The Evolution of Biopharmaceutics: Risk Assessment and Clinical Relevance

Public Workshop
April 30-May 1, 2026
Agenda

Thursday, April 30
Day 1

7:45 AM – 8:30 AM ***Registration***

Session 1: Biopharmaceutics Risk Assessment Framework
Session Leads: Dr. Helena Engman and Dr. Hailing Zhang
Scope: This foundational session establishes the core framework that connects dissolution testing to in vivo pharmacokinetic profiles. Presentations will cover how API physicochemical properties and drug product CBAs interact with gastrointestinal physiological conditions (pH, food effects, GI tract mobility) to determine in vivo dissolution and absorption. The session will demonstrate how this understanding enables the development of dissolution tests that are indicative of bio-performance rather than simply ensuring batch-to-batch consistency.

8:30 AM – 9:00 AM ***Welcome & Keynote (Introductions for Session 1 Speakers)***
TBD

9:00 AM – 9:30 AM ***Keynote: The Future of Biopharmaceutics***
Lawrence Yu, PhD Director, OPQA II, OPQ, CDER, FDA; Adjunct Professor, Univ. of Michigan

9:30 AM – 10:00 AM ***Industry Implementation of Risk-Based Biopharmaceutics Assessment***
Andreas Abend, PhD Director, Merck

10:00 AM – 10:30 AM ***Recent Scientific Assessment***
James Polli, PhD Professor and Ralph F. Shangraw/Noxell Endowed Chair in Industrial Pharmacy and Pharmaceutics, University of Maryland School of Pharmacy

10:30 AM – 10:45 AM ***Break***

Session 2: High Risk Drug Products-IVIVC and IVIVR
Session Leads: Dr. Haritha Mandula
Scope: This session focuses on products where in vivo pharmacokinetic profiles are dictated by in vivo drug release. Discussions will cover required mitigation strategies including in vivo studies to establish and validate IVIVC, the development of IVIVR to define "Bioequivalence Safe Spaces," and the supplementary role of Physiologically Based Biopharmaceutics Modeling (PBBM) in understanding and establishing these correlations.

10:45 AM – 10:50 AM ***Speaker Introductions***
Haritha Mandula, PhD Lead Pharmacologist, DPQA VI, OPQA I, OPQ, CDER, FDA

10:50 AM – 11:10 AM ***The Biopharmaceutics Risk Assessment Framework***
Bhagwant Rege, PhD Division Director, DPQA VI, OPQA I, OPQ, CDER, FDA

11:10 AM – 11:30 AM ***Title***
TBD Organization

11:30 AM – 11:50 AM ***Title***
TBD Organization

11:50 AM – 12:10 PM ***Title***
TBD Organization

12:10 PM – 1:10 PM ***Lunch Break***

Session 3: Medium Risk Drug Products-How to Use Biopharmaceutics Tool to Understand and Mitigate Risk?
Session Leads: Dr. Hailing Zhang
Scope: This session addresses products where in vivo dissolution and absorption are impacted by GI physiological conditions. The focus will be on developing dissolution methods, including biorelevant methods that mimic and may therefore be, indicative of in vivo performance, the potential for these methods to exist separately from QC dissolution methods, and their use in mitigating BA/BE requirements for lifecycle management. Discussions will also center on what data and scientific justifications are required to potentially downgrade, rather than just mitigate, the risk from medium to low from a regulatory perspective and therefore, reduce the dissolution testing requirements throughout the product's lifecycle.

