

Lyophilization Formulation and Process Development

DIRECTED BY

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ACCREDITED
COURSE

Course Topics Include:

- Review of Basics of Lyophilization
- Formulation Development
- Selection of Excipients
- Process Development
- Optimization of Primary Drying: Design Space Modeling
- Optimization of Secondary Drying and Residual Moisture Level

about the course

Lyophilization is a very common technique used in preparing finished drug products. Yet there are many problems that can arise in production if the process has not been carefully developed. Without a good understanding of the development of this formulation and the process, these problems can readily occur.

This 2-hour accredited course will provide a brief review of the basics of Lyophilization. Participants will be able to dive deep into understanding how to select excipients for formulations, solution formulation development, thermal analysis, and lyophilization formulation development. Discussions will then address how to develop ideal lyophilization process conditions through optimization of primary and secondary drying. The lecture will then go over the first principles of heat and mass transfer in the process. Participants will also learn to establish a residual moisture specification.

who should attend

This course is intended for those professionals who have a basic understanding of lyophilization technology and would like to learn formulation and process development from a Research & Development perspective.

The course will specifically benefit those in the pharmaceutical, diagnostic, biomedical engineering and biotechnology industries working in the areas of R & D, manufacturing, and quality control.

learning objectives

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

- Understand the role of formulation excipients and apply knowledge in judicious selection of excipients
- Appreciate differences between small and large molecules and develop formulations accordingly
- Describe the process parameters and development of efficient process controls
- Demonstrate the ability to use process conditions to optimize primary drying
- Establish connection between secondary drying and residual moisture levels and how to optimize the latter

course outline

Review of Learning Objectives

Module 1: Basics of Lyophilization

- Why lyophilization?
- Different steps of lyophilization

Module 2: Formulation Development

- Understanding of small and large molecules from formulation perspective
- Properties of excipients and compatibility with drug substance and other components
- Development of a solution formulation screening and identify a candidate for lyophilization
- Examination of formulations by thermal analysis

Module 3: Lyophilization Process Development

- Factors to consider for the development of a robust lyophilization cycle
- Determination of failure point during lyophilization
- First principles of heat and mass transfer
- Design space modeling for optimization of primary drying
- Optimization of secondary drying
- Establishment of residual moisture level range

Assessment Opportunity

course instructor

Dr. Jayasree (Jay) M. Srinivasan is a Research Scientist in the R&D laboratory at Baxter BioPharma Solutions in Bloomington, IL. She received her BSc from University of Madras (India), MS in Synthetic Organic Chemistry from the University of Houston, and PhD in Synthetic Organic Chemistry from Indiana University. Her areas of focus at Baxter include formulation (both solution and lyophilized) and process development of sterile products.

Accreditations



International Accreditors for Continuing Education and Training (IACET)

Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 2 contact hours, or .2 CEUs. For further information, visit www.iacet.org