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: 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***

Friday, May 1

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

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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