

# Fleming

MASTERCLASS

## FREEZE DRYING FOR BIOLOGICS/ PHARMACEUTICS

13 & 14 NOVEMBER 2025 | VIENNA, AUSTRIA

# COURSE OVERVIEW:

With the rise of biologics and new types of biotechnological drugs, which are usually very sensitive and unstable, reliable freeze drying in Pharma & Biotech is becoming more important than ever.

Freeze-drying is considered a delicate drying process. However, it can cause numerous stresses that induce chemical and physical instabilities. Subsequently, the inclusion of suitable excipients along with optimizing the process parameters is crucial to attain stable lyophilizates with high-quality attributes. It is also a high-cost technology with a substantial environmental footprint, so process optimisation is an important consideration.

This practical course will focus on the freeze-drying process from formulation and thermal analysis to cycle development and optimization, packaging and troubleshooting.

Join us and master the complexities & new challenges of lyophilization process to ensure that life-saving medications remain stable, potent, and safe for patient use.

# KEY TOPICS:

- ✓ Freeze drying process overview
- ✓ Understanding thermal properties
- ✓ Freezing, primary & secondary drying
- ✓ Formulation design & function
- ✓ Container formats & their impact
- ✓ Back to the cycle
- ✓ Equipment
- ✓ Quality control, testing & troubleshooting
- ✓ Future of freeze drying for biologics/pharmaceuticals

# LEARNING OBJECTIVES:



## DEEP DIVE

into the freeze-drying process, together with the factors that influence the product and process



## CHARACTERIZATION

to determine a product critical temperature prior to freeze-drying



## REVIEW

formulation development to gain understanding of typical excipients and their purpose in formulation



## LEARN

about typical CQAs in freeze-dried products, what factors influence these attributes, and methods of monitoring and controlling attributes



## CONSIDER

the energetics of the freeze-drying process



## GAIN INSIGHTS

into monitoring of the freeze-drying process and when primary drying is complete



## CONSIDER

the challenges of scale up and economic manufacture

# TRAINING FEATURES:

- 💡 Discussions & networking onsite in Vienna
- 💡 Comprehensive course documentation
- 💡 Case studies & practical examples
- 💡 Certificate of completion

# WHO SHOULD ATTEND:

- ✓ R&D Scientists
- ✓ Formulation Scientists, Formulation Development
- ✓ Product & Process Scientists/Managers
- ✓ Quality Control departments
- ✓ Quality Assurance
- ✓ Production Managers
- ✓ Sterile Manufacturing departments
- ✓ Process Development
- ✓ R&D Technology



# MEET THE COURSE LEADERS:



## **PAUL MATEJTSCHUK BSc PhD CChem FRSC**

**MHRA, UK**  
Section Head Formulation Science

Paul Matejtschuk PhD, CChem, FRSC currently leads the Formulation Science Section at the Medicines and Healthcare products Regulatory Agency, at their South Mimms laboratories, in the UK, whose mission is to safeguard the quality of biological medicines. He has over 20 years' experience of developing freeze drying and formulation conditions for a wide range of biological materials including those developed on behalf of the WHO as International Reference Standards for Biological Standardization. His team is focused on delivering formulation and lyophilization conditions and his research interests include Process Analytical Technology in freeze drying, the relationship between structure and stability in biologicals, thermal analysis and other methods for the characterization of lyophilized proteins. Paul Matejtschuk (0000-0002-4646-800X) - ORCID

Paul has over 30 years postdoctoral experience working in both academic and industrial settings in the areas of biologicals, with broad experience across downstream processing, characterization and analysis. He is a Director of the International Society for Lyophilization/Freeze Drying ([www.islyophilization.org](http://www.islyophilization.org)) and a committee member of the Thermal Methods Group of the Royal Society of Chemistry ([www.thermalmethodsgroup.org.uk](http://www.thermalmethodsgroup.org.uk)).

He has successfully co-supervised five PhD studentships, with UCL and Imperial College London, published over 50 peer-reviewed papers and lectured widely in the field and has recently co-edited a book on freeze drying with Dr Kevin Ward (Lyophilization of Pharmaceuticals and Biologicals, New Technologies & Approaches, Ward KR & Matejtschuk P, Springer Press, 2019).

In his career he has collaborated on research grants funded by EPSRC, BBSRC and Innovate UK as well as working with the United States Pharmacopoeia Commission and the European Pharmacopoeia and led on contract research and reference material production.



## **GEOFF SMITH**

**De Montfort University, UK**  
Professor of Pharmaceutical Process Analytical Technology at Leicester School of Pharmacy

Geoff Smith is Professor of Pharmaceutical Process Analytical Technology in the Leicester School of Pharmacy at De Montfort University (UK). His research group focuses on pharmaceutical applications for impedance, dielectric and terahertz spectroscopies alongside optical techniques such as laser speckle and optical flow. He is responsible for the development of through-vial impedance spectroscopy (TVIS) as a PAT tool for monitoring phase behaviour (ice formation and eutectics), ice interface temperatures, primary drying rates and end points.

