COBBLESTONE

COURSE ID 2977

Introduction to Lyophilization Technology

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Basics of lyophilization
- Formulation development
- Lyophilization process development
- Analytical characterization
- Aseptic manufacturing

about the course

The course introduces participants to the basics of lyophilization and why we lyophilize drug products. Typical approaches to developing a drug product formulation and lyophilization process development will be discussed. At the end of the course, participants will be able to identify analytical techniques that are available to characterize drug products. The final goal of the course is to understand challenges involved in aseptic manufacturing and transfer of lyophilization cycles from R&D to Production.

who should attend

This course is intended for those new professionals working in the pharmaceutical or biotechnology industries in the area of lyophilization of parenteral drug products. The course will discuss basics of lyophilization, product and process development, characterization of drug products, and aseptic manufacturing. Participants may also include those that need a refresher on these topics.

- R&D
- Production
- Quality Control

For information on pricing, terms/conditions, Team Training, and other courses, please visit **www.TrainwithCobblestone.com**

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learning objectives

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

- Demonstrate appreciable knowledge in the area of lyophilization
- Explain the role of each component present in drug products, both small and large molecules
- Apply learnings to design efficient lyophilization process controls
- Identify analytical techniques for drug product characterization
- Compare and contrast lab scale versus production manufacturing of parenterals

course outline

Review of Learning Objectives

Module 1: Basics of Lyophilization

- Introduction to currently available parenterals on the market
- Requirements of sterile parenterals
- Why lyophilization?
- Different steps of lyophilization

Module 2: Formulation and Process Development

- Formulation requirements for small and large molecules
- Examination of formulations by thermal analysis
- Factors to consider for the development of a robust lyophilization cycle

Module 3: Characterization Techniques and Aseptic Manufacturing

- Critical quality attributes of lyophilized drug products
- Analytical tools available for characterization
- Key components of aseptic manufacturing

Assessment Opportunity

course instructor

Dr. Jayasree (Jay) M. Srinivasan is a Research Scientist in the R&D laboratory at Baxter BioPharma Solutions in Bloomington, IN. She received her BSc from University of Madras (India), MS in Synthetic Organic Chemistry from University of Houston, and PhD in Synthetic Organic Chemistry from Indiana University. Her areas of focus at Baxter include formulation (both solution and freeze dried) 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 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org