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

Public Workshop
May 12-13, 2026
Agenda

Tuesday, May 12
Day 1: Dissolution Method Development, Control of CBAs, and In Vitro Drug Release Product Specifications for Immediate Release Solid Oral Dosage Products

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8:00 AM – 8:30 AM **Continental Breakfast**

Session 1 Introduction and Objectives

8:30 AM – 8:45 AM ***Welcome & Workshop Objectives***
Hailing Zhang, PhD Division Director, DPQA XII, OPQA II, OPQ, CDER, FDA

8:45 AM – 9:15 AM ***Keynote***
Lawrence Yu, PhD Director, OPQA II, OPQ, CDER, FDA; Adjunct Professor, Univ. of Michigan

Session 2: Gaps/Challenges in Dissolution Method Development and Specification Settings

9:15 AM – 9:45 AM ***Role of Dissolution Testing in Biopharmaceutics Risk Assessment and Control***
Ta-Chen Wu, PhD Senior Pharmaceutical Quality Assessor, DPQA XII, OPQA II, OPQ, CDER, FDA

9:45 AM – 10:15 AM ***Dissolution and Drug Product Quality Risk Management-Industry Perspectives***
Andreas Abend, PhD Director, Merck

10:15 AM – 10:30 AM ***Break***

10:30 AM – 12:00 PM ***Case Studies: Identification and Control of Critical Biopharmaceutics Risk Attributes Practices in the Pharmaceutical Industry***
Carrie Coutant Eli Lilly
Anna Externbrink
Christian Jede, PhD Scientific Associate Director, Global Healthcare Operations & CMC Development, Merck Healthcare KGaA, Darmstadt, Germany
Rob Ju, PhD Director, AbbVie
Filipoos Kesisoglou, PhD, FAAPS Distinguished Scientist, Pharmaceutical Sciences, Merck & Co., Inc.
Joe Kusher Pfizer
Other industry members to be announced (TBA) soon

12:00 PM – 1:00 PM ***Lunch Break***

1:00 PM – 2:00 PM ***Case Studies: Regulatory Experiences with Critical Biopharmaceutics Risk Attribute Identification and Control***
Payal Agarwal, PhD Biopharmaceutics Reviewer, DPQA VI, OPQA I, OPQ, CDER, FDA
Parnali Chatterjee, PhD Senior Pharmacokineticist, DPQA XII, OPQA II, OPQ, CDER, FDA

Breakout Sessions: TBD

2:00 PM – 2:30 PM ***Introduction to Breakout Sessions and Transition to Breakout Rooms***
Sandra Suarez Sharp, PhD President, Regulatory Strategies, Simulations Plus, Inc.

2:30 PM – 3:30 PM ***Breakout Session 1***

3:30 PM – 3:45 PM ***Break***

3:45 PM – 4:45 PM ***Breakout Session 2***

4:45 PM – 5:05 PM ***End of Day 1 Closing Remarks***

5:05 PM – 6:05 PM ***Networking Reception***

Wednesday, May 13

Day 2: Dissolution Method Development, Control of CBAs, and In Vitro Drug Release Product Specifications for Extended Release (ER) Solid Oral Dosage Products

8:00 AM – 8:30 AM	**Continental Breakfast**	
Session 3 Gaps/Challenges in Dissolution Method Development and Specification Settings for ER Products		
8:30 AM – 8:45 AM	***Day 2 Welcome & Workshop Objectives and Day 1 Breakouts Review***	
	Giuseppe Randazzo, MS	Senior VP, Sciences & Regulatory Affairs Association for Accessible Medicines
8:45 AM – 9:15 AM	***Challenges Critical Biopharmaceutics Risk Attribute Identification/Control for ER Products: Case Study***	
	Haritha Mandula, PhD	Senior Pharmaceutical Quality Assessor, DPQA VI, OPQA I, OPQ, CDER, FDA
9:15 AM – 9:45 AM	***Industry Perspective (Innovator): Biopharm Risk Assessment and Dissolution Testing in Product Development: Case Study***	
	Helena Engman, PhD	Associate Principal Scientist, Regulatory Biopharmaceutics, AstraZeneca
9:45 AM – 10:15 AM	***Industry Perspective (Generic): Biopharm Risk Assessment and Dissolution Testing in Product Development: Case Study***	
	Emilija Fredo-Kumberadzi	Director, Biopharmaceutics & Statistics, Apotex
10:15 AM – 10:30 AM	***Break***	
10:30 AM – 11:00 AM	***Regional Differences in Dissolution Requirements for ER Products***	
	TBD	TBD
11:00 AM – 11:30 AM	***Role of IVIVC/IVIVR in Product Lifecycle Management-Regulatory Perspective***	
	James Polli, PhD	Professor, University of Maryland, Baltimore; Co-Director, M-CERSI
11:30 AM – 12:00 PM	***Opportunities to Update SUPAC MR***	
	Rebecca Moody, PhD	Pharmaceutical Scientist, OPQA II, OPQ, CDER, FDA
12:00 PM – 1:00 PM	***Lunch Break***	
Breakout Sessions: TBD		
1:00 PM – 1:30 PM	***Introduction to Breakout Sessions and Transition to Breakout Rooms***	
	TBD	TBD
1:30 PM – 2:30 PM	***Breakout Session 1***	
2:30 PM – 2:45 PM	***Break***	
2:45 PM – 3:45 PM	***Breakout Session 2***	
3:45 PM – 4:05 PM	***Summary of Breakout Session 1 and 2***	
4:05 PM – 4:20 PM	***Close-out Remarks/Next Steps/End of Workshop***	
	Bhagwant Rege, PhD	Division Director, DPQA VI, OPQA I, OPQ, CDER, FDA
	Andreas Abend, PhD	Director, Merck