Lyophilization USA
Day One | Thursday 15th November 2018

8.30 Registration & Coffee

9.00 Chairman’s Opening Remarks
Timothy McCoy, Associate Director, Global Pharmaceutical Development, Biologics Research and Development, Sanofi

NOVEL TECHNIQUES AND ADVANCES WITHIN LYOPHILIZATION

9.10 OPENING ADDRESS
Comparing and contrasting two methods of controlled nucleation for use in lyophilization: A live viral vaccine (LVV) perspective
• Evaluation of two methods of controlled nucleation: pressurization / depressurization technology and “ice-fog” technology
• Can controlled nucleation impart consistency whilst maintaining vaccine potency?
• Impact on cycle time, consistency and moisture levels
Morissa Jones, Senior Scientist, Vaccine Drug Product Development, Merck & Co., Inc.

9.50 Continuous monitoring of sublimation rate for individual containers in freeze drying processes
• Negating the need for conventional gravimetric measurements
• Providing more accurate measurements than TDLAS
• Introducing minimal disturbance to the freeze drying process
• Facilitating data acquisition for recipe design
Pouya Tavousi, Post-Doctoral Fellow, Biomedical Engineering, University of Connecticut

10.30 Morning Coffee

11.00 Development of Lyophilized Anthim® for Injection
• Liquid Drug product developed into Lyophilized Drug Product
• Process Development, Transfer, Scale Up and Validation
• Working with several CMOs
• Working within US Government funding and regulatory restrictions
Colin Campbell, Director, Process Development, Elusys Therapeutics

11.40 Reconstitution challenges of lyophilized highly concentrated protein products
• Why highly concentrated protein products are difficult to reconstitute
• Formulation strategies to improve reconstitution
• Processing strategies to improve reconstitution
Robin Bogner, Professor in Pharmaceutics, University of Connecticut

12.20 Networking Lunch

NOVEL ANALYTICAL & OTHER TECHNOLOGIES IN LYOPHILIZATION

13.30 Novel technologies to enhance the freeze drying process
• Freeze-drying process optimization
• Understanding the effect of each step of the cycle on the drug product
• Clinical parameters in primary drying
• How to ensure the right process conditions
Session Reserved for Sponsor

14.10 KEYNOTE ADDRESS
 Freeze dryer characterization and application to drug product development and scale up
• Characterization of bench, pilot and industrial scale freeze dryers
• Product characterization & measurement of Rp
• Application of models to the development of a lyophilization cycle
• Scale up
• PAT applications to development and scale up
Timothy McCoy, Associate Director, Pharmaceutical Development, Biologics Research and Development, Sanofi

14.50 Afternoon Tea

15.20 Embedding predictive in-silico models into Amgen’s lyophilization processes
• Operationalizing in-silico models through the deployment of web-based applications for:
  - Lyo process development
  - Tech transfer and scale up
  - Recovery from process deviation at the manufacturing scale (models as soft-sensors)
• Beyond the vial model:
  - Roadmap for more complex first principle models
Fabrice Schlegel, Senior Engineer, Amgen

16.00 KEYNOTE ADDRESS
 Formulation and excipient selection for lyo product development of vaccines
• Challenges in handling labile vaccine antigen
• Approaches for excipient selection and formulation
• Long term product stability and potency assays
Sushma Kommareddy, Associate Director, Formulation Development, Takeda

16.40 Chairman’s Closing Remarks and Close of Day One
### Challenges in Freeze Drying

#### OPENING ADDRESS

**9.10 Challenges of lyophilized product development**
- **Formulation challenges**
  - Excipients selection
  - Dosage forms: solution, suspension, & oral melt
  - Route of administration: iv, im and oral
  - Solvents: aqueous and non-aqueous
  - API: biologics & small molecules
- **Process challenges**
  - Device selections

*Yanming Zu*, Director, Research and Development, Abon Pharmaceuticals

#### ssHDX/MS for solid protein formulations

**11.00 ssHDX/MS for solid protein formulations**
- Current methods used for the characterization of protein stability in lyophilized formulations
- Solid state hydrogen deuterium exchange coupled with mass spectrometry (ssHDX/MS)
- ssHDX/MS provide better correlation with accelerated stability results compared to other techniques

