COBBLESTONE

COURSE ID 279

REVISED!

Lyophilization of Pharmaceutical Drug Products

DIRECTED BY

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8 Hours

ACCREDITED COURSE

- The Basics of Lyophilization
- Lyophilization Formulation and Process Development
- Selection of Excipients
- Optimization and Design Space Modeling
- Residual Moisture Level

about the course

Lyophilization offers unique properties for delivering critical parenteral drugs. Therefore, developing the formulation and the manufacturing process is challenging. Only through a clear identification of the process and key excipients can a robust formulation be developed and manufactured.

This intensive, 8-hour accredited training included a demonstration conducted by The McCrone Group, Inc. The first session 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.

Next, after a brief review of the basics of lyophilization, participants will be able to dive deep into understanding selection of excipients for formulations, solution formulation development, thermal analysis, and lyophilization formulation development. Participants will then learn how to develop ideal lyophilization process conditions through optimization of primary and secondary drying.

Discussions will then address the first principles of heat and mass transfer in the process. Participants will also learn to establish a residual moisture specification. This will be followed by a demonstration on the use of the freeze-dry microscope by The McCrone Group, Inc.

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 offer an understanding of the challenges involved in aseptic manufacturing and transfer of lyophilization cycles from R&D to

Production.
Since this training is highly interactive, you must have a webcam on your computer equipped with a microphone and speakers/headset in order to fully participate.

who should attend

This course is intended for those who are new to the area of lyophilization as well as those that 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 R&D, formulation, and manufacturing.
Managers and supervisors of this personnel will also benefit from this training by learning the challenges faced by them.

learning objectives

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

- Demonstrate appreciable knowledge in the area of lyophilization
- Describe the role of each component present in drug products, both small and large molecules and apply knowledge in judicious selection of excipients
- Review the process parameters and development of efficient process controls
- Identify analytical techniques for drug product characterization
- Establish connection between secondary drying and residual moisture levels and how to optimize the latter
- 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: Overview of Formulation and Process Development

- Formulation requirements for small and large molecules
- 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

Module 4: Formulation Development

- Understanding of small and large molecules from a 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 5: 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

McCrone Demonstration/Lecture: The use of the freeze-dry microscope

Question and Answer Session

Assessment Opportunity

course instructor

Dr. Jayasree (Jay) M. Srinivasan is a Research Scientist in the R&D laboratory at Simtra BioPharma Solutions in Bloomington, IN. 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 Simtra 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 X contact hours, or X CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)

Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.