APRIL 24 - 25, 2024
YORK, PA

Lyophilization of Pharmaceuticals and Biologics:
Concepts to Commercialization

Directed by:

Dr. Madhav Kamat, Ph.D., R. Ph.

Hosted by:

BioTechnique®

COURSE TOPICS INCLUDE:

- Small molecules and biologics
- Design of freeze drying cycles
- Cycle optimization, Scale-up/transfer considerations
- Quality control, validation, regulatory aspects
- Equipment, temp/pressure probes, control and qualification
- Container-closure selection and qualification

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COURSE DESCRIPTION:

This course presents the principles and techniques of lyophilization based on theoretical concepts and practical examples. Scientific aspects of aqueous systems, phase transitions, and collapse phenomena are explained. Emphasis on pharmaceutical aspects including formulation, stability, cycle development, process scale-up and analytical instrumentation is provided. Regulatory requirements including cGMPs, validation and qualification will be discussed. Engineering elements of heat and mass transfer, process control, and lyophilizer qualification are reviewed as well. The principles presented will be related to practical industrial examples throughout the course.

WHO SHOULD ATTEND:

This course is designed for personnel in the pharmaceutical, diagnostic, biomedical engineering and biotechnology industries responsible for the specification, development and production of lyophilized products, including:

- R&D Personnel
- Production Supervisors
- QA/QC
- Chemists
- Microbiologists
- Project Management
- Pilot Plant Operations
- Managers
- Regulatory Affairs
- Chemical Engineers
- Pharmacists

Those new to the industry and those with previous experience will find the course beneficial

LEARNING OBJECTIVES:

Upon completion of this course, you will be able to:

- Outline the fundamentals of lyophilized product development and the underlying scientific and engineering principles involved in freezing, primary drying, and secondary drying
- Explain the requirements needed to develop efficient freeze drying cycles
- List the factors involved in process scale-up, control and optimization
- Describe the equipment and instrumentation involved in lyophilization
- Explain the requirements for validation of lyophilization products and processes
- Discuss recent trends in lyophilization of pharmaceuticals

COURSE OUTLINE:

First Day:

Introduction to Freeze-Drying

• Basic theory and brief history

Physical Properties and Characterization of Materials

• Crystalline vs. amorphous vs. mixed systems
• Eutectic melting, glass transition, and collapse temperatures
• Principles of thermal analysis – theory and equipment
• Freeze-dry microscopy equipment and techniques

Fundamentals of Freeze-Drying – Freezing

• Ice nucleation and growth
• Eutectic and/or glass formation
• Annealing theory and techniques

Fundamentals of Freeze-Drying – Various stages

• Primary drying: Introduction to heat and mass transfer operations
• Influence of pressure and temperature on process characteristics

- Secondary drying: Mechanism for moisture loss and retention
- End of drying: Determination of termination of cycles

Container Closure Systems

• Influence on heat and mass transfer: Impact of molded vs tubing vials
• Container closure qualifications: Container-closure operational qualification (CCOQ), Container-closure integrity testing (CCIT), Delamination issues, vial breakage etc.

Second Day:

Formulation Development – Small and Large Molecules

• Pre-formulation assessment
• Selecting acceptable formulation components
• Examples

Lyophilization Process Development and Cycle Design

• Reviewing and utilizing the thermal analysis data
• Designing optimized freezing, primary, and secondary drying regimens

Quality Control of Lyophilized products

• Finished product testing
• Appearance of cake, moisture content, other inspection issues

• Stability tests

Scale-Up and Cycle Transfer, Maximum Throughput Capability

Understanding Pharmaceutical Freeze Dryers

• Components of a freeze dryer
• Measurement/Control systems
• CIP, SIP; Stoppering; Automated loading
• Computer/PLC control of research and production freeze drying

Other considerations

• Non-aqueous lyophilization, controlled nucleation, vacuum in vials, bulk freeze drying, remote sensing of product temperatures
• Syringe Freeze-drying
• Review of some representative freeze drying cycles
• Some significant publications

Validation and regulatory aspects

• Regulatory requirements, QbD Principles
• Validation of the Freeze-Dryer
• IQ/OQ, FAT/SAT
• Regulatory Compliance: Review of applicable regulatory guidance documents, Inspectional observations and corrective actions

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SPECIAL PRESENTATIONS AND DEMONSTRATIONS BY:

THE McCRONE GROUP

Use of freeze drying microscopy (FDM) for pre-process analysis of pharmaceutical formulations in the liquid-frozen state to establish the critical events and corresponding temperatures.

METTLER TOLEDO

Post-process analyses of dry-state lyophilized pharmaceuticals using modulated differential scanning calorimetry (MDSC) to determine the glass transition temperature (Tg) thermal behavior and the use of Karl Fischer titration and reconstitution to assess the residual moisture.

West

Manufacturer of container closure systems and drug product packaging testing services.

SCHOTT PHARMA

Manufacturer of prefillable syringes, cartridges, vials, and ampoules with container closures and product testing services. Lyophilizer make, model and size selection, maintenance, and repair

COURSE DIRECTOR:

Dr. Madhav Kamat is a Founder/CEO of Kamat Pharmatech LLC, a pharmaceutical consultancy firm, having 25 years of sound industrial experience specializing in the area of injectable products and processes. Dr. Kamat has significant experience in product/process development (small molecule and biologicals) involving formulation development, lyophilization, scale-up/technology transfer, and sterile manufacturing of more than 20 injectable products. He is well recognized for his expertise in lyophilization, nanosuspension technology, aseptic technology, and other sterile manufacturing processes.

Dr. Kamat received his B. Pharm and M. Pharm from Bombay University and Ph.D. from the College of Pharmacy at the University of Kentucky, USA. Dr. Kamat worked at Bristol-Myers Squibb Company for the last seventeen (17) years in Technical Operations and R&D–most recently as a Director. Prior to BMS, Dr. Kamat worked at Centocor Inc. and Johnson& Johnson. Dr. Kamat has been a visiting professor at the College of Pharmacy, University of Kentucky, and at New Jersey Institute of Technology, NJ. Dr. Kamat is also a Registered Pharmacist in the States of Pennsylvania and New Jersey.

COURSE VENUE:

Onsite

- The course will be held at **250 Cross Farm Lane, York, PA 17406**.
- See www.biotechnique.com for hotel information

Virtually

- Those who cannot attend in person are able to stream the event for **FREE**.
- See the event website for the streaming link.

Note: Those who choose to attend virtually will only have access to the lectures, as the equipment demonstrations will not be streamed.

REGISTRATION FEES:

Regular Tuition	**$1,500**
Student Tuition	**$150**

Group Discount: Register 2 or more from the same company, at the same time, for this course and receive a 10% discount off each registration.

Tuition payable in US funds net of all charges includes continental breakfast, luncheon, breaks, and course notes.

Livestream: **FREE** (only includes lectures and course notes)

Note: Payment is due 2 weeks prior to course or at time of registration.

HOW TO REGISTER?

Step 1: Scan the QR code to register for the course.

Step 2: You will receive a call or email from our training event coordinator with confirmation of participation and payments.

Step 3: Receive order confirmation through email.

Training event coordinator:

Noelle Crowley
ncrowley@biotech.com