biopharma group

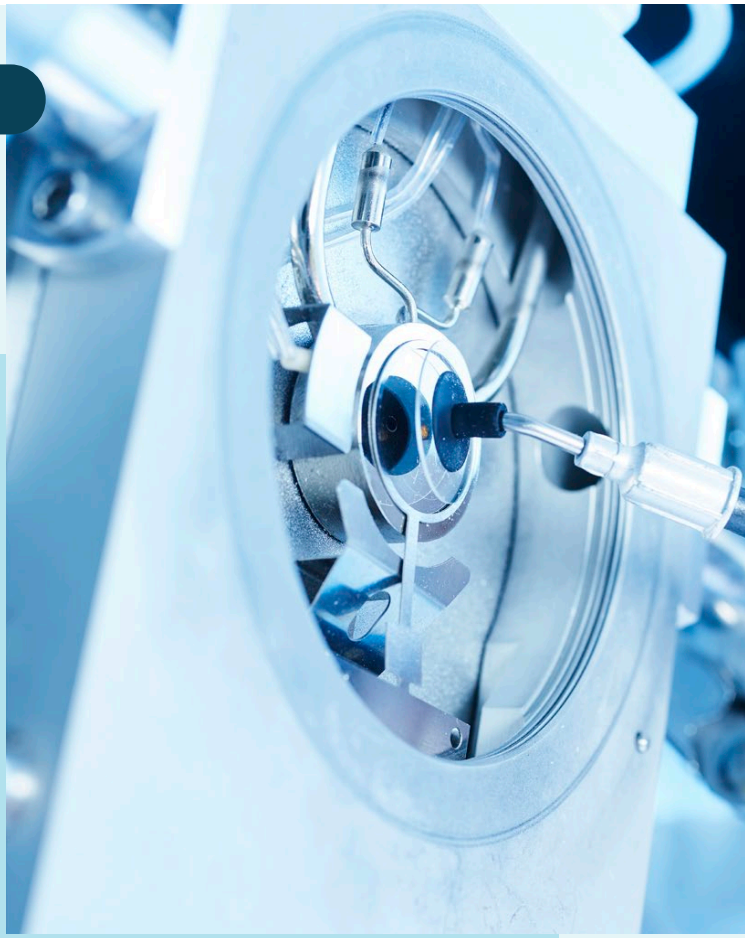
Fundamentals of freeze drying

in a pharmaceutical context

Accredited by the University of Limerick

UNIVERSITY OF LIMERICK
OLLSCOIL LUIMNIGH

Course **overview**



Course title:

Fundamentals of Freeze Drying in a Pharmaceutical Context

Start date:

Starting April 2024

Course cost:

€7,695*

Additional information:

Participants will have to attend two practical sessions in Winchester, UK.

*Please be aware that there are different financing options available for this course, including paying in stages. We also have a student rate for those currently in higher education. Contact our team today to find out more.

Course Benefits

- The only university accredited program of its type
- An in-depth comprehensive freeze drying course with practical lab sessions that combines Biopharma Groups's 30 plus years of freeze drying expertise with the University of Limerick's commitment to building the level of excellence in the pharmaceutical lyophilisation community
- This course at completion of assessment is worth 6 European CreditTransfer System (ECTS) Credits at European Qualification Framework (EQF) Level 6 (Bachelors degree standard)
- A six month long program with live webinars and tutorials,
- It is aimed at the commercial pharmaceutical market to reinforce the technical knowledge of the employees in this sector
- Counts as credit toward a degree

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

Consisting of

- Fundamentals of freeze drying in a pharmaceutical context
- Focus on the process with particular regard to heat and mass transfer
- Formulation design and characterisation
- Process development and monitoring
- Analysis of the freeze-dried product

Delivery methods

- Formal live webinars *(12 x 2.5h)*
- Regular tutorials *(6)*
- Practical laboratory sessions *(2 days)*
- Assignments (5) and self study supported by educational materials provided
- 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 freeze drying 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 lyophiliser
- Gaining knowledge of the different approaches to developing a freeze drying cycle for products with various requirements (Critical Quality Attributes)
- Learning about the range of methods available for characterisation 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 characterisation methods that can be applied prior to freeze drying
- Operate analytical instruments and interpret data from:
  - Freeze drying microscope
  - Thermal and impedance analyser
  - MicroPress mechanical tester
- Recognising physical defects in products by observation
- At the end of this module the participants will have gained the in-depth knowledge of lyophilisation that would be equivalent to 5 years of working experience of the science - a valuable asset to have in the workplace
- Please note that this course requires two practical sessions at Biopharma Group's headquarters based in Winchester, UK

About the module

Pharmaceutical freeze drying 1 – formulation and process development

Module rationale and purpose:

To familiarise students with the fundamentals of freeze drying (lyophilisation) in a pharmaceutical context. This module will focus on the freeze-drying process itself (with particular regard to heat and mass transfer), formulation design, characterisation, process development, product monitoring, and analysis of the freeze-dried product.

