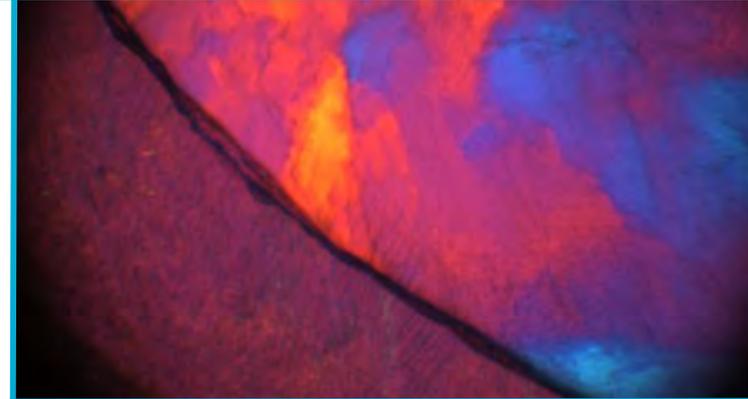


8th, 9th & 10th March 2016 | Clearwater, Florida

**Freeze drying experts Biopharma Technology and SP Scientific present a series three-day courses covering the science and application of lyophilization.**

- Practical instruction that can be easily applied to real life situations
- Key concepts that will affect all job 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 lyophilization over other stabilization methods
- Different equipment systems within a freeze dryer: how the systems interact, diagnosing faults from process errors, and tips for maintenance
- 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
- Free networking event—enjoy drinks and hors d'oeuvres with classmates and lecturers



Day 1	Day 2	Day 3
<b>Continental breakfast buffet provided each morning 7.30—8.15</b>		
<p><b>08.15 Welcome &amp; Course Opening</b>  <b>Introduction to Freeze Drying Technology</b>            The advantages and challenges of freeze drying</p> <p><b>Freeze Dryer Design (1)</b> Different types of equipment and key design factors</p>	<p><b>08.15 Formulation Characterization</b> Different techniques for determination of critical temperatures, including FDM and thermal methods</p> <p><b>Vacuum Systems</b> Application, measurement and control of vacuum for freeze drying</p>	<p><b>08.15 Maintenance Strategy for Freeze Dryers</b>            Improving reliability of equipment and robustness of cycles</p> <p><b>QbD in Freeze Drying</b> Methodologies for designing quality in from the start</p>
<b>Break</b>	<b>Break</b>	<b>Break</b>
<p><b>Product Freezing</b> How ice structure and solute behavior can affect freeze drying</p> <p><b>Freeze Dryer Design (2)</b> Condenser types and how to size for your application</p>	<p><b>Temperature Measurement &amp; Calibration</b> A vital parameter for successful processing—discussion of tools and methods</p> <p><b>Refrigeration Systems (2)</b> Distribution of cooling to the various areas of a freeze dryer; discussion of different refrigeration systems</p>	<p><b>Sterilization Systems</b> Technologies, techniques and application to ensure sterility</p> <p><b>Containers, Stoppers &amp; Barrier Technology</b>            Technologies available and the benefits for different applications</p>
<b>Lunch (included)</b>	<b>Lunch (included)</b>	<b>Lunch (included)</b>
<p><b>Primary and Secondary Drying</b> The vapor pressure differential; balancing heat and pressure for optimal drying</p> <p><b>Freeze Dryer Systems</b> How the key systems within a freeze dryer operate</p>	<p><b>Cycle Development &amp; Scale-Up</b> Practical methodologies for developing cycles and scaling up to production</p> <p><b>Validation &amp; Qualification Systems</b> Ensuring systems meet required standards: the classic validation model and modern approach</p>	<p><b>Freeze Dried Product Analysis</b> Methods for analyzing freeze-dried product, including moisture determination, thermal analysis and other methods</p> <p><b>CIP Systems</b> Techniques, technologies and validation</p> <p><b>Workshop 2 (Introduction)</b> Problem solving of process defects in a production scenario: evaluating the data, identifying the cause, and proposing rectification</p>
<b>Break</b>	<b>Break</b>	<b>Refreshments available during workshop</b>
<p><b>General Concepts of Formulation</b> Benefits and drawbacks of different excipients and issues affecting usage</p> <p><b>Refrigeration Systems (1)</b> Theory and practice of refrigeration in a freeze dryer</p> <p><b>End 17.15</b></p>	<p><b>SMART and ControlLyo Technology</b> Using the latest technologies for process development and control</p> <p><b>Workshop 1</b> An exercise to visually assess freeze-dried product and diagnose process defects</p> <p><b>End 17.10</b></p> <p><b>17.10 Onward</b> Free networking event—enjoy drinks and canapés with classmates and lecturers</p>	<p><b>16.00 Course Ends</b></p> <p>Timetable shown is representative and may be subject to change</p>

# Course details and booking form

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

Email to [spotentier@biopharma.co.uk](mailto:spotentier@biopharma.co.uk) or book online at [www.intelligentfreeze-drying.com/training-courses/](http://www.intelligentfreeze-drying.com/training-courses/)

**Date:** 8th—10th March 2016, Clearwater, Florida. USA.  
**Fees:** \$2320  
**Early Bird Discount:** \$2100 - Book and pay by 26 January 2016 to qualify.

Discounts are also available for group booking and academia. Contact Sally Potentier for more information:  
[spotentier@biopharma.co.uk](mailto:spotentier@biopharma.co.uk)

**Free networking event**—enjoy drinks and hors d'oeuvres with classmates and lecturers.

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.

Other courses are available - please take a look at [intelligentfreeze-drying.com/training-courses](http://intelligentfreeze-drying.com/training-courses) for more details.



**Biopharma Technology, C/O**  
**Biopharma House, Winnall Valley**  
**Road, Winchester, Hampshire. UK.**  
**SO23 0LD** [Intelligentfreeze-drying.com](http://Intelligentfreeze-drying.com)



815 New York 208, Gardiner, NY 12525,  
United States  
[www.spscientific.com](http://www.spscientific.com)

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 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.

## About Biopharma Technology

Biopharma Technology Ltd has provided specialist services in lyophilization since 1997. We have worked with over 1000 products, from small drug molecules to large complex biomolecules, cells, tissues and even some more unusual products such as archaeological artifacts. 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 analyzer. We continually participate in research projects to further the science and our understanding of freeze drying, with projects including red blood cells, collagen scaffolds and probiotics.

### Richard Wood

Richard Wood was Technical Director of the service department at Biopharma, the UK's leading freeze drying equipment company, for 25 years. The 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 Biopharma and regularly lectures on the freeze drying process as well as analytical and process related issues.



## Venue

The \*location of our Annual East Coast training course will be:  
**Sheraton Sand Key Resort**  
**Address: 1160 Gulf Boulevard, Clearwater Beach, Florida. FL 33767. United States.**  
**Phone: +1 727-595-1611**

\*Please note accommodation is not included in the course fee.

