M-CERSI Workshop: CBA and Dissolution Testing

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

Day 1 – Tuesday March 11th 8:30 AM – 4:30 PM US EST	
8:00 – 8:30 AM	Continental Breakfast
Session 1: Introduction and Objectives:	
8:30 – 8:45 AM	Welcome & Workshop Objective
8:45 – 9:15 AM	Keynote (Dr. Lawrence Yu, FDA)
Session 2: Gaps/Challenges in Dissolution Method Development and Spec Settings	
9:15 – 9:45 AM	Dissolution and Drug Product Quality Risk Management - Industry Perspectives
9:45 – 10:15 AM	Role of Dissolution Testing in Biopharmaceutics Risk Assessment and Control-FDA
10:15 – 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
12:00 – 1:00 PM	Lunch
1:00 – 2:00 PM	Case Studies: Regulatory experiences with critical Biopharmaceutics Risk Attribute Identification and Control
2:00 – 2:30 PM	Introduction of breakout sessions and transition to breakout rooms
Break Out Sessions: Topics developed with Attendee in-put	
2:30 – 3:30 PM	Breakout Session 1
3:00 – 3:15 PM	Break
3:15 – 4:15 PM	Breakout Session 2
4:25 – 4:45 PM	End of Day 1/Closing Remarks

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

Day 2 – Wednesday March 12th 8:30 AM – 5:00 PM US EST	
8:00 – 8:30 AM	Continental Breakfast
Session 3: Gaps/Challenges in Dissolution Method Development and Spec Settings for ER products	
8:30 – 8:45 AM	Welcome & Workshop Objective- Day 2/ Review of Day 1 Breakouts
8:45 – 9:15 AM	Challenges Critical Biopharmaceutics Risk Attribute Identification/Control for ER products: Case Study (FDA)
9:15 – 9:45 AM	Industry Perspective (Innovator): Dissolution Testing in product development & Biopharm Risk Assessment. Case study
9:45 – 10:15 AM	Industry Perspective (Generic): Dissolution Testing in product development & Biopharm Risk Assessment. Case study
10:15 – 10:30 AM	Break
10:30 – 11:00 AM	Regional Differences in Dissolution Requirements for ER products
11:00 – 11:30 AM	Role of IVIVC/IVIVR in Product Lifecycle Management – regulatory perspective
11:30 – 12:00 PM	Opportunities to up-date SUPAC MR
12:30 – 1:30 PM	Lunch
Break Out Sessions:	
1:30 – 2:00 PM	Introduction to Breakout Sessions
2:00 – 3:00 PM	Breakout Session 1
3:00 – 3:15 PM	Break
3:15 – 4:15 PM	Breakout Session 2
4:25 – 4:45 PM	Summary of Breakout Session 1 and 2
4:45 – 5:00 PM	Close-out Remarks/ Next Steps and End of Workshop