

**Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches**

June 08, 2023 | 9:00 a.m. – 4:30 p.m. ET

National Press Club, Washington D.C.

**9:00 a.m. Welcome and Opening Remarks**

*Mark McClellan*, Duke-Margolis Center for Health Policy

**9:15 a.m. Current Regulatory Frameworks and Tools**

U.S. Food and Drug Administration (FDA) leadership will present key information about FDA's work on promoting innovative manufacturing, including the work of the CDER Emerging Technology Program (ETP) and the CBER Advanced Technologies Team (CATT). The presentations will include an overview of high-level FDA aims for advanced manufacturing under each program and relevant regulatory guidance to date.

Presenters:

- *Larry Lee*, Center for Drug Evaluation and Research, FDA
- *Manuel Osorio*, Center for Biologics Evaluation and Research, FDA

**10:00 a.m. Break**

**10:15 a.m. Case Studies and Lessons Learned**

Several sponsors of submissions using innovative manufacturing technology will each briefly present case studies detailing their experience with the ETP and CATT. Then, during a moderated discussion, sponsors will discuss best practices and key lessons learned to support future successful submissions.

Moderator: *Thomas O'Connor*, Center for Drug Evaluation and Research, FDA

Panelists:

- *Ahmad Almaya*, Eli Lilly and Company
- *Paul Kirwan*, Amgen
- *Celeste Frankenfeld Lamm*, Merck
- *Kimberly Schultz*, Center for Biologics Evaluation and Research, FDA
- *Nandita Vishwanathan*, EMD Serono

**11:25 a.m. Break**

**12:35 p.m. Regulatory Challenges to Adoption**

FDA will review recent work identifying regulatory challenges to adoption of advanced manufacturing. Then, a panel of speakers with expertise in multiple types of innovative manufacturing technologies will share their perspectives on perspectives on regulatory

barriers that could still pose challenges and further steps to enable more widespread adoption of these technologies.

Presenter: *Riley Myers*, Center for Drug Evaluation and Research, FDA

Moderator: *Adam Fisher*, Center for Drug Evaluation and Research, FDA

Panelists:

- *Ahmad Almaya*, European Federation of Pharmaceutical Industries and Associations
- *Ingrid Markovic*, Center for Biologics Evaluation and Research, FDA
- *Fernando Muzzio*, Rutgers University
- *Roger Nosal*, International Society for Pharmaceutical Engineering
- *Gert Thurau*, Roche

**2:00 p.m. Break**

**2:20 p.m. Advanced Manufacturing Technologies Designation Program**

FDA will provide an overview of the Advanced Manufacturing Technologies Designation Program as established by the Consolidated Appropriations Act of 2023, including the program's aims, scope, and timeline for implementation.

Presenter: *Ranjani Prabhakara*, Center for Drug Evaluation and Research, FDA

**2:30 p.m. Regulatory Strategies for Adoption and Next Steps**

Panelists will provide feedback on implementation and scope for the Advanced Manufacturing Technologies Designation program, as well as any additional considerations that should guide implementation. Drawing on presentations and discussions throughout the day, panelists will also consider additional regulatory strategies or approaches FDA could consider to support the adoption of innovative manufacturing technologies.

Moderator: *Stephen Colvill*, Duke-Margolis Center for Health Policy

Panelists:

- *Celeste Frankenfeld Lamm*, Merck
- *Andrew Kuzmission*, Vertex Pharmaceuticals
- *Cornell Stamoran*, Catalent
- *Ben Stevens*, GlaxoSmithKline
- *Joel Welch*, Center for Drug Evaluation and Research, FDA

**4:15 p.m. Closing Remarks**

*Gerrit Hamre*, Duke-Margolis Center for Health Policy

**4:30 p.m. Adjourn**