

**→ Advancements in
In-Vitro Performance
Testing of Drug Products**

December 11-12, 2019

USP Meetings Center | Rockville, MD

Draft Agenda
(as of March 18, 2019)

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

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| 8:30 – 9:00 a.m. | Registration & Coffee |
| 9:00 – 9:30 a.m. | First-Principles and Empirical Approaches to Predicting In Vitro Dissolution for Pharmaceutical Formulation and Process Development and for Product Release Testing
<i>Andre Hermans, Ph.D., Director, Analytical Sciences, Merck & Co.</i> |
| 9:30 – 10:00 a.m. | 3D Printing for Fast Prototyping of Pharmaceutical Dissolution Testing Equipment for Nonstandard Applications
<i>Przemysław Dorożyński, Ph.D., Professor, Instytut Farmaceutyczny</i> |
| 10:00 – 10:30 a.m. | A Systematic Approach to Develop Predictive Dissolution Models
<i>Fernando J. Muzzio, Ph.D., Distinguished Professor, Chemical and Biochemical Engineering, Rutgers University</i> |
| 10:30 – 11:00 a.m. | Morning Break |
| 11:00 – 11:30 a.m. | Dissolution Modeling for Real Time Release Testing (RTRT)
<i>Hanlin Li, Ph.D., Associate Director, Vertex Pharmaceuticals</i> |
| 11:30 a.m. – 12:00 p.m. | Assessing Dissolution of Oral Tablets Using an Artificial Stomach Duodenum System
<i>Changquan Calvin Sun, Ph.D., Professor and Director of Graduate Studies, Associate Department Head, Department of Pharmaceutics, University of Minnesota</i> |
| 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
<i>Shirlynn Chen, Ph.D., Distinguished Research Fellow, Material & Analytical Sciences, Boehringer Ingelheim Pharm Inc.</i> |

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- 2:00 – 2:30 p.m.** **In vitro Evaluation of the Impact of Formulation and Dose on Early Exposure to Low Solubility Drugs After Oral Administration**
Christos Reppas, Ph.D., *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**

DAY TWO: Thursday, December 12, 2019

Moderator: Martin Coffey, Ph.D.

Member, USP General Chapters-Physical Analysis 2015 Expert Committee

Principal Scientist/Group Leader, Formulations, Medline Industries

- 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**
Anne Seidlitz, Ph.D., *University of Greifswald, Center of Drug Absorption and Transport*
- 10:30 – 11:00 a.m.** **Morning Break**

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11:00 – 11:30 a.m.	In Vitro Characterizations of Topical and Transdermal Drug Products from the Product Quality Assessment Perspective Yang Yang, Ph.D., <i>Division of Product Quality Research, U.S. Food & Drug Administration</i> Daniel Willett, Ph.D., <i>Chemist, U.S. Food & Drug Administration</i>
11:30 a.m. – 12:00 p.m.	In Vitro Performance Testing for Intra-uterine, Topical and Transdermal Dosage Forms from the Biopharmaceutics Review Perspective Tapash Ghosh, Ph.D., <i>Quality Assessment Lead, Biopharmaceutics, U.S. Food & Drug Administration</i>
12:00 – 12:30 p.m.	Q&A/Morning Panel Discussion
12:30 – 1:30 p.m.	Lunch
1:30 – 2:00 p.m.	Title TBD Guenther Hochhaus, Ph.D., <i>Professor, Pharmaceutics, University of Florida, College of Pharmacy</i>
2:00 – 2:30 p.m.	Dissolution of Inhalers Paul W.S. Heng, <i>National University of Singapore</i>
2:30 – 3:00 p.m.	Afternoon Break
3:00 – 3:30 p.m.	TBD
3:30 – 4:00 p.m.	Updates on IVIVC Johannes Kraemer, Ph.D., <i>Member, USP General Chapters-Dosage Forums Expert Committee</i>
4:00 – 4:30 p.m.	Q&A/Moderated Discussion
4:30 – 4:40 p.m.	Closing Comments
4:45 p.m.	Workshop Concludes