*Mohamed AbouGhaly*, Postdoctoral Research Associate, Purdue University

### Beyond Vial Lyophilization: Alternatives to Conventional Methods

#### KEYNOTE ADDRESS

**15.20 Vacuum-foam drying of biotherapeutics: Process considerations and stabilization of human T cells**
- Development of vacuum-foam drying technology
- Comparison of foam drying and freeze-drying
- Future direction

*Alex Langford*, Senior Associate Scientist, Biotherapeutics Pharmaceutical Research and Development, Pfizer

#### The future of lyophilization through participation in LyoHub

**16.00 The future of lyophilization through participation in LyoHub**
- Overview of unmet needs in lyophilization
- Strategies to address these unmet needs
- Future direction of lyophilization
- LyoHub key action points

*Alina Alexeenko*, Professor, Purdue University

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Current and Future Freeze-Drying Technologies and Methods

Workshop Leaders:
- Alexander Tambovzev, Project Engineering and Development
  Leader, Optima Pharma
- Dena Flamm, Business Development Manager, Optima Pharma
- Tom Robinson, Managing Director, Aerosol Therapeutics

Workshop overview:
Freeze dried products are well established in the market and there is an increasing trend in aseptically produced lyophilized products, including peptides and proteins. This workshop will give an introduction into the physics and thermodynamics of Freeze-Drying, including both presentation of topics and an open discussion within the group. The session will support a better understanding of the Freeze-Drying process with the different methods available in the market, including technical aspects for consideration. The session will also discuss an alternative Freeze-Drying process for consideration.

Why You Should Attend this Workshop:
The workshop is aimed at individuals from various backgrounds within the pharmaceutical, animal health and diagnostic industry including, but not limited to, Process / Site Engineers, Production, Validation Engineers, Project Managers and Cycle Developers (R&D). The workshop will also be of interest to participants working in areas of manufacturing / final fill process and packaging. Participants will have the opportunity to engage in an in-depth discussion with industry experts from Optima on the latest technological developments in the Lyophilization industry. Participants will gain a better understanding of the most up to date freeze-drying technology which is available on the market, as well as what the future of this field looks like. Enhance your knowledge on controlled nucleation, available PAT’s and the future of flexible PAT processes, and alternative freeze dryer technologies including spray drying, spin freeze-drying and microwave drying.

Agenda
8.30  Registration & Coffee
9.00  Chairman’s Opening Remarks
9.10  Theory of freeze drying
  • What is freeze drying?
  • GMP consideration for aseptic equipment design
  • Layout considerations
  • Automatic loading and unloading of freeze-dryers
9.50  Controlled nucleation
  • Scalability of controlled nucleation
  • Production
  • Controlled nucleation now and in the future
10.30  Morning Coffee
11.00  PAT as tools for freeze drying with variable process parameters
  • Existing freeze-drying processes
  • Available PAT’s
  • Future of flexible PAT processes – is this feasible?
11.40  Alternative and advanced freeze dryer technologies
  • Spray freeze drying technology
  • Spin freeze drying technology
  • Microwave drying technology
12.20  Closing Remarks and End of Workshop

About the Workshop Leaders:
- Dr. Alexander Tambovzev received his Ph.D. in refrigeration technology at the Technical University of Dresden in 2008 with a focus on modeling of dynamic processes. He was working in research and development of refrigeration systems for commercial and industrial applications. Currently he is a project engineering and development group leader at Optima pharma, Germany. The area of his responsibility is leading the project engineering of the freeze dryers as well as the R&D effort in the freeze dryer technology area.
- Dena Flamm is a Business Development Manager for Optima Machinery Corporation. She is responsible for freeze dryer development in the North American market and has over 17 years of experience in the pharmaceutical industry. Studies include, an MBA in International Management from the University of St. Thomas with an undergraduate degree in Business and Physics.
- Dr. Tom Robinson is a founder of Aerosol Therapeutics and serves as Managing Director. He focuses on the Atmospheric Spray Freeze Drying [ASFD] process, starting with intellectual property and extending to all aspects of ASFD development. This includes testing, to scale-up, to equipment manufacturing. Dr. Robinson worked in pharmaceuticals as a physician for over 20 years at several companies such as Pfizer and Sankyo. His broad experience spans a number of positions in clinical development, marketing, and management. He has worked in many different product categories and has guided several programs, including Procardia, Procardia XL, and Benicar, through the NDA approval process.

