This course is designed to provide attendees with a practical approach to understanding the scientific and engineering principles of lyophilization. The topics discussed during the course will be presented to explain the physical, physicochemical, biochemical, and engineering principles of the science and engineering behind modern freeze-drying. The practicality of the course allows the attendees to get a firm understanding of the theoretical applications of freeze-drying and how these can be easily used and applied to their day to day lyophilization projects.

WHO SHOULD ATTEND
This two-day lyophilization training course is designed for those in the pharmaceutical, biomedical, medical device/diagnostic, and biotechnology industries who develop and/or produce lyophilized (freeze-dried) products. This includes, but is not limited to, professionals in Quality Control, Validation, Pharmacists, Managers, Microbiologists, R&D Groups, Biochemists, Pilot Plant Operators, Chemical Engineers, Production Supervisors, Chemists, Equipment Maintenance, and Mechanical Engineers. The course will also benefit those in other departments who find lyophilization among their responsibilities.
Edward W. Sunbery, R.Ph. is a pharmaceutical technology consultant. His fields of expertise include product development, engineering and technical management experience with such organizations as Merck, Onco Therapeutics, Warner Lambert and Wyeth Laboratories.

Mr. Sunbery’s product-development experience includes the design and execution of pre-formulation studies, analytical methods development and product evaluations from pre-clinical studies through scale-up – including process and cleaning validation. This experience includes both oral and topical forms – as well as injectable forms of liposomes, solutions/suspensions and lyophilized products.

His engineering experience includes facility/equipment design, start up, trouble shooting and qualification. In addition, he has technical-management experience in the preparation and execution of validation master plans, factory-acceptance tests and equipment-qualification protocols. Mr. Sunbery also holds multiple patents for the detection of product tampering.

INSTRUCTOR CREDENTIALS

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FIRST DAY

Module 1: Introduction
- Harris and Shakell – Vacuum Desiccation of Rabies Virus
- Changes in the State of Water
- Molecular Structure
  - Ionic Bonds
  - Covalent Bonds
  - Hydrogen Bonds
  - Van der Waals Force
- Water and Transient Hydrogen Bonds
  - Molecular Distance and Kinetic Energy
  - Molecular Structure of Liquid Water and Solid Ice
  - Molecular Structure of Liquid water and Gas Vapor
- Sensible Heat Versus Latent Heat
- Heating Curve of Water
  - From Below 0ºC to Above 100ºC
- Heating Character of Water and Volume
- Barometric Pressure
- Barometric Pressure and Altitude
- Vapor Pressure
- Water Vapor – Temperature and Pressure
- Dew Point
- Frost Point
- Ice / Water / Vapor- Phase Diagram – Temperature and Pressure
- Colligative Properties of Water and Chemical Potential
  - Solubility
  - Polar Versus Non-Polar
  - Vapor Pressure
  - Boiling Point
  - Freezing Point
  - Osmotic Pressure
- Other Issues
  - Glass Transition Temperature
- Polymorphism

Module 2: Solidification
- Challenge – Converting Solutes in Water to Solutes in Ice
  - Temperature – Regulate Molecular Motion and Attraction
  - Chemical Potential – Impacts Freezing Point Depression
  - Glass Transition – Unique to Polymeric Molecules
- Solid Phase Transition and Pressure
- Solid Phase Transition and Solutes
- Solidification of Water
  - Locking Hydrogen Bonds
  - Nucleation – Molecular Clusters
    - Delayed Nucleation
  - Crystal Morphology and Cooling Rates
- Solidification and Density (Water Floats)
- Solidification Patterns and Fill Depth
- Solidification of Water and Chemical Potential
- Electrolytes and Freezing Point Depression
- Salt is Water Exhibits Multiple Freezing Points

Module 3: Sublimation (Primary Drying)
- Non-Electrolytes and Freezing Point Depression
- Solidification of Water and Electrical Conductivity and Resistance
- Solidification and Glass Transition Temperature
  - Low Temperature Differential Scanning Calorimetry
- Cooling Rates
  - Nucleation and Crystal Growth
  - Uncontrolled Nucleation
- Other Process Variables
  - Temperature
    - Shelf Temperature Equilibrium Time During Start Up
    - Product Temperature and Distribution Equilibrium During Loading
- Trays – Limit Direct Contact Between Containers and Shelf
- Tubing Versus Molded Vials
- Nucleation Control
  - Ice Fog
  - Depressurization
  - Ultra Sonic Vibration
  - Container Modification
- Crystalline Material in Solution
  - Freezing Temperature
  - Complex Solutions and Colloidal Suspensions
  - Collapse Temperature
  - Hot and Cold Stage Microscopy
  - Cellular Material and Protein Formulations
  - Super Cooling
  - Spray Freezing
  - Crystal Size Control
  - Annealing
  - Spray Freezing and Particle Size Control

Module 3: Sublimation (Primary Drying)
- Challenge – Convert Ice to Vapor and Back to Ice with no
  Liquid Phase
- Collapse Temperature
- First Law of Thermodynamics
  - Energy, Heat & Work
- Second Law of Thermodynamics
  - Entropy & Efficiency
- Third Law of Thermodynamics
  - Motion & Temperature
- Water Boiling Point Temperature and Pressure