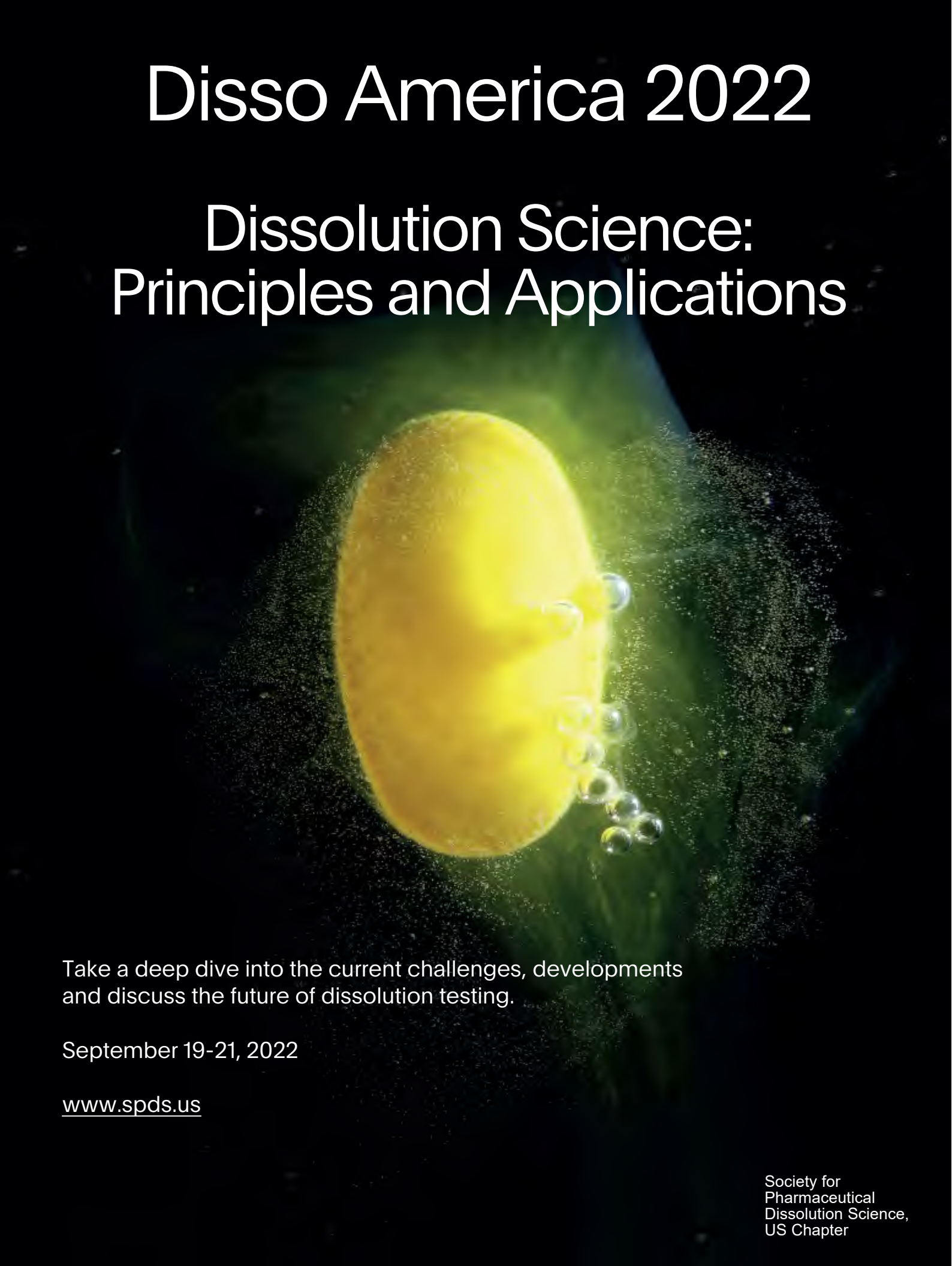
Disso America 2022

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

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

SPDS US Chapter

In collaboration with

aaps American Association of Pharmaceutical Scientists

What to expect.

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

Click here to meet the speakers

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

The Agenda.

Three days with five unique sessions!

Click here to view agenda!

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

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.**

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

Your Participation.

Click here to book your ticket!

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).

Attend in-person and network with experts from:

aaps
MERCK
sotax
amneal
tolmar
UCONN SCHOOL OF PHARMACY
PHARMACY UNIVERSITY OF MICHIGAN
FDA
UNIVERSITY OF MARYLAND
Lilly
Bristol Myers Squibb
Lonza
Pfizer

....and more.