

Freeze drying experts BTL present a three-day course covering the science and application of lyophilisation.

- Practical instruction that can be easily applied to real life situations
- Key concepts that will be relevant to all roles, including plant operation, quality assurance, product and process R&D, production
- Fundamentals of equipment design and function for operators and engineers
- Product characterization methods and interpretation and application of analytical data
- Formulating for freeze drying: concepts, key considerations and practical methodology
- Systematic cycle development for efficient, reliable processes
- Scaling up to production: formulation, process and equipment issues
- Using Process Analytical Technology (PAT) in development and troubleshooting
- Residual moisture content: effect on stability and shelf life and different analyses
- Clean-In-Place and Sterilize-In-Place (CIP and SIP) in freeze drying and their impact on freeze dryer design
- Benefits of lyophilisation over other stabilization methods
- Different equipment systems within a freeze dryer: how the systems interact, diagnosing faults from process errors, and tips for maintenance
- Containment options available for freeze dryers of all configurations, from laboratory scale to production, flexible and permanent, and how to specify the right containment
- Ensuring fitness for purpose: validation and qualification of systems
- Tips for maintenance and ensuring smooth operation, for operators and engineers
- Proteins: the unique challenges and complexities posed by these molecules when developing products and processes for freeze drying
- Analysis of freeze dried product demonstrates practical techniques for diagnosing processing failures and discusses methodologies to correct them



About BTL

Biopharma Technology Ltd (BTL) has provided specialist services in freeze drying since 1997. We have worked with hundreds of product types, from small drug molecules to large complex biomolecules, cells, tissues and even some more unusual products such as archaeological artefacts. As well as R&D, consultancy and training, we also worked to develop analytical instruments that would provide additional in-depth information for product and process development: the Lyostat freeze drying microscope and Lyotherm frozen state analyser. We continually participate in research projects to further the science and our understanding of freeze drying, with recent projects including red blood cells, collagen scaffolds and probiotics.

Richard Wood

Richard Wood served as Technical Director at BPS, the UK's leading freeze drying equipment company, for 25 years. BPS' service department is responsible for coordinating a range of technical services including installation, commissioning, validation and maintenance of machines that range from bench-top laboratory units to full-scale fully automated production facilities. Richard also has extensive experience writing custom documentation for freeze dryer operation, maintenance and qualification.



Dr Kevin Ward

Kevin was awarded his PhD for studies in pharmaceutical freeze-drying, focusing on the use of protective agents in formulations of proteins and liposomes for drug and vaccine delivery. He has worked in the pharmaceutical industry and as a research fellow in vaccine development. Kevin is R&D Director at BTL and regularly lectures on the freeze drying process as well as analytical and process related issues.



Venue

From its canals to world-famous museums and historical sights, Amsterdam is one of the greatest small cities in the world.

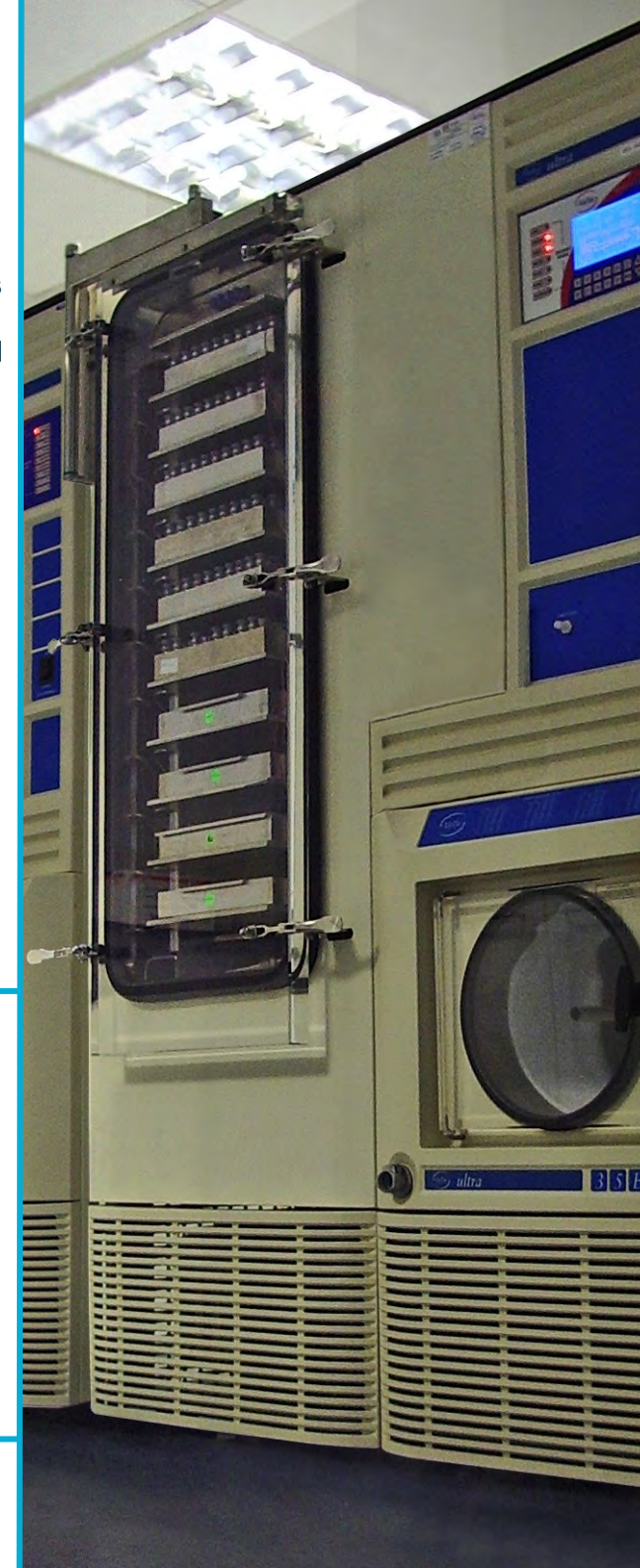
The Crowne Plaza Amsterdam City Centre hotel is a traditional townhouse with a modern twist, just 300 metres from Centraal Station. Receive a warm welcome in the bright, modern lobby, relax in the spacious Lobby Connect Lounge, and enjoy international favourites with a Dutch twist in the New Dorrius restaurant.

