



# Lyophilization Technology

## The Theory and Practice of Freeze Drying of Pharmaceuticals

20-21 April 2017



Baldiri Reixac, 10 - 08028 Barcelona - Spain

### Course Topics Include:

- Small molecules and biologicals
- 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

### 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
- Chemists
- Pilot Plant Operations
- Chemical Engineers
- Production Supervisors
- Microbiologists
- Managers
- Pharmacists
- QA/QC
- Project Management
- Regulatory Affairs

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 Description

This course presents the principles and techniques of lyophilization based on theoretical concepts and practical examples. Scientific aspects of aqueous systems, phase transitions, 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.

### Course Director

**Dr. Madhav Kamat** is a Founder/CEO of Kamat Pharmatech LLC, a pharmaceutical consultancy firm. He has 25 years of industrial experience specializing in the area of injectable product and process development (small molecule and biologicals), formulation development, lyophilization, scale-up/technology transfer, and sterile manufacturing of more than 20 injectable products. He is recognized for his expertise in lyophilization, nanosuspension technology, aseptic technology, and other sterile manufacturing processes. His recent interests are formulation and process development of biological products and IV injectable products of water insoluble drugs.

Dr. Kamat holds a B. Pharm, M. Pharm from Bombay University and a Ph.D. from College of Pharmacy, University of Kentucky,

USA, where he graduated with a dissertation on lyophilization technology. He has authored many publications on sterile products and lyophilization. Dr. Kamat worked at Bristol-Myers Squibb for seventeen 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 University of Kentucky and at New Jersey Institute of Technology, and he is also a Registered Pharmacist in the States of Pennsylvania and New Jersey.

### Additional Faculty

**Mukund 'Mike' Yelvigi**, Founder & Principal at Center for Pharmaceutical Integration, LLC. New Jersey (USA).

Course offered by



**FIRST DAY**

8:30-9:00

**Registration**

9.00-17:30

**Review of Learning Objectives**

- Course introduction and format

**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.

**Formulation Development – Small and Large Molecules**

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

**SECOND DAY**

9.00-17:30

**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

**Review of the course**

**Assessment Opportunity**

**TUITION AND PAYMENT**

**Early registration \*\*:**

(received before February 20, 2017) - Euro 1750+VAT/1575+VAT (group discount\*)

**Regular registration:**

(received after February 20, 2017) - Euro 1950+VAT/1755+VAT (group discount\*)

(Fee includes course materials, lunches and coffee breaks)

Participants are responsible for their own hotel reservations.

\* Group discount is for two or more enrollments from the same company.

\*\* Early Registration means: registrations forms received by the deadline and payments made within one week from invoice date. Otherwise regular registration fee will be applied

**Payable by bank transfer upon issuing an invoice. Payment instructions will be provided upon registration.**

**Registration**

Name .....

Surname .....

Position .....

Organization .....

VAT .....

Address .....

Postal Code .....

City .....

Country .....

Phone/Fax .....

Participant e-mail .....

Billing e-mail .....

PLEASE RETURN BY FAX OR E-MAIL



**General information**

Cancellations received after March 30, 2017 will be invoiced completely. All cancellations will be subject to euro 300 processing fee. Substitutions may be made at any time. Payment is due once the participant receives an invoice. Certificates will be issued to participants upon completion of the course.

**For Information please contact us at:**

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