Role of In Vitro Dissolution Studies for Predictive Insight into In Vivo Performance and Biopharmaceutics Risk Mitigation

Public Workshop
April 30-May 1, 2026
Agenda

Thursday, April 30
Day 1:

7:45 AM – 8:30 AM	***Registration and Continental Breakfast***	
Session 1: Biopharmaceutics Risk Assessment Framework		
8:30 AM – 9:00 AM	***Welcome & Keynote (Introductions for Session 1 Speakers)***	
	Michael Kopcha, PhD	Director, OPQ, CDER, FDA
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		
10:45 AM – 10:50 AM	***Speaker Introductions***	
10:50 AM – 11:20 AM	***The Biopharmaceutics Risk Assessment Framework***	
	Bhagwant Rege, PhD	Division Director, DPQA VI, OPQA I, OPQ, CDER, FDA
11:20 AM – 11:50 AM		
11:50 AM – 12:20 PM		
12:20 PM – 1:20 PM	***Lunch Break***	
Session 3: Medium Risk Drug Products-Why and Why Not Biorelevant Dissolution Testing		
1:20 PM – 1:25 PM	***Speaker Introductions***	
1:25 PM – 1:55 PM		
1:55 PM – 2:25 PM		
2:25 PM – 2:55 PM		
Breakout Sessions		
2:55 PM – 3:05 PM	***Introduction to Breakout Sessions and Transition***	
	Sandra Suarez Sharp, PhD	President, Regulatory Strategies, Simulations Plus, Inc.
3:05 PM – 4:05 PM	***Breakout Session 1A: Risk Assessment Implementation Challenges***	
	Breakout Session 1B: IVIVC/IVIVR Development Strategies	
4:05 PM – 4:20 PM	***Break***	

4:20 PM – 5:20 PM	***Breakout Session 2A: Biorelevant Method Selection Criteria*** ***Breakout Session 2B: Regulatory Pathway Optimization***
5:20 PM – 5:35 PM	***Day 1 Closing Remarks***
5:35 PM – 6:35 PM	***Networking Reception***

Friday, May 1
Day 2:

7:45 AM – 8:30 AM	**Continental Breakfast**	
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 Products-What is Needed and What is Not

8:45 AM – 8:50 AM	***Speaker Introductions***	
8:50 AM – 9:20 AM		
9:20 AM – 9:50 AM		
9:50 AM – 10:20 AM		
10:20 AM -10:35 AM	***Break***	

Session 5: The Future of Dissolution-Beyond Quality Control

10:35 AM – 10:40 AM	***Speaker Introductions***	
10:40 AM – 11:10 AM		
11:10 AM – 11:40 AM		
11:40 AM – 12:10 PM		
12:10 PM – 1:10 PM	***Lunch Break***	

Breakout Sessions

1:10 PM – 1:25 PM	***Introduction to Breakout Sessions and Transition***	
	TBD	TBD
1:25 PM – 2:25 PM	***Breakout Session 3A: Implementation Roadmap for Risk-Based Framework***	
	Breakout Session 3B: Global Regulatory Harmonization Strategies	
2:25 PM – 2:45 PM	***Call to Action: Next Steps for the Biopharmaceutics Community***	
	Hailing Zhang, PhD	Division Director, DPQA XII, OPQA II, OPQ, CDER, FDA
2:45 PM – 3:00 PM	***Closing Remarks***	
	Geoff Wu, PhD	Director, OPQA I, OPQ, CDER, FDA