The syllabus

Virtual lectures *(12 x nominally 2.5-hour sessions)*

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

Lab sessions *(total 2 days)*

- **Session 1:** Hands on analysis of liquid samples with freeze drying microscopy/DSC/DTA/impedance – part 1 - analysis of simple dextran solution
- **Session 2:** Hands on analysis of liquid samples with freeze drying microscopy/DSC/DTA/impedance – part 2 - analysis of a complex liquid formulation
- **Session 3:** Start freeze drying 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, start DVS analysis, send samples for SEM, and MicroPress
- **Session 6:** Review cycle data with additional data from KF, DSC, DVS, SEM, MicroPress
- Appearance and visual defects inspection for comparison to cycle traces and critical temperature for root cause determination of example freeze drying cycles

Practical work *(Write-ups – Assignments – Self study – Background reading)*

- Practical laboratory sessions will need to be written up in a formal report format, with methods described, and data presented and discussed. Write-ups would be expected to require another 15 hours in total.
- Students will be set further learning activities including background reading and other assignments as part of the module, which are estimated to require another 18 hours.

Total expected learning / study time on module : 120 **hours**

Learning outcomes

Cognitive

- Understanding the science of how freeze drying works:
  - Physics and chemistry of freezing, sublimation and desorption
  - Aspects of equipment (lyophiliser) design to effect heat and mass transfer
  - Control and monitoring of the process and the lyophiliser
- Learning about aspects of formulation design and the value of characterization methods that can be applied prior to freeze drying
- Gaining knowledge of the different approaches to developing a freeze drying cycle for products with various requirements (Critical Quality Attributes)
- Learning about the range of methods available for characterisation of the final product

Psychmotor *(Physical skills)*

- Programming, loading, operating and unloading a freeze dryer
- Preparing a liquid formulation and pipetting it into containers in defined 'doses'
- Operating analytical instruments and interpreting the data:
  - Freeze drying microscope
  - Thermal and impedance analyser
  - MicroPress mechanical tester
- Recognising physical defects in products by observation

Outlining the module

How the module is taught and how recent development or research findings in the subject are included:

- The module will be taught through a combination of formal lectures, tutorials and practical laboratory sessions. Students will be split into groups to promote collaborative skills in line with UL graduate attributes.
- There will be case studies and workshops that will include identifying defects in the product and how to solve such problems.

How the module will develop graduate attributes:

- **Knowledgeable**
  - About what the science of lyophilisation is: freezing, sublimation, desorption
  - On how to design and characterise a formulation
  - In how to develop a freeze drying cycle based on the critical temperature(s) of a formulation, its concentration, volume and the heat transfer properties of its container
- **Creative**
  - In terms of 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**
  - Be able to explain the process of freeze drying, how it compares to other methods of preservation (freezing, other drying/heating methods), the science and challenges of formulation, freezing and sublimation, aspects of freeze drying equipment design and their influence on the process and the product

Module **assessment**

What are the assessment methods for this module?

Assessment methods will vary depending on whether participants are from the University (and completing the module as part of a qualification) or from external organisations (typically paying for training). For the latter, attendance of the lectures and completion of practical sessions might be considered sufficient in itself.

For academic students, assessment would be by:

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

Completion of assessment is worth 6 European Credit Transfer System (ECTS) Credits at European Qualification Framework (EQF) Level 6 (Bachelors degree standard).

Level	England	Level	Northern Ireland	Level	Wales	Level	Ireland	Level	Scotland
8	Equivalent to PhD	8	Equivalent to PhD	8	Equivalent to PhD	10	Equivalent to PhD	12	Equivalent to PhD
7	Equivalent to Masters Degree	7	Equivalent to Masters Degree	7	Equivalent to Masters Degree	9	Equivalent to Masters Degree	11	Equivalent to Masters Degree
6	Equivalent to BSc Degree	6	Equivalent to BSc Degree	6	Equivalent to BSc Degree	8	Equivalent to BSc Degree	10	Equivalent to BSc Degree

About Biopharma Group

Biopharma Group was established in 1989, and have become an industry leader with expertise in freeze drying equipment and techniques. The technical lyo division assists companies internationally to improve their freeze drying practices and processes across the disciplines of consultancy 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 lyophilisation. With this course offering, we have collaborated with PMTC and the University of Limerick to provide a unique, accredited 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 lyophilisation. As experts in freeze drying we support the pharma /biotech and diagnostic industries to develop their knowledge of the lyophilisation 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 manufacturing and packing lines that can be offered as additional services.

Our lyo instruments engineers develop specific equipment for the analysis of freeze dried products with a view to ease the use and interpretation of results for users and supplies them to customers worldwide. Our courses are well respected throughout the industry, and we have trained over 6,000 people globally. We welcome you to investigate what Biopharma Group can do for you and please don't hesitate to contact us with any enquiries!

biopharma group

For more **information**

Biopharma Group
Biopharma Process Systems Ltd.
Biopharma House, Winnall Valley Road,
Winchester, SO23 0LD

+44 (0)1962 841092

btl@biopharma.co.uk

www.biopharmagroupcdmo.com

Designed and produced by blue bee bluebee.co.uk

UNIVERSITY OF LIMERICK
OLLSCOIL LUIMNIGH