Welcome to Day 3

Diane Paskiet, Director of Scientific Affairs
West Pharmaceutical Services

Day 2 Recap

- ***Session 3: DM/POC Location and Sizes of Spaces at Sites***
  - Moderator: Cat Vicente, Johnson & Johnson
  - Distributed Manufacturing Spaces – Options and Considerations
    - Dennis Powers, G-CON
  - Modular Robotic Systems for the Distributed Manufacturing of Personalized Drug Products
    - Fred Parietti, Multiply Labs
  - Q&A Panel, including Rakhi Shah, FDA and Christine Moore, Organon
- ***Session 4: Structure of DM/POC Pharmaceutical Quality Systems and Assuring Quality Oversight***
  - Moderator: Dave Schoneker, Black Diamond Regulatory Consulting, LLC
  - Distributed Manufacturing Pharmaceutical Quality Systems
    - Celeste Frankenfeld Lamm, Merck & Co., Inc.
  - Point-of-Care Pharmaceutical Quality Systems
    - Paul Smolenski, DEKA
  - Q&A Panel, including Ashley Boam, FDA
- ***Breakout Rooms on Session 3 and 4***

Day 3 Looking Ahead

- ***Session 5: Strategies to Ensure that Drugs and Biologics Meet Established Specifications***
  - Moderator: Diane Paskiet, West
  - Ensuring the Quality of Therapeutics Proteins
    - Chris Love, MIT
  - Ensuring the Quality of Small Molecules
    - Tom Roper, VCU
  - **NOTE: We will not have a Q&A Panel after this session. There will be time after each presentation to ask Questions of the presenters.**
- ***Breakout Rooms on Session 5***
- ***Session 6: DM/POC Suitability for CBER Regulated Products***
  - Moderator: Carolyn Yong, FDA
  - CBER's Perspective on Distributed Manufacturing and Point-of-Care Manufacturing of Complex Biologics
    - Laura Ricles, FDA
  - DM and POC – Ensuring the Quality of Autologous Cell Therapy
    - Laura Sands, Lonza
  - Design of Quality Systems and Oversight for CGT Products under DM/POC Manufacturing Models
    - Richard McFarland, ARMI
  - Panel Discussion and Q&A, including Steven Oh, FDA
- ***Breakout Rooms on Session 6***

REMINDER

If you have additional feedback, please submit comments on the DM/POC Discussion Paper under docket number FDA-2022-N-2316 by December 13th, 2022.