Lunch*

12:50 pm — *Antimicrobial Combination Medical Device Translation: Barriers in the University-Industry Translational Ecosystem*
David Grainger, University of Utah

1:40 pm	*The Necessity for Alignment and Collaboration Across Regulatory and Reimbursement Axes in Product Development* Scott Bruder, Consultant
2:30 pm	*Break*
2:45 pm	*Accelerating Innovation Through External Partnerships* Nicholas Pachuda, Johnson & Johnson
3:35 pm	*BioFabUSA: A New Strategy for Advancing the Scale of Manufacturing Infrastructure for Engineered Organs and Tissues* Richard McFarland, ARMI
4:25 pm	Rapporteur Report – Stacey Sullivan, FDA
4:45 pm	Planning for next meeting
5:00 pm	Adjourn