

FREEZE-DRYING OF PHARMACEUTICALS AND BIOLOGICALS – Short Course & Conference



One voice for pharmaceutical quality®

The National Institute for Pharmaceutical Technology & Education

FINAL PROGRAM

AUGUST 1–4, 2023

BEAVER RUN RESORT & CONFERENCE CENTER
BRECKENRIDGE, CO



UConn | SCHOOL OF PHARMACY



FREEZE-DRYING OF PHARMACEUTICALS AND BIOLOGICALS – Short Course & Conference

TUESDAY, AUGUST 1, 2023

8:00 A.M. – 5:00 P.M. **Fundamentals of Freeze-Drying: A Short Course**

Taught by **Steve Nail** from Purdue and **Greg Sacha** from Baxter Biopharma Solutions. This course is intended primarily for those new to the science and technology of freeze-drying.

6:00 – 8:00 P.M. **Opening Reception - Sponsored & Hosted by Lyo-Hub**

We welcome you back to Breckenridge after a too-long hiatus from face-to-face meetings. We hope that the informal atmosphere of this conference will promote a deeper understanding of the science and technology of pharmaceuticals freeze-drying and facilitate exchange of knowledge among participants.

The Organizing Committee:

- Alina Alexeenko, Purdue
- Bakul Bhatnagar, Pfizer
- Robin Bogner, University of Connecticut
- Taylor Candia, NIPTE
- Lorri Chapman, NIPTE
- Wolfgang Friess, University of Munich
- Arnab Ganguly, Amgen
- Steve Nail, Purdue
- Sajal Patel, AstraZeneca
- Ingo Presser, Boehringer Ingelheim
- Ed Trappler, Lyophilization Technology
- Gerhard Winter, University of Munich

FREEZE-DRYING OF PHARMACEUTICALS AND BIOLOGICALS – Short Course & Conference

WEDNESDAY, AUGUST 2, 2023

- 7:30 – 8:15 A.M. Continental Breakfast
- 8:15 – 8:30 A.M. Introduction and Overview of Meeting
Steve Nail, Purdue
- 8:30 – 9:15 A.M. Keynote: Lessons Learned from the Covid Pandemic
Nick Warne, Vice President, Pharmaceutical R&D, Pfizer, Inc.

❖ THE PHYSICS OF FREEZING AND FREEZE-DRYING

- 9:15 – 9:45 A.M. Managing the Cataclysm - Insights from the Fluid Dynamics of Freezing / **Miguel Rodrigues**, Professor, University of Lisbon
- 9:45 - 10:15 A.M. Protein/ice and Excipient/ice Interactions: Insights from High-Resolution Synchrotron X-Ray Scattering
Evgenyi Shalaev, AbbVie, Inc.
- 10:15 – 10:45 A.M. **Coffee Break – Exhibits & Poster Presentations Open**
- 10:45 – 11:15 A.M. Role of Vial-to-Vial Thermal Interactions: Impact on Nucleation Temperature Distribution / **Roberto Pisano**, University of Torino
- 11:15 – 11:45 A.M. Phase Transitions during Freezing and Freeze-Drying
Raj Suryanarayanan (Sury), University of Minnesota
- 11:45 A.M. – 12:15 P.M. Panel Discussion: The Physics of Freezing and Freeze-
- 12:15 – 1:30 P.M. Drying Lunch – Exhibits and Posters Open - **Lunch is Sponsored & Hosted by Millrock Technology**

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WEDNESDAY, AUGUST 2, 2023 cont...

❖ CHARACTERIZATION OF FREEZE-DRIED SOLIDS

Moderator(s): Robin Bogner and Sajal Patel

1:30 – 2:00 P.M. Correlation of Miscibility and Mobility with Protein Formulation Stability Using Solid-State NMR Spectroscopy
Eric Munson, Purdue University

2:00 – 2:30 P.M. Overcoming Challenges in Lyo Product Evaluation, Cycle Development, and Process Modeling with Microstructure Analysis /
Shawn Zhang, DigiM Solution LLC

2:30 – 3:30 P.M. **Mini-Presentations from Posters**
All poster presenters are invited to give a one-minute, single slide overview of their work.

3:30 – 4:00 P.M. **Afternoon Break – Exhibits and Posters Open**

Moderator(s): Gerhard Winter and Arnab Ganguly

4:00 – 6:30 P.M. **Technical Briefs and “Soapbox” Presentations**
Note: “Soapbox” presentations are 10-minute descriptions of products and/or services by exhibitors. The timing of the Soapbox Session may be adjusted based on final number of presentations.

