The Evolution of Biopharmaceutics: Risk Assessment and Clinical Relevance

Public Workshop
April 30–May 1, 2026

Universities at Shady Grove
Rockville, Maryland

Hosted by the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)

Workshop Planning Team

We extend our sincere gratitude to the distinguished members of the planning team whose expertise and dedication made this workshop possible:

Dr. James Polli – Professor and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics, University of Maryland School of Pharmacy

Dr. Andreas Abend – Director, Merck & Co., Inc.

Dr. Emilija Fredro-Kumbaradzi – Director, Biopharmaceutics & Statistics, R&D, Apotex, Inc.

Dr. Robert Gaines, Jr. – Senior Director, Sciences and Regulatory Affairs, Association for Accessible Medicines

Dr. Helena Engman – Senior Principal Scientist, ADME Sciences, Seda Pharmaceutical Development Services

Dr. Rebecca Moody – Pharmaceutical Scientist, OPQA II, OPQ, CDER, FDA

Dr. Hailing Zhang – Division Director, DPQA XII, OPQA II, OPQ, CDER, FDA

Special thanks goes to Ms. Dana Hammell, M.S. Department of Pharmaceutical Sciences University of Maryland-School of Pharmacy!

Thank You to Our Workshop Sponsors

- Johnson and Johnson / Janssen
- Merck Research Laboratories
- Takeda Pharmaceuticals
- Drug Delivery Foundation
- Verder Scientific
- Physiolution Polska

Workshop Vision and Objectives

-A Transformative Approach to Dissolution Testing

This two-day public workshop represents a paradigm shift in the role of dissolution testing in regulatory decision-making—moving beyond traditional quality control toward a predictive, patient-centric science.

Key Workshop Themes:

- From Quality Control to Predictive Tool – Exploring dissolution testing's evolution from a compliance measure to a strategic tool that ensures adequate clinical performance throughout a drug product's lifecycle
- Comprehensive Risk Assessment Framework – Examining the interplay between API physicochemical properties, formulation complexity and release characteristics, and gastrointestinal physiological conditions to classify products from very low to very high risk. The risk level determines the appropriate dissolution testing strategy and regulatory requirements, ensuring consistent clinical performance.
- Patient-Centric Quality Standards – Aligning dissolution testing with actual patient outcomes rather than specifications with limited clinical correlation, improving product understanding while reducing regulatory burden for moderate- to high-risk drug products

Day 1 Agenda Overview

Morning Sessions:

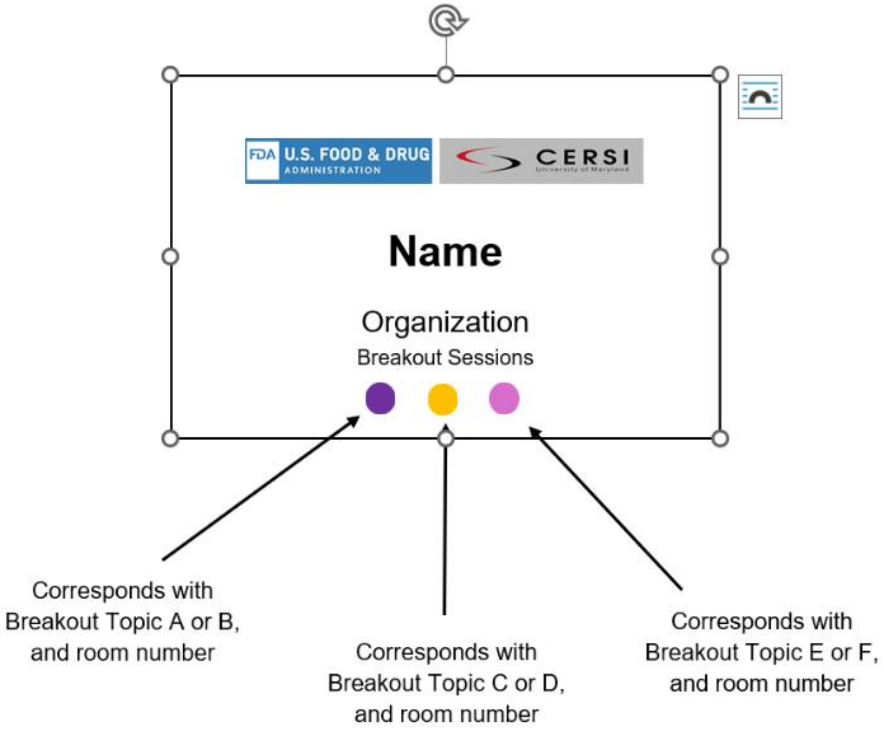
- *Session 1*: Biopharmaceutics Risk Assessment Framework (Session Leads: Dr. Helena Engman & Dr. Hailing Zhang)
- *Session 2*: High Risk Drug Products – IVIVC and IVIVR (Session Leads: Dr. James Polli, Dr. Filippos Kesisoglou, & Dr. Haritha Mandula)

