UMASS LOWELL

CRF Core Research Facilities
Shared Laboratories & Services at UMass Lowell

Fundamentals of Lyophilization for Life Science, Bioprocess, and Pharmaceuticals

Training Course

biopharma group

Course **overview**

Course certificate:

Upon completion of this course a certificate of achievement from UMass Lowell will be awarded to participants.

Start date:

Starting 6th November, 2024

Course cost:

Early Registration (secure by 31st August)

- Individual Rate: $6,250 per person
- Groups of 3+: $6,000 per person

Standard Registration (1st September onwards)

- Individual Rate: $6,750 per person
- Groups of 3+: $6,500 per person

Additional information:

Participants will attend an on-campus, 3-day lab session at UMass in Lowell, MA

The course is designed to familiarize students with the **fundamentals of lyophilization** and is applicable to life sciences, pharmaceuticals, food processing, and general bioprocessing.

The course focuses on the lyophilization process itself (with emphasis on heat and mass transfer), formulation design, characterization, process development, product monitoring, and analysis of the freeze-dried product.

This is a **6-month course** taught remotely by experts at **Biopharma Group**, with **live webinars, tutorials, and a 3-day, on campus lab practicum** at UMass Lowell's lyophilization lab in Lowell, MA.

At the end of this course, participants will have gained an in-depth knowledge of lyophilization & lyophilization equivalent to **5 years of working experience** in the science of lyo.

Find out if this is the right learning course **for you!**

This course if designed for professionals in life science, pharmaceuticals, and bioprocessing who would like to expand and reinforce their technical knowledge in these sectors.

Consisting of

- Fundamentals of lyophilization applicable to life science, pharmaceuticals, and bioprocessing
- Focus on the process with particular regard to heat and mass transfer
- Formulation design and characterization
- Process development and monitoring
- Analysis of the freeze-dried product
- Self-study supported by educational materials provided

Delivery methods

- Formal live online lectures *(15 x 1h)*
- Regular live online tutorials *(6 x 1h)*
- On-site practical laboratory sessions *(3 days)*
- Assignments (5), including lab write-ups
- There will be case studies and workshops including identifying defects in products and how to solve such problems
- Recordings of sessions will be available for playback and repeated viewing

Learning **outcomes**

- Understanding the science of how lyophilization works
- The physics and chemistry of freezing, sublimation and desorption
- Aspects of equipment design to effect heat and mass transfer
- Control and monitoring of the process and lyophilizer
- Gaining knowledge of the different approaches to developing a lyophilization cycle for products with various requirements (Critical Quality Attributes)
- Learning about the range of methods available for characterization of the final product
- Program, load, operate and unload a freeze-dryer
- Prepare a liquid formulation and pipette into containers in defined doses
- Learning about aspects of formulation design and the value of characterization methods that can be applied prior to lyophilization
- Operate analytical instruments and interpret data from:
  - Lyophilization microscope
  - Thermal and impedance analyser
- Recognizing physical defects in products by observation
- At the end of this module the participants will have gained the in-depth knowledge of lyophilization that would be equivalent to 5 years of working experience of the science - a valuable asset to have in the workplace

About the **course**

Course title:

Fundamentals of Lyophilization for Life Science, Bioprocess, and Pharmaceuticals

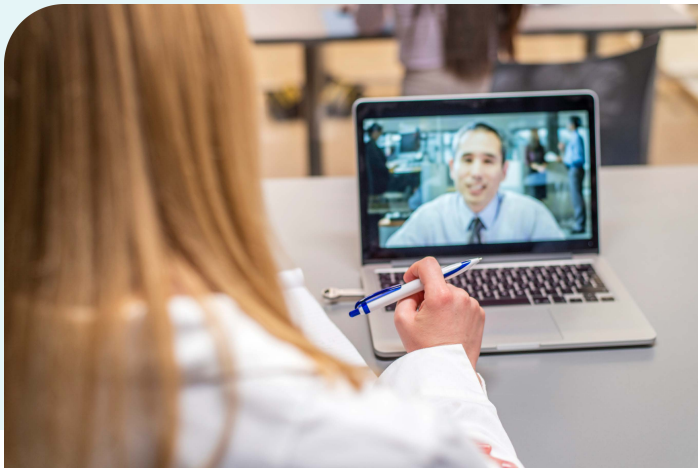
Course rationale and purpose:

To familiarize students with the fundamentals of lyophilization for life sciences, pharmaceuticals, and bioprocessing. This module will focus on the lyophilization process itself (with particular regard to heat and mass transfer), formulation design, characterization, process development, product monitoring, and analysis of the freeze-dried product.

