

Pharmaceutical Freeze-Drying

25th-27th October 2010 • San Francisco, CA

New &
Updated for
2010!

LYOPHILIZATION TECHNOLOGY

For the Pharmaceutical & Biotechnology Industries

A 3-DAY COMPREHENSIVE COURSE

25th-27th October 2010 • Hilton San Francisco Airport •

This 3-day course will bring you up to date on the latest technology by covering a broad range of topics related to both the equipment and the process. It will be relevant to those whose activities include:

Process Engineering
Pilot Plant Operation
Production
Quality Assurance
Formulation & Process R&D

Course Covers These Topics

- ***Principles of Freeze-Drying:***
The Design & Operation of Freeze Dryers
- ***Product Formulation & the Freeze-Drying Process***

It's not just academic!

This course will benefit those who regularly work in lyophilization, who need practical information about the process and problems they are likely to encounter. Our course is not based just on academic theory. Our lecturers have the benefit of years of hands-on experience and are still working within the industry today.

Presented By:



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Sponsored By:



Introduction to equipment, design and application

General Introduction to Freeze-Drying: Outlines history of process; reviews basic concepts of technology; outlines stages in process; discusses advantages and disadvantages.

Design of a Freeze-Dryer: Describes and discusses the design features of simple and industrial freeze-dryers

Containers and Stoppers: Discusses essential elements in tray (bulk) drying; ampoule and vial drying; special containers; impact of container design and manufacture on freeze-drying processes; outlines methods of container sealing including discussion of rubber stopper formulations and impact on product response to freeze drying

Issues in Industrial Freeze-Drying: Outlines and discusses concepts and design features of industrial freeze-drying equipment, automatic loading and modern control systems including validation and 21CFR11 issues

Process Analytical Technology: Current methods of monitoring the freeze drying-process

Vacuum Systems: Discusses the requirements of vacuum systems; describes vacuum pump systems including oil-filled rotary pumps; roots pumps; oil-free pumps; vacuum measurements

Condenser Operation and Design: Discusses requirements for vapour traps; describes design and operation of condenser systems on simple and industrial plant.

SIP & SIP: Current practices & design, comparison of different systems and user issues.

Refrigeration Systems in Freeze-Drying: Outlines refrigeration systems, including direct expansion and diatherm systems

Equipment Validation: Reviews and discusses requirements for validation process (IQ/OQ)

Maintenance and Troubleshooting: What can go wrong and suitable maintenance policy

Loading Systems: Principles and current practice

New,
Updated
Content

Product Formulation & the Freeze-Drying Process

The Steps of the Freeze Drying Process: Describes and discusses product freezing, primary drying and secondary drying.

The Importance of Formulation Characterisation Prior to Freeze Drying: Discusses the concept of crystalline vs amorphous states; discusses methods of measuring key transition temperatures.

Product Formulation Design : Discusses essential elements in Product Formulations; discusses strategies adopted in product formulation and cycle development; outlines practical problems associated with developing formulations for pharmaceutical, biotech or industrial applications

Freeze-Drying Microscopy and Thermal Analysis: Describes how a range of techniques can provide valuable information about the freeze-dried product, enabling prediction of stability issues and effect of moisture on the final product

Cycle Development and Scale-Up Issues: Describes conventional and non-conventional cycles used during pharmaceutical and industrial freeze-drying and the issues encountered in scaling up the process from lab to production

End Point Determinations: Describes theoretical, present and future trends in defining critical end-points in the process including product freezing; primary and secondary drying

Freeze-Drying Proteins and Biological Materials: Discusses issues specific to the freeze-drying of bioactive molecules, both in terms of the formulation and that process. Includes a number of real-life case studies

Analysis of the Freeze Dried Product: Including moisture content and thermal analysis, assessing appearance, residual oxygen and vial integrity.

