FDA/M-CERSI Workshop: Role of In Vitro Dissolution Studies for Predictive Insight into In Vivo Performance and Biopharmaceutics Risk Mitigation

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

Day 1 – Tues March 11th 8:30 AM – 5:05 PM US EST		
8:00 – 8:30 AM	Continental Breakfast	
Session 1: Introduction and Objectives:		
8:30 – 8:45 AM	Welcome & Workshop Objective	Dr. Hailing Zhang (FDA)
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	Role of Dissolution Testing in Biopharmaceutics Risk Assessment and Control	Dr. Ta-Chen Wu (FDA)
9:45 – 10:15 AM	Dissolution and Drug Product Quality Risk Management - Industry Perspectives	Dr. Andreas Abend (Merck)
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	Drs. Christian Jede (EMD Serono), Rob Ju (AbbVie), Filippos Kesisoglou (Merck), other industry members to be announced (TBA) soon
12:00 – 1:00 PM	Lunch	
1:00 – 2:00 PM	Case Studies: Regulatory experiences with critical Biopharmaceutics Risk Attribute Identification and Control	Drs. Payal Agarwal and Parnali Chatterjee (FDA)
Break Out Sessions:Topics developed w/Attendee input		
2:00 – 2:30 PM	Introduction of breakout sessions and transition to breakout rooms	Dr. Sandra Suarez Sharp (Simulations Plus)
2:30 – 3:30 PM	Breakout Session 1	
3:30 – 3:45 PM	Break	
3:45 – 4:45 PM	Breakout Session 2	
4:45 – 5:05 PM	End of Day 1/Closing Remarks	
5:05 – 6:05 PM	Networking Reception	

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 – 4:20 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	Dr. G. Randazzo (AAM)
8:45 – 9:15 AM	Challenges Critical Biopharmaceutics Risk Attribute Identification/Control for ER products: Case Study (FDA)	Dr. Haritha Mandula (FDA)
9:15 – 9:45 AM	Industry Perspective (Innovator): Biopharm Risk Assessment and Dissolution Testing in product development. Case study	Dr. Helena Engman (AZ)
9:45 – 10:15 AM	Industry Perspective (Generic): Dissolution Testing in product development & Biopharm Risk Assessment. Case study	TBA
10:15 – 10:30 AM	Break	
10:30 – 11:00 AM	Regional Differences in Dissolution Requirements for ER products	TBA
11:00 – 11:30 AM	Role of IVIVC/IVIVR in Product Lifecycle Management – regulatory perspective	Dr. Jim Polli (UMaryland)
11:30 AM – 12:00 PM	Opportunities to update SUPAC MR	Dr. Rebecca Moody (FDA)
12:00 – 1:00 PM	Lunch	
Break Out Sessions:		
1:00 – 1:30 PM	Introduction to Breakout Sessions	TBA
1:30 – 2:30 PM	Breakout Session 1	
2:30 – 2:45 PM	Break	
2:45 – 3:45 PM	Breakout Session 2	
3:45 – 4:05 PM	Summary of Breakout Session 1 and 2	
4:05 – 4:20 PM	Close-out Remarks/ Next Steps and End of Workshop	Dr. Bhagwant Rege (FDA) Dr. Andreas Abend (Merck)