

# **Disso America 2024**

## **Dissolution Science: Complex Drug Products**

**June 11-12, 2024**

**Rutgers  
Ernest Mario School of Pharmacy  
New Jersey, USA  
[www.spds.us](http://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**

Priti Jagani, 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**