



LYOPHILIZATION TECHNOLOGY:
PRODUCT, PROCESS
AND SYSTEMS



Surface Measurement Systems
World Leader in Sorption Science

2021
PENNSYLVANIA, USA



COURSE SCHEDULE

Course Overview

Biopharma is pleased to announce our collaboration with SMS Labs to provide upgraded facilities for our training course delegates, future events and local technical support. This course provides an opportunity to explore a wide range of elements in the lyophilization process. From characterization of products to cycle development and scale up, we cover the science and engineering of lyophilization. In addition, the programme will include SMS innovative instruments, such as their DVS and how it can assist in product analysis.

+ Day One

- **Welcome & Course Introduction**
- **Introduction to Lyophilization** - process, features and equipment
- **Break**
- **Product Freezing** - conditions to influence ice crystals and solutes, Controlled Nucleation
- **Refrigeration and Thermal Transfer Systems** - design elements of refrigeration systems in lyophilizers
- **Lunch**
- **Primary and Secondary Drying** - principles and practical aspects of primary drying (sublimation) and secondary drying (desorption)
- **Stoppering Systems** - functional requirements of shelf stoppering systems, alternative designs
- **Break**
- **Formulation for Lyophilization** - formulation design issues and strategies for lyophilized products
- **Process Condensers (Vapour Trap)** - protecting the product and the vacuum system from damage

+ Day Two

- **Formulation Characterization** - methods applied to formulations prior to lyophilization
- **Vacuum Systems** - pumps used to achieve the desired pressure, types of pressure gauge employed, methods for leak detection
- **Break**
- **Cycle Development & Scale-Up** - conditions for loading lyophilizer, freezing and drying
- **Lunch**
- **Process Monitoring** - temperature measurement and process analytical technology (PAT)
- **Alternative Approaches to Cycle Development** - the use of software-based cycle development programs, application of a Quality by Design (QbD)
- **Break**
- **Workshop Session** - evaluating lyophile appearance

+ Day Three

- **Containers, Closure and Barrier Technologies** - container designs and materials, types of closure and containment options
- **Product Analysis (Part 1)** - moisture content and long term stability, methods of moisture thermal analysis
- **Break**
- **Cleaning and sterilization of Freeze-Dryers** - manual cleaning and automated 'clean-in-place' (CIP) and 'steam-in-place' (SIP) systems
- **Product Analysis (Part 2)** - the appearance, structure and mechanical properties of lyophilized products, modern techniques such as DVS
- **Lunch**
- **Maintenance and Troubleshooting** - pros and cons of maintenance strategies, common problems
- **Product Analysis (Part3)** - modern techniques such as DVS employed to quantify specific aspects of the lyophilized products
- **Workshop Session** - multidisciplinary problem-solving group exercise, designing your own lyophilizer



WHO IS THIS COURSE RIGHT FOR?

INDUSTRIES:

- 1) Biotechnology
- 2) Pharmaceuticals
- 3) Biopharmaceuticals
- 4) Diagnostics e.g. medical

JOBS:

- 1) Formulation Scientists
- 2) Engineers/ Technical Support
- 3) Quality Assurance
- 4) Production operatives

MEET THE EXPERTS



+ Dr. Kevin Ward

Kevin has been in the field of lyophilization since 1993 and was awarded his PhD for studies in pharmaceutical freeze drying, focusing on protective agents in formulations of proteins and liposomes for drug and vaccine delivery. He is R&D Director at Biopharma, where he has worked since 2000 and regularly lectures on the freeze drying process.



+ Kevin Smith

With 25 years of industry experience, Kevin recently retired as Biopharma's Technical & Service Director. He has carried out installations, qualifications and re-location of a variety of freeze drying machines and was responsible for overseeing the day to day operation of the engineering team.

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Please note that the cost of accommodation is not included in the course fee* and that bedroom bookings must be made by the participants.

A list of local hotels will be provided with the registration confirmation.

*fees include morning and afternoon breaks, lunch and full lecture notes

Early bird prices to be confirmed.

Payment must be made in full before the start of the course to guarantee a place. Payment by BACS or credit/debit card is acceptable - please note we cannot accept payment by check. An invoice will be issued on receipt of booking. Payments in credit/debit card will be charged in GBP at the prevailing exchange rate as set by xe.com. An invoice will be issued on receipt of booking. Discounts are also available for academia and multiple bookings from the same company, please contact **Sally Potentier** at spotentier@biopharma.co.uk for more information. Cancellation in writing more than 5 weeks before the course start date will incur a service charge of 30% of the applicable fee. No refunds can be made for cancellation after this date. Substitutes will be accepted at any time. Transfer to another scheduled course must be made in writing and a service charge will be incurred. Full T&Cs available on request.