About the Organisation:
Optima Pharma develops and manufactures packaging technologies for pharmaceutical products. Systems from Optima Pharma are used to process blood plasma products, vaccines, oncology and biotech products. Our extensive technology portfolio includes washing machines, sterilization tunnels, filling and sealing, robotic production systems, spray drying systems, isolator technology and other functions.
NIPTE Workshop on Freeze-Drying/Lyophilization Fundamentals

Workshop Leader:
Robin Bogner, Professor in Pharmaceutics, University of Connecticut

Workshop overview:
This workshop is an abbreviated short course intended for those who are new to the area of freeze-drying/lyophilization. Participants will be provided an understanding of the essential aspects of freeze-drying necessary to better understand the more advanced topics to be presented at the subsequent conference.

Why You Should Attend this Workshop:
Students will learn:
- The variety of products that are manufactured by freeze-drying
- Details of the major steps in the freeze-drying process
- Formulation of solutions to be freeze-dried
- How to approach freeze-drying process design using common process analytical technologies

Agenda

13.30 Registration and Coffee
14.00 Opening Remarks and Introductions
14.10 Introduction to freeze-drying
  - Why dry?
  - What we dry – drug substance, intermediates, small molecular therapeutics, protein drugs, complex dosage forms, cells and tissues
  - Freeze-drying containers – vials, trays, dual chamber syringes, etc.
14.50 Steps in the freeze-drying process
  - Ice nucleation and changes in ice crystals during freezing
  - Heat and mass transfer for sublimation of ice (or other solvents) during primary drying
  - Maintaining the product temperature below Tg' or a eutectic temperature
  - The difference between primary drying and secondary drying
15.30 Afternoon Tea
16.00 Formulation and fill
  - When and what quantity to use for formulation components including lyoprotectants, surfactants, buffers, bulking agent
  - Why fill depth matters
  - Understanding and measuring the Tg' of the formulation
  - Phase changes in the formulation during freezing and drying
16.40 Process design and process analytical technologies
  - Design space and batch uniformity
  - When is the product dry?
  - Real time measures of sublimation rate
  - Real time measures of product temperature
17.20 Closing Remarks and End of Workshop

About the Workshop Leader:
Robin Bogner is a Professor of Pharmaceutics in the Department of Pharmaceutical Science at the University of Connecticut where she is also a member of the Institute of Materials Science. She received her B.S. in Pharmacy from Rutgers University, M.S. from the University of Iowa, and Ph.D. from Rutgers University after which she joined the faculty of the University of Connecticut. Dr. Bogner’s research interests are focused on the characterization and dissolution of pharmaceutical solids, both freeze-dried parenteral and oral dosage forms. She teaches a course in mass transfer and in a freeze-drying course at the University of Connecticut. Dr. Bogner has served on several editorial boards, a USP committee, an FDA advisory committee and in various leadership roles in the American Association of Pharmaceutical Scientists (AAPS). Dr. Bogner is a faculty member of the National Institute for Pharmaceutical Technology and Education (NIPTE), a group of faculties from 17 universities with the mission of improving the way medicines are designed, developed and manufactured to meet the needs of patients in the 21st century. She has been involved in the NIPTE since its inception. Dr. Bogner is also a Teaching Fellow at the University of Connecticut, and Fellow of the AAPS.

About the Organisation:
The National Institute for Pharmaceutical Technology and Education (NIPTE), is a group of faculties from 17 universities with the mission of improving the way medicines are designed, developed and manufactured to meet the needs of patients in the 21st century.