1:10 PM – 1:15 PM	***Speaker Introductions***	
	Hailing Zhang, PhD	Division Director, DPQA XII, OPQA II, OPQ, CDER, FDA
1:15 PM – 1:35 PM	***Title***	
	TBD	Organization
1:35 PM – 1:55 PM	***Title***	
	TBD	Organization
1:55 PM – 2:15 PM	***Title***	
	TBD	Organization
2:15 PM – 2:35 PM	***Title***	
	TBD	Organization

Breakout Sessions

2:35 PM – 2:45 PM	***Introduction to Breakout Sessions and Transition***	
	TBD	Organization
2:45 PM – 3:45 PM	***Breakout Session 1A: Risk Assessment Implementation Challenges***	
	Breakout Session 1B: IVIVC/IVIVR Development Strategies	
3:45 PM – 4:00 PM	***Break***	
4:00 PM – 5:00 PM	***Breakout Session 2A: Biorelevant Method Selection Criteria***	
	Breakout Session 2B: Regulatory Pathway Optimization	
5:00 PM – 5:15 PM	***Day 1 Closing Remarks***	
5:15 PM – 6:15 PM	***Networking Reception***	

Friday, May 1
Day 2

7:45 AM – 8:30 AM	***Registration***	
8:30 AM – 8:45 AM	***Day 2 Welcome and Day 1 Recap***	
	Giuseppe Randazzo, MS	Senior VP, Sciences & Regulatory Affairs Association for Accessible Medicines

Session 4: Low and Very Low Risk Drug Products-What is Needed and What is Not

Session Leads: Dr. Hardikkumar Patel

Scope: This session examines products where in vivo dissolution is minimally impacted by formulation variables or GI conditions. For very low-risk products, discussions will explore the potential for waiving dissolution testing for batch release. For low-risk products, the session will cover how simple dissolution tests are sufficient to ensure in vivo dissolution is not the rate-limiting step in absorption, and the minimal development data required.

8:45 AM – 8:50 AM	***Speaker Introductions***	
	Hardikkumar Patel, PhD	Senior Staff Fellow, DPQA XII, OPQA II, OPQ, CDER, FDA
8:50 AM – 9:10 AM	***Title***	
	TBD	Organization
9:10 AM – 9:30 AM	***Title***	
	TBD	Organization
9:30 AM – 9:50 AM	***Title***	
	TBD	Organization
9:50 AM – 10:10 AM	***Title***	
	TBD	Organization
10:10 AM -10:25 AM	***Break***	

Session 5: The Future of Dissolution - Beyond Quality Control

Session Leads: Dr. Rebecca Moody

Scope: This forward-looking session explores the evolution toward predictive, patient-centric standards including Clinically Relevant Dissolution Specifications (CRDS) and the concept of "safe space" dissolution ranges where bioequivalence is assured. Discussions will cover the totality-of-evidence approach, the vision for harmonized global regulatory frameworks where scrutiny is proportional to biopharmaceutical risk, and how enhanced biopharmaceutics understanding represents a strategic investment yielding cost savings and development efficiency.

10:25 AM – 10:30 AM	***Speaker Introductions***	
	Rebecca Moody, PhD	Pharmaceutical Scientist, OPQA II, OPQ, CDER, FDA
10:30 AM – 10:50 AM	***Title***	
	TBD	Organization
10:50 AM – 11:10 AM	***Title***	
	TBD	Organization
11:10 AM – 11:30 AM	***Title***	
	TBD	Organization
11:30 AM – 11:50 AM	***Title***	
	TBD	Organization
11:50 AM – 12:50 PM	***Lunch Break***	

Breakout Sessions

12:50 PM – 1:00 PM	***Introduction to Breakout Sessions and Transition***	
	TBD	TBD
1:00 PM – 2:00 PM	***Breakout Session 3A: Implementation Roadmap for Risk-Based Framework***	
	Breakout Session 3B: Global Regulatory Harmonization Strategies	

2:00 PM – 2:20 PM	***Call to Action: Next Steps for the Biopharmaceutics Community***	
	Hailing Zhang, PhD	Division Director, DPQA XII, OPQA II, OPQ, CDER, FDA
2:20 PM – 2:35 PM	***Closing Remarks***	
	Geoff Wu, PhD	Director, OPQA I, OPQ, CDER, FDA