6:30 – 8:00 P.M. **Wine and Cheese Reception**
- Exhibits, Posters, and Informal Discussion

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THURSDAY, AUGUST 3, 2023

7:30 – 8:15 A.M. Continental breakfast

❖ FREEZE DRY PROCESS DEVELOPMENT

Moderator(s): Ingo Presser

8:15 – 8:45 A.M. Design of the Freezing Step to Minimize Primary Drying Time
Robin Bogner, University of Connecticut

8:45 – 9:15 A.M. Maximum Quality at Maximum Speed: A novel Modeling-Based Approach to Primary Drying Cycle Design
Brecht Vanbillemont, Coriolis-Pharma Research GmbH

9:15 – 9:45 A.M. On the Importance of Residual Moisture Level at the end of Primary Drying / **Wolfgang Friess**, University of Munich

9:45 – 10:15 A.M. Coffee Break

10:15 – 10:45 A.M. Modeling of the Distribution of Individual Vial K_v Values and Application to Process Development / **Jean-Rene Authelin**, Sanofi S.A.

10:45 – 11:15 A.M. The Graphical Design Space for Primary Drying: Sources of Variability in the Dried Product Layer Resistance and Impact on Cycle Design / **Jayasree Srinivasan**, Baxter International Inc.

❖ PROCESS ANALYTICAL TECHNOLOGY

Moderator(s): Wolfgang Friess

11:15 – 11:45 A.M. Effect of Comparative Pressure Reading on Quality Attributes of Protein Formulations / **Lokesh Kumar**, Genentech Inc.

11:45 A.M. – 12:15 P.M. TDLAS Smart Freeze-Drying Control Using a Heterogeneous Drying Model / **Bill Kessler**, Physical Sciences Inc.

12:15 – 12:45 P.M. A Quantitative Study of Volatile Byproducts Generated During Primary and Secondary Drying Using Residual Gas Analysis
Alina Alexeenko, Purdue University

12:45 – 1:15 P.M. Panel: Freeze Dry Process Dev & Process Analytical Tech

Afternoon is for relaxation—**BOX LUNCHESES PROVIDED.**

6:00 – 8:00 P.M. **New addition to program!**
Reception or Brewery gathering
- Drinks & snacks

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FRIDAY, AUGUST 4, 2023 cont...

7:30 – 8:15 A.M. **Continental Breakfast**

❖ **FREEZE-DRYING OF NOVEL MATERIALS, ALTERNATIVES TO TRADITIONAL FREEZE-DRYING, AND QUALITY CONSIDERATIONS**

Moderator(s): [Alina Alexeenko](#)

8:15 – 8:45 A.M. Freeze-Drying of Red Blood Cells, and Beyond
Michael Menze, University of Louisville

8:45 – 9:15 A.M. How's Your Vision: A Closer Look at the Current State of Automated Inspection of Lyophilized Products / **Jeff Najarian**, Merck

9:15 – 9:45 A.M. A Breath of Fresh Air: Challenges and Opportunities in Development of Inhaled Biologics / **Sajal Patel**, AstraZeneca

9:45 – 10:15 A.M. **Coffee Break**

10:15 – 10:45 A.M. Thin-Film Freeze-Drying / **Bill Williams**, University of Texas

10:45 – 11:15 A.M. Continuous Freeze-Drying / **Jos Corver**, RheaVita BV

11:15 – 11:45 A.M. Spray Freeze-Drying: The Road to Commercial Implementation
Serguei Tchessalov, Pfizer

11:45 A.M. – 12:15 P.M. Panel Discussion: Novel Materials and Alternatives

12:15 – 1:30 P.M. **Lunch**

❖ **MANUFACTURING SCIENCE, QUALITY, AND REGULATORY**

Moderator(s): [Bakul Bhatnagar](#)

1:30 – 2:00 P.M. Big Data Analytics for Lyoprocess and Equipment Health Monitoring / **Arnab Ganguly**, Amgen Inc.

2:00 – 2:30 P.M. Cloudy with a Chance of Freezing Rain: Vial Headspace Meteorology during Controlled Ice Nucleation by Rapid Depressurization
Andrew Strongrich, Purdue University

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FRIDAY, AUGUST 4, 2023 cont...

❖ **MANUFACTURING SCIENCE, QUALITY, AND REGULATORY cont...**

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| 2:30 – 3:00 P.M. | Microwave-Assisted Freeze-Drying / Gerhard Winter , University of Munich <i>and</i> Ingo Presser , Boehringer Ingelheim GmbH |
| 3:00 – 3:30 P.M. | Lyo-Hub Freeze-Drying Technology Roadmapping Project Summary. Alina Alexeenko , Purdue University |
| 3:30 – 4:00 P.M. | General discussion and meeting wrap-up |
| 4:00 P.M. | Adjourn |
| 4:00 P.M. | New addition to program! Happy Hour/Celebration (<i>details will be sent via email week of July 24 and again at conference start</i>) |

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