Final Agenda

DAY ONE: Wednesday, December 11, 2019
Moderator: John Mauger, Ph.D.
Member, USP General Chapters-Dosage Forms 2015 Expert Committee
Professor & Associate VP for Health Sciences, University of Utah College of Pharmacy

8:30 – 9:00 a.m. Registration & Coffee

9:00 – 9:30 a.m. First-Principles Approaches and Surrogate Testing for Predicting In Vitro Dissolution
Andre Hermans, Ph.D., Director, Analytical Sciences, Merck & Co.

9:30 – 10:00 a.m. 3D Printing for Fast Prototyping of Pharmaceutical Dissolution Testing Equipment for Nonstandard Applications*
Przemysław Dorożyński, Ph.D., Professor, Instytut Farmaceutyczny

10:00 – 10:30 a.m. A Systematic Approach to Develop Predictive Dissolution Models
Fernando J. Muzzio, Ph.D., Distinguished Professor, Chemical and Biochemical Engineering, Rutgers University

10:30 – 11:00 a.m. Morning Break

11:00 – 11:30 a.m. Dissolution Modeling for Real Time Release Testing (RTRT)
Hanlin Li, Ph.D., Associate Director, Vertex Pharmaceuticals

11:30 a.m. – 12:00 p.m. Development of Real Time Release Test of Tablet Dissolution*
Sarah Nielsen, Ph.D., Principal Scientist, Janssen Pharmaceuticals

12:00 – 12:30 p.m. Q&A/Morning Panel Discussion

12:30 – 1:30 p.m. Lunch

1:30 – 2:00 p.m. Bio-relevant In vitro GI Model (TinyTIM-1) for Food Effect Prediction
Shirlynn Chen, Ph.D., Director, External Alternative CMC Development, Boehringer Ingelheim Pharm Inc.

*Virtual Presentation
### DAY ONE: Wednesday, December 11, 2019

#### 2:00 – 2:30 p.m.

**The BioGIT System for Assessing the Impact of Dose and Formulation on Early Exposure After Oral Administration**

Professor Christos Reppas, *Department of Pharmacy, National and Kapodistrian University of Athens*

#### 2:30 – 3:00 p.m.

**Afternoon Break**

#### 3:00 – 3:30 p.m.

**Dissolution for Products Applied to the Oral Cavity**

Sandra Klein, Ph.D., Professor, *University of Greifswald, Department of Pharmacy*

#### 3:30 – 4:00 p.m.

**Utilizing Conventional Dissolution Technique to Predictive and Guide Successful Development of Gastro-Retentive Drug Delivery Systems**

Sanjay Patel, *Associate Principal Scientist, Analytical Sciences, Merck*

#### 4:00 – 4:30 p.m.

**Q&A/Moderated Discussion/Day One Conclusion**

#### 4:30 – 5:15 p.m.

**Networking Reception**

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### DAY TWO: Thursday, December 12, 2019

**Moderator:** Martin Coffey, Ph.D.

*Member, USP General Chapters-Physical Analysis 2015 Expert Committee*

*Research Fellow, Bausch & Lomb*

#### 8:30 – 9:00 a.m.

**Registration & Coffee**

#### 9:00 – 9:30 a.m.

**Dissolution of Dosage Forms Containing Nanomaterials**

Matthias Wacker, Ph.D., *Associate Professor, Department of Pharmacy, Faculty of Science, National University of Singapore*

#### 9:30 – 10:00 a.m.

**Use of Vertical Diffusion Cells in Dissolution Testing of Suppositories**

Kailas Thakker, Ph.D., *Co-Founder Emeritus, Tergus Pharma, LLC*

#### 10:00 – 10:30 a.m.

**Dissolution of Stents**

Katharina Pruessmann, *Ph.D. Student, University of Greifswald, Center of Drug Absorption and Transport*

#### 10:30 – 11:00 a.m.

**Morning Break**

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*Virtual Presentation*
11:00 – 11:30 a.m. In Vitro Performance Testing for Intra-uterine, Topical and Transdermal Dosage Forms from the Biopharmaceutics Review Perspective
Tapash Ghosh, Ph.D., Quality Assessment Lead, Biopharmaceutics, U.S. Food & Drug Administration

11:30 a.m. – 12:00 p.m. In Vitro Characterizations of Topical and Transdermal Drug Products from the Product Quality Assessment Perspective
Yang Yang, Ph.D., Division of Product Quality Research, U.S. Food & Drug Administration
Daniel Willett, Ph.D., Chemist, U.S. Food & Drug Administration

12:00 – 12:30 p.m. Q&A/Morning Panel Discussion

12:30 – 1:20 p.m. Lunch

1:20 – 1:30 p.m. Attendee Survey

1:30 – 2:00 p.m. Dissolution Methods for Orally Inhaled Drug Products*
Guenther Hochhaus, Ph.D., Professor, Pharmaceutics, University of Florida, College of Pharmacy

2:00 – 2:30 p.m. Dissolution of Inhalers
Paul W S Heng, Ph.D., GEA-NUS Pharmaceutical Processing Research Laboratory, Department of Pharmacy, National University of Singapore

2:30 – 3:00 p.m. Afternoon Break

3:00 – 3:30 p.m. Assessing Dissolution of Oral Tablets Using an Artificial Stomach Duodenum Apparatus
Changquan Calvin Sun, Ph.D., Professor and Director of Graduate Studies, Associate Department Head, Department of Pharmaceutics, University of Minnesota

3:30 – 4:00 p.m. Updates on IVIVC
Johannes Kraemer, Ph.D., Member, USP General Chapters-Dosage Forums Expert Committee

4:00 – 4:30 p.m. Q&A/Moderated Discussion

4:30 – 4:40 p.m. Closing Comments

4:45 p.m. Workshop Concludes

*Virtual Presentation