The **syllabus**

Virtual lectures *(15 hours)*

- Introduction to lyophilization
- Freezing and thermal treatment of aqueous solutions
- Primary drying (sublimation)
- Secondary drying (desorption)
- Concepts of formulation for freeze-dried pharmaceuticals
- Formulation characterization methods part 1 – lyophilization microscopy
- Formulation characterization methods part 2 – frozen state thermal analysis
- Container-closure systems and their impact on the process and shelf stability
- Lyophilization cycle development part 1 – classical iterative methodology
- Lyophilization cycle development part 2 – software-based process design
- Process monitoring and process analytical technology (PAT) in lyophilization
- Scaling up from benchtop trials to full-scale production
- Freeze-dried product analysis part 1 – residual moisture, container-closure integrity
- Freeze-dried product analysis part 2 – dry state thermal analysis and stability
- Freeze-dried product analysis part 3 – mechanical properties and rehydration



Practical Lab Sessions *(3-days, on campus at UMass Lowell)*

The 3-day, laboratory practicum will be taught at the UMass Lowell Lyophilization lab. Participants are expected to attend this session. Information will be provided on travel and accommodations.

- **Session 1:** Hands on analysis of liquid samples with lyophilization microscopy/DSC/DTA/impedance – part 1 - analysis of simple dextran solution
- **Session 2:** Hands on analysis of liquid samples with lyophilization microscopy/DSC/DTA/impedance – part 2 - analysis of a complex liquid formulation
- **Session 3:** Start lyophilization cycle for dextran formulation
- **Session 4:** Remove samples from freeze dryers; retrieve and review cycle data
- **Session 5:** Visual inspection of dried products, analysis of freeze-dried product with KF, DSC, send samples for SEM, and MicroPress
- **Session 6:** Review cycle data with additional data from KF, DSC, SEM, MicroPress
- Appearance and visual defects inspection for comparison to cycle traces and critical temperature for root cause determination of example lyophilization cycles

Supplementary Learning

- Practical laboratory sessions will need to be written up in a formal report format, with methods described, and data presented and discussed.
- Students will be set further learning activities including background reading and other assignments.

How the course will develop transferable skills:

- **Knowledgeable**
  - About what the science of lyophilization is: freezing, sublimation, desorption
  - On how to design and characterize a formulation
  - In how to develop a lyophilization cycle based on the critical temperature(s) of a formulation, its concentration, volume and the heat transfer properties of its container
- **Creative**
  - Developing the formulation and process in a way that goes beyond it being simply an exercise 'on paper'
- **Collaborative**
  - Learning to work in collaboration with operators, production and quality control people
- **Articulate**
  - Ability to explain the process of lyophilization, how it compares to other methods of preservation (freezing, other drying/heating methods), the science and challenges of formulation, freezing and sublimation, aspects of lyophilization equipment design and their influence on the process and the product

About the **Instructors**

Dr Kevin Ward

Biopharma Group's Director of R&D is globally recognised as a lyophilisation expert. Kevin has been in the field since 1993 and joined Biopharma Group in 2000. He's been involved numerous academic research projects and, together with his team, has worked on over 4,000 projects for customers worldwide. Kevin received his PhD for investigations into the freeze-drying of pharmaceutical formulations and drug/vaccine delivery systems. Prior to joining the team, Kevin worked at Pfizer Central Research and as a Research Fellow in vaccine development at Aston University. Dr. Ward is an editor and a contributing author of articles and texts on freeze drying, most recent being the Springer book 'Lyophilization of Pharmaceuticals and Biologicals'. He is also in demand as a frequent lecturer to many of the leading regulatory agencies and prominent pharma companies.

Dr Edmond Ekenlebie

Edmond is the Research & Development Manager at Biopharma Group. With over a decade of experience in the pharmaceutical industry spanning roles as a Pharmacist, Principal Scientist, and now an R&D manager, Edmond joined the team in 2014 after a PhD from Aston University in Birmingham, UK. His PhD focused on optimising the bulk freeze-drying process and the implications of powder rheology using methods including the novel use of Micro X-ray tomography. He also holds an MSc in Pharmaceutical Science with Management Studies (Distinction) from Kingston University in London. Edmond brings a unique perspective to drug development, leading a team of talented scientists and brings a wealth of expertise in stabilising parenteral, biologics, small molecules and in vitro diagnostics using rigorous research and development.