Afternoon Sessions:

- *Session 3*: Medium Risk Drug Products (Session Leads: Dr. Emilija Fredro-Kumbaradzi, Dr. Duxin Sun, Dr. Hailing Zhang, & Dr. Ahmed Zidan)
- Breakout Sessions (2:15 PM – 5:00 PM): Interactive discussions on implementing the framework, characterizing high-risk products, and differentiating and managing medium-risk products
  - ❑ Breakout session 1
  - ➢ Topic A: Implementing Biopharmaceutics Risk Assessment Framework: Practical Strategies for Drug Development and Regulatory Decision-Making (**Topic Lead- Dr. Claire Mackie**)
  - ➢ Topic B: A Framework for Biopharmaceutics Risk Characterization and Mitigation Strategies for High-Risk Drug Products with Emphasis on Clinical Relevance **(Topic Lead – Dr. Jim Polli)**

  - ❑ Breakout Session 2
  - ➢ Topic C - What Biopharmaceutics Characteristics Differentiate a Medium Risk Product from a Low or High Risk Product? **(Topic Lead - Dr. Xiaoming Xu)**
  - ➢ Topic D - What Would be the Appropriate Control Strategy for Medium Risk Products to Ensure Bioperformance? (Topic **Lead - Dr. Joseph Kushner)**

Breakout Sessions -Decode the color



Breakout Sessions -Decode the color

Day 1 Session 1 - 2:15 PM – 3:30 PM				
Topic A	1032	2032	2052	Ballroom
Topic B	2062	3012	3022	3032

Day 1 Session 2 - 3:45 PM – 5:00 PM				
Topic C	1032	2032	2052	Ballroom
Topic D	2062	3012	3022	3032

Day 2 Session 3 - 1:00 PM – 2:15 PM				
Topic E	1032	2032	2052	Ballroom
Topic F	2062	3012	3022	3032

Session 1: Biopharmaceutics Risk Assessment Framework

Featured Presentations:

- **8:35 AM – Keynote Address**
  "The Evolution of Dissolution Testing: Toward Prediction of In Vivo Performance"
  Dr. Lawrence X. Yu – Director, OPQA II, OPQ, CDER, FDA; Adjunct Professor, University of Michigan

- **8:55 AM**
  "Current Biopharmaceutical Risk Assessment Practices in New Drug Product Development of Solid Oral Dosage Forms"
  Dr. Filippos Kesisoglou – Scientific Associate VP, Pharmaceutical Sciences, Merck & Co., Inc.

- **9:15 AM**
  "Underutilized and Recent Laboratory and Data Analysis Approaches to Assess Oral Biopharmaceutics Risk"
  Dr. James Polli – Professor and Ralph F. Shangraw/Noxell Endowed Chair, University of Maryland School of Pharmacy

- **9:35 AM**
  "Predictive Biopharmaceutics: A Deep Dive into the Risk Assessment Framework"
  Dr. Bhagwant Rege – Division Director, DPQA VI, OPQA I, OPQ, CDER, FDA