

Disso America 2024

Dissolution Science:

Complex Drug Products

June 11-12, 2024

**Rutgers
Ernest Mario School of Pharmacy
New Jersey, USA
www.spds.us**



**Society for
Pharmaceutical
Dissolution Science
US Chapter**

Agenda

Day 1: Tuesday, June 11th, 2024

Theme: Long Acting Injectables

Welcome Session | Chair: Sanjay Patel, Merck | Co-Chair: Dr. Lakshmanan Ramaswamy, Sotax

09:00 am – 09:05 am

Welcome Address

Dr. Vinod P. Shah, President, SPDS US Chapter

09:05 am – 09:15 am

Keynote Speaker: SPDS and SPDS-US Chapter – Strategies and the Way Forward

Dr. B. Suresh, Pro-Chancellor, JSS Academy of Higher Education

09:15 am – 09:35 am

Keynote Speaker: Biorelevant, Bioindicative and Biopredictive Dissolution: Current Perspectives and Future Challenges

Prof. Dr. Patrick Sinko, Immediate Past President, AAPS

09:35 am – 10:00 am

Long Acting Injectables: Opportunities and Challenges in Product Development

Dr. Sujata Sonti, GSK

Session 1: Biorelevant / Bio Predictive Models for LAI

Chair: Dr. Sandip Tiwari, BASF | Co-Chair: Vijay Kshirsagar, TRAC Pharma Consulting

10:00 am – 10:30 am

Development of Biorelevant In Vitro Models for the Prediction of Subcutaneous Drug Release and Absorption – What are the Challenges and Where are We?

Prof. Dr. Sandra Klein, University of Greifswald

10:30 am – 11:00 am: **Coffee Break**

11:00 am – 11:30 am

Computational Biopharmaceutics: Exploring the Drug Delivery Lifecycle of Complex Injectables

Prof. Dr. Matthias G Wacker, National University of Singapore

11:30 am – 12:00 pm

Bio-Predictive, Accelerated Release Testing of Single Agent and Combination LAIs

Dr. Kruthika Harish Jain, Gilead

12:00 pm – 12:30 pm: **Panel Discussion. Questions & Answers**

12:30 pm – 02:00 pm: **Lunch Break**

Session 2: Leading Edge Formulations and In Vitro Techniques for LAI

Chair: Vivek Shah, Sotax | Co-Chair: Dr. Rajiv Desai, Indian Pharmaceutical Alliance

02:00 pm – 02:30 pm

The Next Frontier in Pharma: AI and Robotics-Driven Drug Formulation

Prof. Dr. Christine Allen., University of Toronto

02:30 pm – 03:00 pm

Real-time Release and Accelerated Dissolution of an Implant

Dr. Maureen Marsales and Dr. Hyunho Kang, Merck

03:00 pm - 03:30 pm: **Coffee Break**

03:30 pm – 04:00 pm

In Vitro Release Testing for Liposomal Formulations: Challenges and Key Considerations

Prof. Dr. Nikoletta Fotaki, University of Bath

04:00 pm – 04:30 pm

Prolonged Release Single Dose Antimalarial Injection of an ACT Combination

Prof. Dr. Padma V. Devarajan, Institute of Chemical Technology, Mumbai

04:30 pm – 05:00 pm

In Vitro Release Test for Complex Drug Products: Thinking Outside the Box

Dr. Xiaoming Xu, FDA

05:00 pm – 05:30 pm: **Panel Discussion. Questions & Answers**

05:30 pm – 06:30 pm: **Wine & Cheese Reception**

Day 2: Wednesday, June 12th, 2024

Theme: Complex Oral Drug Products

Session 3: Lipid Based Formulations

Chair: Dr. Deanna Mudie, Simulations Plus | Co-Chair: Dr. Padma Devarajan, Institute of Chemical Technology

09:00 am – 09:30 am

Roles of In-Vitro Tools for Elucidating Product Performance of Complex Oral Drug Products and their Relationship with Dissolution Testing

Dr. Ju Tzuchi, AbbVie

09:30 am – 10:00 am

Developing SNEDDS for Improving Peptide Oral Delivery

Prof. Dr. Anette Mullertz, University of Copenhagen

10:00 am – 10:30 am: Innovative Soft gel Technologies for Modulated Drug Release and Overcoming Challenges in Dissolution Method Development

Dr. Karunakar (Karu) Sukuru, Catalent

10:30 am – 11:00 am: Coffee Break

11:00 am – 11:30 am

Annealing Effects on Dissolution of Oral Lipid Multi-particulates for Controlled Release

Dr. Mika Mast, Lonza

11:30 am – 12:00 pm

Dissolution testing of Lipid Based Formulations

Dr. Sanjay Jain, Amneal

12:00 pm – 12:30 pm

Panel Discussion. Questions & Answers

12:30 pm – 02:00 pm: *Lunch Break*

Session 4: Amorphous Solid Dispersion

Chair: Dr. Xujin Lu, SPDS-US | Co-Chair: Suhas Yewale, Sotax

02:00 pm – 02:30 pm

Non-Sink Dissolution Conditions for Predicting Product Quality

Dr. Andre Hermans, Merck

02:30 pm – 03:00 pm

Elucidating Product Performance of Erosion-Based Dosage Forms through Assessment of Excipient-Functionality in a Non-Sink Environment and Evolution of 3-Dimensional Structure

Dr. Ricardo Sosa, Abbvie

03:00 pm – 03:30 pm: **Coffee Break**

03:30 pm – 04:00 pm

Crystallization Inhibitors in ASD and Supersaturated Systems

Dr. Sandip Tiwari, BASF

04:00 pm – 04:30 pm

Complex Oral Formulations and Dissolution Testing: FDA's Regulatory Perspective

Dr. Payal Agarwal, FDA

04:30 pm – 05:00 pm: **Panel Discussion. Questions & Answers**