Crowne Plaza Amsterdam City Centre

Nieuwe Zijds Voorburgwal 5, Amsterdam 1012 RC, Netherlands

Phone: +31 20 620 0500 Email: amsnl.reservations@ihg.com

Please note: Accommodation is not included in the course fee.



Day 1	Day 2	Day 3
<p>08.15 Welcome & Course Opening</p> <p>08.45-09.45 Introduction to Freeze Drying Technology The advantages and challenges of freeze drying</p> <p>09.45-10.25 Freeze Dryer Design (1) Different types of equipment and key design factors</p>	<p>08.15-08.55 Formulation Characterization (1) Use of freeze drying microscopy for determination of critical temperatures</p> <p>08.55-09.45 Vacuum Systems Application, measurement and control of vacuum for freeze drying</p> <p>09.45-10.25 Formulation Characterization (2) Discussion of thermal methods of analysis including DTA, DSC, Zsinφ</p>	<p>08.15-09.15 Maintenance Strategy for Freeze Dryers Improving reliability of equipment and robustness of cycles</p> <p>09.15-10.15 Freeze Dried Product Analysis Methods for analysing freeze-dried product, including moisture determination, thermal analysis and other methods</p>
Break	Break	Break
<p>10.45-11.35 Product Freezing How ice structure and solute behaviour can affect freeze drying</p> <p>11.35-12.15 Freeze Dryer Design (2) Condenser types and how to size for your application</p>	<p>10.45-11.35 Temperature Measurement & Calibration A vital parameter for successful processing—discussion of tools and methods</p> <p>11.35-12.25 Secondary Drying, PAT & Endpoint Determination Monitoring & cycle considerations</p>	<p>10.35-11.15 Sterilization Systems Technologies, techniques and application to ensure sterility</p> <p>11.15-12.15 Vials, Stoppers & Barrier Technology Technologies available and the benefits for different applications</p>
Lunch (included)	Lunch (included)	Lunch (included)
<p>13.25-14.25 Primary Drying The vapour pressure differential; balancing heat and pressure for optimal drying</p> <p>14.25-15.25 Freeze Dryer Systems How the key systems within a freeze dryer operate</p>	<p>13.35-14.25 Refrigeration Systems (2) Distribution of cooling to the various areas of a freeze dryer; discussion of different refrigeration systems</p> <p>14.25-15.15 Cycle Design & Scale-Up Practical methodologies for developing cycles</p>	<p>13.25-14.05 Freeze Drying of Proteins The unique challenges posed by large complex molecules, from characterization to product / process design</p> <p>14.05-14.45 CIP Systems Techniques, technologies and validation</p> <p>14.45-15.25 Workshop 2 (Introduction) Problem solving of process defects in a production scenario: evaluating the data, identifying the cause, and proposing rectification</p>
Break	Break	Break
<p>15.40-16.25 General Concepts of Formulation Benefits and drawbacks of different excipients and issues affecting usage</p> <p>16.25-17.05 Refrigeration Systems (1) Theory and practice of refrigeration in a freeze dryer</p>	<p>15.30-16.30 Validation & Qualification Systems Ensuring systems meet required standards: the classic validation model and modern approach</p> <p>16.30-17.10 Workshop 1 An exercise to visually assess freeze-dried product and diagnose process defects</p>	<p>15.40-16.10 Workshop 2 (Conclusion) Discussion of results</p> <p>16.10 Course Ends</p>

Timetable shown is representative and may be subject to change.

Course details and booking form

Name		
Job Title		
Organisation		
Address		
Invoice Address (if different)		
Phone		
Fax		
Email		
Please reserve		places

Fax to: +44 (0)1962 841147 Email to: btl@biopharma.co.uk or book online at

www.biopharma.co.uk/training-courses/

Date: 19-21 April 2016

Location: Crowne Plaza Amsterdam City Centre. Nieuwe Zijds Voorburgwal 5, Amsterdam 1012 RC, Netherlands
www.crowneplaza.com Phone: +31 20 620 0500

Fees: €2000

Early Bird Rate: €1700 - Book & Pay by 7th February 2016 to qualify.

Discounts also available for group booking and academia.
Contact Sally Potentier for more information:
spotentier@biopharma.co.uk

A block of rooms will be reserved for participants to make their own bookings at a special Biopharma rate. This rate is typically available for a limited time so early booking is recommended. 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. Fees include morning and afternoon breaks, lunch and full lecture notes.

Other course types and locations are also available —see biopharma.co.uk/training-courses for more.

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 cheque. 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 us for details.

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.



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