Mervyn Middleton

Mervyn holds a BSc (hons) Biochemistry Degree from the University of Portsmouth. After graduating in July 2009, Mervyn joined Biopharma Group in December 2009, where he worked through to 2015. During this time, Mervyn gained significant experience of product analysis and freeze-drying cycle development/optimisation. Mervyn returned to Biopharma Group as a Senior Scientist in February 2021 and has since worked on over 50 customer projects involving a range of activities, including characterisation of both pre-lyophilised and lyophilised products, formulation development, freeze-drying cycle development and optimisation, process auditing and consultancy on all stages of the freeze-drying development and scale-up process.

Dr Bhaskar Pandya

Bhaskar joined Biopharma Group in 2021 as a Senior Scientist after a PhD from De Montfort University in Leicester, UK. Working with Professor Geoff Smith, his PhD was centred on the single vial monitoring of the freeze-drying process using through vial impedance spectroscopy (TVIS). At Biopharma Process Systems in Winchester, Bhaskar is managing several highly collaborative projects for clients in the pharma and diagnostics sectors involving product and process assessments, formulation development, lyophilization cycle development, post process analyses, packaging and consultancy for new and existing products.

Course **assessment**

What are the assessment methods for this module?

A Certificate of Completion will be issued to registrants who complete the course.

Assessment would be by:

- Attendance at lectures and practical laboratory sessions
- Practical write-ups (in the form of written reports)
- A series of marked assignments

To book your spot:

CONTACT US

UMass Lowell Core Research Facilities

The Core Research Facilities (CRF) at UMass Lowell comprises 12 laboratories housing more than 150 high-end instruments and testing facilities supporting research in lyophilization, small animal imaging, materials testing, surface and forensic analysis, nanofabrication/nanotechnology, next generation sequencing (NGS), materials characterization, mass spectroscopy, chromatography, microscopy, radiation testing, and robotics. Instruments and professional level services are available to outside users.

Learn more about UML CRF here: www.uml.edu/research/crf

About **Biopharma Group**

Biopharma Group was established in 1989 and has become an industry leader with expertise in freeze drying equipment and scientific techniques. The technical lyophilization division assists companies internationally to improve their freeze-drying processes and practices across the disciplines as a CRO, and CDMO, analytical instruments and training. Our scientific team has been involved with many University research projects since our inception, keeping Biopharma Group at the forefront of the field of lyophilization. With this course offering, we have collaborated with UML to provide a unique opportunity to learn and develop skills in this specialist field. Dr Kevin Ward, Biopharma Group's Director of Research and Development, has recently edited and published a textbook on lyophilization. As experts in freeze-drying, we support the pharma/biotech and diagnostic industries to develop their knowledge of the lyophilization process. Our consultancy/contract research team provides independent R&D services from proof of concept to scale-up and everything in between, as well as GMP manufacturing and packing lines that can be offered as additional services. We have developed several pieces of analytical equipment for the analysis of freeze-dried products, the resulting data can be applied to produce a robust formulation and lyo cycle for users. These instruments are sold to our customers globally. Our courses are well respected throughout the industry, and we have trained over 6,000 people worldwide.

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"I am thoroughly enjoying this course, which has given me a much better understanding of freeze-drying. The content, delivery, and pacing have all been fantastic. The online nature of the course provides great flexibility, allowing me to catch up on lectures between busy periods at work. The course and the practical session have already benefited me greatly in my current role."

-Stephen Hayes, Merck

"I joined this course to improve my knowledge of freeze drying. I wish I could have done it years ago! The complex process of freeze drying has been presented in a polished and proficient manner by obvious experts in the field. The course content has covered every aspect of the subject and I feel that I have a more in depth understanding of the whole process. I thank the presenters for an outstanding course."

-Anne Richter, Evik Diagnostics

"This is an excellent course for those wanting to learn about lyophilization. The course materials and documentation are excellent, the presentations are comprehensive and understandable, delivered with a graded approach that commences with the simpler concepts, ramping up to more technical aspects. Basic physical and chemical principles are well explained and there is excellent mentoring and tutorial support."

-Fergal Hassett, Jabil

For more **information**

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