Lyophilization Basics for Pharmaceuticals: History, Scientific Principles, Cycles and Formulations

1. Training Overview

This course will act as an introduction to freeze-drying of pharmaceutical parenteral products. Many drug substances require the extra protection that lyophilization provides, and the formulation of the liquid drug product must be designed to optimize efficacy of the finished dried product. The course will cover how lyophilization works to convert a liquid drug product into a dried, more-stable powder. Cycle and formulation design will be explained, along with the scientific principles that are at play.

2. Learning Objectives

- Definition of freeze-drying
- Identify ideal characteristics of a freeze-dried product
- Determine when freeze-drying is necessary
- Phases of the lyo cycle, and the scientific principles that drive each phase
- Formulating drug product for successful freeze-drying
- Analytical tools used to aid in formulation and cycle development

3. Who Will Benefit

- Professionals in Quality Control
- Quality Assurance
- Validation
- R&D Groups
- Biochemists, Pilot Plant Operators
- Chemical Engineers
- Production Supervisors
- Chemists
- Equipment Maintenance
- Mechanical Engineers

4. Agenda

Section 1: History and background

- Definition of freeze-drying, history, and commonly freeze-dried materials
- Desired freeze-dried characteristics
- Advantages and limitations of freeze-drying
- Process overview

Section 2: Physical, chemical, and engineering principles

- Vapor pressure
- Sublimation and the phase diagram of water
- The heat of sublimation of ice
- Rate processes in freeze drying – heat transfer and mass transfer
- States of matter – crystalline and amorphous

Section 3: Lyo cycle phases

- Freezing (with optional annealing)
- Primary drying (sublimation of water vapor)
- Secondary drying (diffusion and evaporation of water that did not freeze as ice)

Section 4: Lyo formulations

- Excipients for small and large molecules

Section 5: Quality product attributes

- General and specific to freeze-dried products
- Influence of collapse and eutectic melting

5. Faculty

Lisa Hardwick Thompson

Our faculty Pharmaceutical Lyophilization Expert (25 + yrs Exp.) Indiana, United States

Our trainer is a pharmaceutical technology consultant and educator with quality, regulatory, product/process development, and technical management experience at Cook Medical, Baxter, Catalent, and start-up businesses. During her career based in the pharmaceutical CMO sector, her expertise has been dedicated to the creation and/or transfer of clinical and commercial formulations and processes, specifically focused on lyophilized parenteral drug products. Her current role is devoted to consultation and education in the field of lyophilization.