Course Lecturers

Tom Peacock, Research Scientist

Tom is a research scientist and has specialised in the field of lyophilisation since 2006. He recently completed an MSc in Pharmaceutical Analysis which is a vital part of his R&D role in BTL. Tom has been handling client enquiries and new products specifically in the pharmaceutical and diagnostics fields, characterising products suitable for freeze-drying, looking at key factors and designing robust and efficient cycles. Tom takes a leading role today in the R&D and advising clients in the specialist area. He has also travelled widely commissioning freeze-drying microscopes, one of the vital instruments used in current development work.

Tony Gaster, Business Development Executive

A chemical engineer by training, Tony has been working in freeze-drying for more than 20 years and has regularly worked in freeze-drying in the United States since 1991. He was Director of Global Sales at Usifroid for 9 years, travelling all over the world and meeting different applications for freeze-drying. He helped design, improve and innovate different aspects of the machines whilst at Usifroid, one of the largest manufacturers. Tony started Biopharma in 1989 which has become the leading supplier of machines and services in freeze-drying in UK & Ireland. He has lectured with PDA, ISPE and CFPA in this field.

Richard Wood, Technical Director

Richard trained as a marine engineer specialising in control system engineering, refrigeration and training. In the past 17 years, he has built up a service department responsible for the installation, commissioning and validation of new machines and servicing of installed machines. Richard continues to write documentation concerned with the operation, maintenance and qualification of freeze-dryers.

The structure and content of the course will enable participants to gain a valuable understanding of the wider aspects of freeze-drying. Basic principles are explained and product and process issues and explored in more detail, as well as analytical techniques.

The course also covers aspects of equipment design, installation, validation and maintenance. All lecturers have practical hands-on experience in their fields of freeze-drying. There will be plenty of time allocated for interactions and questions. A comprehensive set of field notes is provided.

Workshops —

Workshop 1, "Critical Review of Freeze-Dried Materials": Held on the second day of the course, during this workshop participants are invited to assess processing defects for troubleshooting.

Workshop 2, "Interdisciplinary Problem-Solving": Held on the last day, this workshop is an interdisciplinary problem-solving exercise involving product processing and scale-up, machine specification and technical issues.

Comments from Previous Participants:

"...lots of opportunities to interact with speakers...excellent set of course notes... good presentations on Powerpoint with copies of slides...lots of new information..."

Previous attendees

GlaxoSmithKline	Fort Dodge
Pfizer	Cardinal Health
Eli Lilly	Merck
Astra Zeneca	Avecia
RP Scherer	Baxter
Abbott	Sigma-Aldrich
Allergan	Aventis
Genentech	

Registration

Registration

Dates: 25th-27th October 2010

Location: Hilton San Francisco International Airport
600 Airport Boulevard, Burlingame CA 94010
Phone: 650 340 8500 Fax: 650 343-1546

Please note the change of venue ownership from Sheraton Gateway to Hilton: www.hilton.com

A block of bedrooms will be reserved for participants to make their own bookings at a special **Biopharma rate**. This rate is available only up until 20th September so early booking is advised to avoid higher rates. Details will be mailed with your reservation confirmation. Please note that the cost of accommodation is not included in the course fee and that bedroom bookings must be made by the participants.

Fee: \$1800

Early Bird Discount: Pay just **\$1600** when Registration and Payment is made by 20th September. Fee includes breaks, lunch and full lecture notes.

Payment can be made via credit card or BACS. We are sorry but we cannot accept payment by check. Please note we have a fixed exchange rate for payments by credit card at £1295 GBP (£1150 Earl Birds). Contact Sharon on sturner@biopharma.co.uk with any questions about payment.

Discounts are also available for academia and multiple bookings from the same company, please contact us for more information.

Name:

Organisation:

Title:

Address:

Purchase order no.:

Email:

Phone:

Fax:

I would like to pay by:

- *Payment must be made in full 2 weeks prior to the start of the course. Select payment option above.*
- *Cancellation in writing before 20th September 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.*