Center for Health Policy at BROOKINGS

Promoting Continuous Manufacturing in the Pharmaceutical Sector

The Brookings Institution • Washington, DC

October 19, 2015

8:30 a.m. **Registration**

9:00 a.m. **Welcome, Overview, and Meeting Objectives**

Mark McClellan, Senior Fellow and Director, Health Care Innovation and Value Initiative, The Brookings Institution

Greg Daniel, Fellow and Managing Director, Center for Health Policy, The Brookings Institution

9:15 a.m. **Promoting the Adoption of Continuous Manufacturing in the Pharmaceutical Industry: the FDA perspective**

Janet Woodcock, Director, Center for Drug Evaluation and Research, US Food and Drug Administration

9:30 a.m. **Session I: Assessing the Current Landscape and Future Direction for Continuous Manufacturing**

Mark McClellan, *Moderator*

Panelists:

- Lawrence Yu, Deputy Director, Office of Pharmaceutical Quality, US Food and Drug Administration
- Fernando Muzzio, Director, Center for Structured Organic Particulate Systems, & Distinguished Professor, Chemical and Biochemical Engineering, Rutgers University
- Alastair Florence, Professor of Pharmaceutical Science & Director, EPSRC Centre for Innovative Manufacturing in Continuous Manufacturing and Crystallisation, University of Strathclyde
- Markus Krumme, Head of the Continuous Manufacturing Unit, Novartis Pharmaceuticals
- Konstantin Konstantinov, Vice President, Late Stage Process Development, Sanofi

10:30 a.m. **Break**

10:45 a.m. **Session II: Improving Scientific and Technical Knowledge to Support Continuous Manufacturing**

Mark McClellan, *Moderator*

Panelists:

- Mel Koch, Principle Scientist, Center for Process Analysis and Control (CPAC), University of Washington
- Richard Braatz, Edwin R. Gilliland Professor of Chemical Engineering, Massachusetts Institute of Technology

- Michael O'Brien, Senior Vice President, Global Science, Technology and Commercialization, Pfizer
- Eliana Clark, Vice President, Global Manufacturing Sciences, Biogen
- Eugene Choi, Technical Advisor to the Defense Advanced Research Projects Agency, Strategic Analysis, Inc.

12:00 p.m. **Lunch**

1:00 p.m. **Session III: Addressing Barriers to the Adoption of Continuous Manufacturing**
Greg Daniel, *Moderator*

Panelists:

- Patricia Hurter, SVP, Global Pharmaceutical Development, Vertex
- Frank Montgomery, Global Head, Regulatory CMC, AstraZeneca
- Johannes Khinast, Head of the Institute of Process and Particle Engineering, & Scientific Director, Research Center of Pharmaceutical Engineering (RCPE), Graz University of Technology
- Robin Robinson, Director, Biomedical Advanced Research and Development Authority, & Deputy Assistant Secretary for Preparedness & Response, US Department of Health and Human Services

2:30 p.m. **Break**

2:45 p.m. **Session IV: Building Stakeholder Collaborations to Facilitate the Implementation of Continuous Manufacturing**
Greg Daniel, *Moderator*

Panelists:

- Clive Badman, Head of Pre-Competitive Collaboration, GSK
- Liam Feely, Vice President, Manufacturing Science & Technology, AbbVie
- Gintaras Reklaitis, Burton and Kathryn Gedge Distinguished Professor of Chemical Engineering, Purdue University
- Seongkyu Yoon, Assistant Professor of Chemical Engineering, University of Massachusetts at Lowell
- Keith Roper, Program Director, Engineering Research Centers, National Science Foundation

3:45 p.m. **Closing Remarks**
Greg Daniel

4:00 p.m. **Adjournment**

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