

The Agenda.

Three days with five unique sessions!

[Click here
to view
agendal](#)

Day 1: September 19th, 2022

09:00 am – 09:05 am	Introduction Patrick Ballmer, Board Member, SPDS US Chapter and Vice President of SOTAX Group
09:05 am – 09:30 am	Welcome Dr. Ramaswamy Lakshmanan, SPDS-India Dr. Vinod P. Shah, President, SPDS US Chapter Dr. Tina Morris, CEO AAPS
09:30 am – 10:00 am	Keynote Addresses by Dr. Navnit Shah, SVP and Scientific Advisor, Amneal Pharmaceuticals Pankajbhai Patel, Chairman, Zydus Life Sciences Ltd., India

Session 1: Development of Quality Drug Products Chair: Samir Haddouchi, Managing Director, SPS Pharma Services

10:00 am – 10:30 am	Evolution of Dissolution in Pharmaceutical Science Dr. Dr. Vinod P. Shah, President, SPDS US Chapter
10:30 am – 11:00 am	Coffee break
11:00 am – 11:30 am	Challenges Dissolution Science is facing in the Brand Name Pharmaceutical Industry Dr. Xujin Lu, Research Fellow, BMS
11:30 am – 12:00 pm	Challenges Dissolution Science is facing in the Generics Industry Dr. Prasad Panzade, Head Analytical Operations and Laboratory Platforms, ProtaGene
12:00 pm – 12:30 pm	Panel Discussion. Questions & Answers.
12:30 pm – 02:00 pm	Lunch break

Session 2: Predictive Dissolution to Guide Formulation Development

Chair: Dr. David Sperry, Sr. Research Advisor, Eli Lilly

02:00 pm – 02:30 pm	Biorelevant dissolution media Dr. Deanna Mudie, Principal Scientist, Lonza
02:30 pm – 03:00 pm	Linking predictive dissolution data in early development and pre-clinical studies Dr. Steve Stamatis, Sr. Consultant Engineer, Eli Lilly
03:00 pm - 03:30 pm	Coffee Break
03:30 pm – 04:00 pm	In vitro predictive tools to understand biopharmaceutics risk assessment – Precipitation risk Sanjay Patel, Principal Scientist, Merck
04:00 pm – 04:30 pm	Prediction of oral drug absorption using a hollow fiber membrane (HFM) module Dr. James Polli, Professor, University of Maryland

Day 1: September 19th, 2022

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

05:00 pm – 06:00 pm **Wine & Cheese**

Day 2: September 20th, 2022

Session 3: Understanding of Dissolution Mechanism to Guide Robust Formulation Development

Chair: Dr. Deanna Mudie, Principal Scientist, Lonza

09:00 am – 09:30 am **Factors influencing dissolution**
Dr. Arvind Bansal, Dean, NIPER, India

09:30 am – 10:00 am **Understanding dissolution mechanism**
Dr. David Sperry, Senior Research Advisor, Eli Lilly

10:00 am – 10:30 am **Modeling and Simulations (driving towards RTRT)**
Dr. Tessa Carducci, Assoc. Principal Scientist, Merck

10:30 am – 11:00 am **Coffee Break**

11:00 am – 11:30 am **Dissolution safe space**
Dr. Tycho Heimbach, Principal Scientist, Merck

11:30 am – 12:00 pm **Use of dissolution testing to support clinical bridging studies**
Dr. Vivek Purohit, Senior Director Clinical Pharmacology, Pfizer

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

12:30 pm – 02:00 pm **Lunch break**

Session 4: Role of Dissolution in Regulatory Submission

Chair: Xujin Lu, Research Fellow, BMS

02:00 pm – 02:30 pm **Dissolution Data Integrity: Who did what, when, and where?**
Ajay Pydah, Lead Software and Data Management, SOTAX Group

02:30 pm – 03:00 pm **M9 and Beyond**
Talia Flannagan, Head of Product Design and Performance, UCB, Belgium

03:00 pm – 03:30 pm **Coffee Break**

03:30 pm – 04:00 pm **Establishing clinically relevant dissolution specifications**
Dr. André Hermans, Director, Merck

04:00 pm – 04:30 pm **Agency perspective on evaluating dissolution data in product development and in product life cycle**
Dr. Mei Ou, Biopharmaceutics Reviewer, FDA

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

Day 3: September 21th, 2022

Session 5: Dissolution of Special Dosage Forms
Chair: Sanjay Patel, Principal Scientist, Merck

09:00 am – 09:30 am	Advanced Third Generation Solid Dispersion Films - Facile Innovative Technology Dr. Padma Devrajan, Professor, Institute of Chemical Technology, India
09:30 am – 10:00 am	Characterization and Quality Comparison of Liposome Formulations Dr. Anna Schwendeman, William I. Higuchi Collegiate Professor, University of Michigan
10:00 am – 10:30 am	The Development of Novel Micro and Nanoparticle-based Therapeutics Dr. Diane Burgess, Board of Trustees Distinguished Professor of Pharmaceutics, University of Connecticut
10:30 pm – 11:00 am	Coffee Break
11:00 pm – 11:30 pm	Biodegradable polymers Dr. John Middleton, Vice President of Polymer Development, Tolmar
11:30 pm – 12:00 pm	Global implementation for automated dissolution testing for commercial Release Testing Dr. Zachery Custer, Sr. Scientist, Merck
12:00 pm – 12:30 pm	Panel Discussion. Questions & Answers.
12:30 pm – 02:00 pm	Lunch break
2:00 pm – 04:00 pm	Tour of SOTAX Westborough Facilities

All times indicated are EST