FDA-MCERSI Workshop on Drug Dissolution in Oral Drug Absorption

In-person Workshop
May 23-24, 2023
8:20 AM-4:30 PM Eastern Time

DAY 1, Tue, May 23

7:30 AM-9:00 AM	***Breakfast and Registration***	
	Room N103 Lecture Hall	
8:20 AM-8:25 AM	***Welcome***	
	James Polli, PhD	Professor and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics, Univ. of Maryland
	Kimberly Raines, PhD	Branch Chief, Division of Biopharmaceutics, ONDP, OPQ, CDER, FDA
8:25 AM-8:30 AM	***Session Overview***	
	Lynne S. Taylor, PhD	Retter Distinguished Professor of Pharmacy, Department of Industrial and Physical Pharmacy, Purdue University
8:30 AM-9:00 AM	***Supersaturation via Acid-Base Interactions***	
	Abu Serajuddin, PhD	Professor of Industrial Pharmacy, St John's University
9:00 AM-9:30 AM	***"Dissolved" Species: Biopharmaceutical Roles and Ways to Measure***	
	Martin Brandl, PhD, Dr. habil	Full Professor, Department of Physics, Chemistry & Pharmacy, University of Southern Denmark
9:30 AM-10:00 AM	***Gastrointestinal Imaging with MRI: Providing Information about Conditions at the Site of Drug Delivery***	
	Werner Weitschies, PhD	Professor of Biopharmaceutics, Center of Drug Absorption and Transport, University of Greifswald, Germany
10:00 AM-10:30 AM	***Break***	
10:30 AM-11:00 AM	***In Vitro Evaluation of Drug Presence in the Micellar Phase of Contents of Upper Small Intestine: Rationale, Challenges, Opportunities***	
	Christos Reppas, PharmD, PhD	Professor of Pharmaceutics, Department of Pharmacy, National and Kapodistrian University of Athens, Greece
11:00 AM-11:30 AM	***Predicting Food Effects on Drug Absorption***	
	Anette Müllertz, PhD	Professor in Oral Drug Delivery and Industrial Relations, University of Copenhagen, Denmark
11:30 AM-12:00 PM	***Panel Discussion***	
Moderator:	Lynne S. Taylor, PhD	Retter Distinguished Professor of Pharmacy, Department of Industrial and Physical Pharmacy, Purdue University
Panelists:	Abu Serajuddin, PhD	Professor of Industrial Pharmacy, St John's University

	Martin Brandl, PhD, Dr. habil	Full Professor, Department of Physics, Chemistry & Pharmacy, University of Southern Denmark
	Werner Weitschies, PhD	Professor of Biopharmaceutics, Center of Drug Absorption and Transport, University of Greifswald, Germany
	Christos Reppas, PharmD, PhD	Professor of Pharmaceutics, Department of Pharmacy, National and Kapodistrian University of Athens, Greece
	Anette Müllertz, PhD	Professor in Oral Drug Delivery and Industrial Relations, University of Copenhagen, Denmark
	Bhagwant Rege, PhD	Division Director, Division of Biopharmaceutics, ONDP, OPQ, CDER, FDA
12:00 PM-12:55 PM	***Lunch***	
12:55 PM-1:00 PM	***Session Overview***	
	Haritha Mandula, PhD	Senior Pharmaceutical Quality Assessor, BB3, DB, ONDP, OPQ, CDER, FDA
1:00 PM-1:30 PM	***Biorelevant In Vitro Testing-Dissolution Method Development Beyond Compendial Approaches***	
	Zongming Gao, PhD	Research Chemist, DCDA, OTR, OPQ, CDER, FDA
1:30 PM-2:00 PM	***In Vivo Formulation Behavior and Drug Absorption***	
	Patrick Augustijns, PhD	Full Professor, University of Leuven
2:00 PM-2:30 PM	***Release Mechanisms of Amorphous Solid Dispersions***	
	Lynne S. Taylor, PhD	Retter Distinguished Professor of Pharmacy, Department of Industrial and Physical Pharmacy, Purdue University
2:30 PM-2:45 PM	***Panel Session***	
Moderator:	Haritha Mandula, PhD	Senior Pharmaceutical Quality Assessor, BB3, DB, ONDP, OPQ, CDER, FDA
Panelists:	Zongming Gao, PhD	Research Chemist, DCDA, OTR, OPQ, CDER, FDA
	Patrick Augustijns, PhD	Full Professor, University of Leuven
	Lynne S. Taylor, PhD	Retter Distinguished Professor of Pharmacy, Department of Industrial and Physical Pharmacy, Purdue University
2:45 PM-3:00 PM	***Break***	
3:00 PM-4:00 PM	***Breakout Sessions A***	

Room N306-Breakout Session A1 [Session Leads: Hanlin Li, Vertex and Haritha Mandula, FDA]

RTRT to replace in vitro dissolution

Room N310-Breakout Session A2 [Session Leads: David Curran, GSK and Anitha Govada, FDA]

Drug dissolution from nano-formulations

Room N314-Breakout Session A3 [Session Leads: Kerstin Schaefer, Boehringer-Ingelheim and Hansong Chen, FDA]

