

B | ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

**Measuring Pharmaceutical Quality through Manufacturing Metrics and
Risk-Based Assessment**

The Brookings Institution • Washington, DC

May 1 & 2, 2014

May 1st, 2014

- 8:30 a.m. Welcome and Overview**
Mark McClellan, Health Care Innovation and Value Initiative, Brookings Institution
Greg Daniel, Engelberg Center for Health Care Reform, Brookings Institution
- 8:45 a.m. Office of Pharmaceutical Quality (OPQ): An Evolution Towards Quality in Review, Inspection, and Surveillance**
Theresa Mullin, U.S. Food and Drug Administration
- 9:00 a.m. Pharmaceutical Quality Metrics: Goals and Stakeholder Feedback**
Mark McClellan — *Moderator*
Russell Wesdyk, U.S. Food and Drug Administration
Katy George, McKinsey & Company
- 10:15 a.m. Break**
- 10:30 a.m. Reflecting on the Consensus Set of Metrics and Approaches**
Mark McClellan — *Moderator*
G.K. Raju, Light Pharma Inc.
Martin VanTrieste, Amgen, Inc.
Donna Gulbinski, Bristol-Myers Squibb
Vinay Bhatt, Zydus Pharmaceuticals (USA) LLC
- 11:30 a.m. Exploring the Use of Metrics in Purchasing Decisions**
Mark McClellan — *Moderator*
Paula Gurz, Premier Healthcare Alliance
Ferdinando Aspesi, Novartis
Deborah M. Autor, Mylan
- 12:30 p.m. Lunch**

*Convened by the Engelberg Center for Health Care Reform at Brookings
and supported by a cooperative agreement with the U.S. Food and Drug Administration*

- 1:30 p.m. Opportunities and Challenges in Implementing a Core Set of Metrics**
Mark McClellan — *Moderator*
Barbara Allen, Eli Lilly and Company
Linda Evans O'Connor, Teva Pharmaceuticals
Joachim Del Boca, Vetter Pharma-Fertigung GmbH & Co. KG
Luisa Paulo, Hovione FarmaCiencia SA
- 3:30 p.m. Presentation of Metrics Discussion Set**
Mark McClellan — *Moderator*
Russell Wesdyk, U.S. Food and Drug Administration
- 4:50 p.m. Closing Remarks**
Greg Daniel
- 5:00 p.m. Adjournment**

B | ENGELBERG CENTER for
Health Care Reform
at BROOKINGS

**Measuring Pharmaceutical Quality through Manufacturing Metrics and
Risk-Based Assessment**

The Brookings Institution • Washington, DC

May 1 & 2, 2014

May 2nd, 2014

- 8:30 a.m.** **Welcome and Overview**
Greg Daniel, Engelberg Center for Health Care Reform, Brookings Institution
- 8:45 a.m.** **U.S. Food and Drug Administration Remarks**
Theresa Mullin, U.S. Food and Drug Administration
- 9:00 a.m.** **Review of Metrics Discussion Set**
Greg Daniel — *Moderator*
Russell Wesdyk, U.S. Food and Drug Administration
- 9:15 a.m.** **Exploring and Adapting the Metrics Discussion Set: Concerns, Additions, and Deletions**
Greg Daniel — *Moderator*
- 10:45 a.m.** **Break**
- 11:00 a.m.** **Exploring and Adapting the Metrics Discussion Set: Definitions**
Greg Daniel — *Moderator*
- 12:00 p.m.** **Lunch**
- 1:00 p.m.** **Exploring and Adapting the Metrics Discussion Set: Issues in Implementation**
Greg Daniel — *Moderator*
- 2:30 p.m.** **Break**
- 2:45 p.m.** **Next Steps in Metrics Discussion Set**
Greg Daniel — *Moderator*
- 3:50 p.m.** **Closing Remarks**
Greg Daniel
- 4:00 p.m.** **Adjournment**

*Convened by the Engelberg Center for Health Care Reform at Brookings
and supported by a cooperative agreement with the U.S. Food and Drug Administration*