

Disso America 2022

Dissolution Science: Principles and Applications



Take a deep dive into the current challenges, developments and discuss the future of dissolution testing.

September 19-21, 2022

DoubleTree by Hilton Hotel Boston,
5400 Computer Drive, Westborough, MA 01581

Registration: www.spds.us

Society for
Pharmaceutical
Dissolution Science,
US Chapter

Hello.

The newly inaugurated US Chapter of the Society for Pharmaceutical Dissolution Science (SPDS) is entering its third year. Its mission is to advance Dissolution Science, Technology, and to organize conferences among professionals in the pharmaceutical industry as well as academia. The US Chapter of SPDS has held a successful virtual conferences focused on Advances in Dissolution Science. The first one being in Sept of 2020, followed by a series of webinars in 2021, and finally a webinar in collaboration with AAPS earlier in 2022.

This LIVE workshop [Dissolution Science: Principles and Applications](#) will cover broad topics associated with dissolution sciences.

Participants of this event will establish a baseline with respect to:

- Predictive dissolution
- QC method development by understanding the mechanism
- Regulatory aspects of the dissolution method
- Introduction of dissolution of special dosage forms

Vinod P. Shah, Ph.D., FAAPS, FFIP

Founding President

What to expect.

5 sessions 18 speakers – Global experts sharing within a collaborative community!

Experts will be sharing their knowledge, strategies, and experience. Diverse sessions ranging from quality attributes to predictive dissolution used during formulation development. We'll have a session on regulatory perspectives and also a special segment dedicated to special dosage forms.

Each session will be presented by representatives from industry, regulation, and academia exchanging their views on current market challenges.

Presentations include speakers from:

- AAPS
- Amneal
- BMS
- US FDA
- Lonza
- ICT
- University of Connecticut
- Eli Lilly
- Merck
- University of Maryland
- NIPER
- Pfizer
- SOTAX
- University of Michigan
- Tolmar



In collaboration with



[Click here to meet the speakers](#)

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, Executive Director, 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, Sotax Pharma Services, France and James Polli, Professor, University of Maryland	
10:00 am – 10:30 am	Evolution of Dissolution in Pharmaceutical Science 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 and Rajiv Desai, Advisor, Corporate Quality, Lupin, India

02:00 pm – 02:30 pm	In Vivo Predictive Dissolution Media Using Drug Formulation and Physiological Properties Dr. Deanna Mudie, Sr. Principal Engineer, 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 Reception**

Day 2: September 20th, 2022

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

Chair: Dr. Deanna Mudie, Sr. Principal Engineer, Lonza and Diane Burgess, Distinguished Professor, University of Connecticut

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 pm – 11:00 am **Coffee Break**

11:00 pm – 11:30 am **PBBM to inform the Bioequivalence Safe Space and pH-mediated DDIs**
Dr. Tycho Heimbach, Director, Merck

11:30 pm – 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 and Dr. Sandip Tiwari, Head of Technical Services - Pharma Solutions, BASF

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 **Assessment of Dissolution Data in Drug Product's Development and Life-Cycle: FDA's Regulatory Perspective**
Dr. Mei Ou, Sr. 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 and Imre Klebovich, Professor,
Semmelweis University, Budapest, Hungary

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 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 (By Invitation Only)

All times indicated are EST

Your Participation.

[Register](#)

Register on-line today!

Register yourself or as a group – complete the simple on-line reservation and start planning your trip to Boston.

General Admission tickets:

- **3-day ticket (full Congress)**
(valid for all sessions on both Congress days)
USD \$300

SPDS US Member price: \$200

Register on-line at www.spds.us and receive your tickets for the entire 3-day meeting.

Standard payment method is by credit card (please book your ticket on-line).

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