Non-compendial methods

Room N301A-Breakout Session A4 [Session Leads: Anette Mullertz, Uof Copenhagen and Leah Falade, FDA]

Drug dissolution from lipid-based formulations

4:00 PM-4:30 PM ***Breakout Session Read-Outs***

DAY 2, Wed, May 24

7:30 AM-9:00 AM	***Breakfast and Registration***	
	Room N103 Lecture Hall	
8:20 AM-8:25 AM	***Welcome***	
	James Polli, PhD	Professor and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics, Univ. of Maryland
	Kimberly Raines, PhD	Branch Chief, Division of Biopharmaceutics, ONDP, OPQ, CDER, FDA
8:25 AM-8:30 AM	***Session Overview***	
	Leah W. Falade, PhD	Pharmacologist, Division of Biopharmaceutics, ONDP, OPQ,CDER, FDA
8:30 AM-9:00 AM	***An FDA Perspective on QC Dissolution Test for Oral Drug Products Containing ASDs***	
	Kevin Wei, PhD	Pharmacologist, Division of Biopharmaceutics, ONDP, OPQ, CDER, FDA
9:00 AM-9:30 AM	***Non-compendial Tools in Early Drug Product Development***	
	Kerstin Julia Schaefer, PhD	Senior Associate Director, Material and Analytical Sciences Department, Boehringer-Ingelheim Pharmaceuticals Inc.
	Corrine Jankovsky, PhD	Senior Scientist, Material and Analytical Sciences Department, Boehringer-Ingelheim Pharmaceuticals Inc.
9:30 AM-10:00 AM	***Setting Up Dissolution Studies to Reflect Product Performance in the GI Tract***	
	Jennifer Dressman, PhD	Group Leader, Pharmaceutical Technology, Fraunhofer Institute of Translational Pharmacology and Medicine
10:00 AM-10:30 AM	***Break***	
10:30 AM-11:00 AM	***Considering Free-Drug Concentrations in the GI Tract: Impact of Cyclodextrin and Food***	
	Shinji Yamashita, PhD	Visiting Professor of College of Pharmaceutical Sciences, Ritsumeikan University
11:00 AM-11:30 AM	***Combined Dissolution/Permeation: Input for Rationalized Drug Formulation Development***	
	Annette Bauer-Brandl, PhD	Full Professor, Department of Physics, Chemistry & Pharmacy, University of Southern Denmark
11:30 AM-12:00 PM	***Panel Session***	
Moderator:	Leah W. Falade, PhD	Pharmacologist, Division of Biopharmaceutics, ONDP, OPQ, CDER, FDA
Panelists:	Kevin Wei, PhD	Pharmacologist, Division of Biopharmaceutics, ONDP, OPQ, CDER, FDA
	Kerstin Julia Schaefer, PhD	Senior Associate Director, Material and Analytical Sciences Department, Boehringer-Ingelheim Pharmaceuticals Inc.
	Corrine Jankovsky, PhD	Senior Scientist, Material and Analytical Sciences Department, Boehringer-Ingelheim Pharmaceuticals Inc.

	Jennifer Dressman, PhD	Group Leader, Pharmaceutical Technology, Fraunhofer Institute of Translational Pharmacology and Medicine
	Shinji Yamashita, PhD	Visiting Professor of College of Pharmaceutcial Sciences, Ritsumeikan University
	Annette Bauer-Brandl, PhD	Full Professor, Department of Physics, Chemistry & Pharmacy, University of Southern Denmark

12:00 PM-12:55 PM ***Lunch***

1:00 PM-2:00 PM ***Breakout Sessions B***

Room N306-Breakout Session B1 [Session Leads: Abu Serajuddin, St Johns U and Alaadin Alayoubi, FDA]

Drug dissolution from co-crystals

Room N310-Breakout Session B2 [Session Leads: Rohit Jaini, Pfizer and Parnali Chatterjee, FDA]

Ionizable drugs or excipients: buffer capacity considerations

Room N314-Breakout Session B3 [Session Leads: Lynne Taylor, Purdue; Andre Hermans, Merck; and Rajesh Savkur, FDA)

Non-compendial testing for ASDs from industry and regulatory perspective

2:00 PM-2:15 PM ***Break***

2:15 PM-3:15 PM ***Breakout Sessions C***

Room N306-Breakout Session C1 (Session Leads: Martin Brandl, U of Southern Denmark; Annette Bauer-Brandl, U of Southern Denmark; and Kimberly Raines, FDA)

In vitro approaches to interpret/predict food effects

Room N310 Breakout Session C2 (Session Leads: Dana Moseson, Pfizer and Debasis Ghosh, FDA)

Drug dissolution from amorphous solid dispersions

Room N314-Breakout Session C3 (Session Leads: Yi Gao, AbbVie and Tapash Ghosh, FDA)

Non-USP methods versus regulatory methods: biopharmaceutic risk assessment

3:15 PM-4:00 PM ***Breakout Session Read-Outs***

4:00 PM-4:30 PM ***Summary***

Speaker Bios

Upcoming Events