He is a specialist in pharmaceutical materials science, physical analytical measurement techniques (including dielectric relaxation spectroscopy, thermal analysis, terahertz spectroscopy), process measurement and control (esp. freeze-drying). Responsible for the development of TVIS - a novel in process analytical technology for monitoring and developing optimised freeze-drying cycles, and Z-FDM - a freeze-drying microscope with integrated impedance spectroscopy capability. Since 2015, and with the expertise of Ahmet Orun, the PAT platform has been extended to include dynamic laser speckle techniques (for tablet characterization and for studying microcollapse in freeze-dried drug products).

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## TESTIMONIALS:

"

Akis Loukas, **Formulation Senior Manager**  
**Adragos Pharma:**

*"I found the seminar I attended to be extremely informative and productive. The speakers were knowledgeable and presented the material with clarity and enthusiasm. The content was highly relevant to my needs and helped me gain new knowledge and skills that I can immediately apply in my work. The organization of the seminar was excellent, with superb time and resource management. Participants had ample opportunities for dialogue and exchange of ideas, which enhanced the learning experience. Overall, I found the seminar to be very useful and productive. I would unreservedly recommend it to anyone interested in the particular topic."*

"

Mohamed A. O. Mohamud, **Freeze Drying Maintenance Professional, Novo Nordisk:**

*"The course was both captivating and informative. The instructors delivered the material in a clear and coherent way, making the presentations easy to comprehend."*

"

Josep M<sup>a</sup> Canal, **Section Manager Process Development Technology, CMC Development, Scientific Innovation Office, Grifols:**

*"I found the course very interesting. The training leaders did an good job explaining every topic and they answered all the questions very professionally."*

"

Dario Di Gesù, **QA Operations Associate, Kedrion**

*"I found the seminar entertaining and informative. The speakers did an excellent job explaining everything in a very clear and pleasant way."*

"

Shunit Gal, **Associate Director Product Development, Teva Pharmaceuticals:**

*"I found the course very interesting and educational. The lecturers and also the presentations were well understandable in a coherent way. There was always time for questions and they were answered very professionally. I think it's one of the best courses that I have attended, so thank you for that."*

"

Brice Gassiat, **Team Leader in Formulation & Product Development, Ichnos Sciences:**

*"Very interesting lectures from experienced trainers that helped decomplexify a complex topic."*

"

Barbara Schuster, **Scientist at Manufacturing Science and Process Development, Vetter Pharma:**

*"The expert trainers gave great professional insights into the field of lyophilization while keeping an enjoyable open atmosphere. Frequent discussion rounds offered an answer to all open questions from the audience."*



# DAY 1

13 November 2025

- 8:45 REGISTRATION & MORNING COFFEE
- 9:00 OPENING REMARKS & WELCOME NOTE
- 9:10 SPEED NETWORKING (ALL PARTICIPANTS)
- 9:20 **Freeze drying introduction**
- The need for stabilisation in labile materials
  - Delivery formats and the role of lyophilizates
  - Water - its properties in the frozen state
  - Principles of freeze drying
    - Energetics of the freeze-drying process
    - Freezing - its impact on drying stability and a successful lyo product
    - Primary Drying
    - Secondary Drying
- 10:20 COFFEE BREAK
- 10:45 **PROCESS IN DETAIL: Understanding thermal properties**
- Thermal analysis of frozen and dried states
  - Determination of critical temperatures
  - Freeze drying microscopy
  - Differential Scanning Calorimetry
  - Dielectrics and Impedance
- 11:40 **Freezing**
- Ice structure - how to influence it and its impact
  - Annealing
  - Induced ice nucleation
  - Challenge of homogeneity during freezing – complex samples
- 12:40 LUNCHEON
- 14:00 **Primary drying & its optimisation**
- Designing an efficient cycle
    - Impact of containers, formulation and fill volume
    - What steps can I shorten and why?
    - When is a product too wet/ too dry?
    - Impact of shelf and pressure parameters on process length
- 15:10 COFFEE BREAK
- 15:30 **Secondary drying & stability**
- Moisture content - its importance and analysis
  - Reconstitution – challenges and solutions
  - Predicting stability & real time storage
- 16:45 **DISCUSSION**
- 17:00 END OF DAY 1

# DAY 2

14 November 2025

- 8:45 REGISTRATION & MORNING COFFEE
- 9:00 **Recap of day 1**
- 9:10 **Formulation – design and function**
- Which stabiliser do I choose and why?
  - Bulking agents and dry mass
  - Balancing the formulation – process and other considerations
- 10:15 **Container formats & their impact**
- Impact of container choice on drying rates
  - Closures – their involvement and pre- treatment
  - Shelf life
- 11:00 COFFEE BREAK
- 11:30 **Back to the Cycle**
- Process Analytical Tools
  - Quality by Design
  - Scale up
- 12:30 LUNCHEON
- 13:45 **Equipment**
- Freeze dryer design
  - Process challenges & developments
  - Challenges in GMP manufacture
- 14:45 COFFEE BREAK
- 15:10 **Quality Control & Testing**
- Critical Quality Attributes
  - Moisture – its measurement and importance
  - Measuring Activity
  - Trouble shooting
  - Common failures and their causes
- 16:10 **Into the future**
- Continuous drying
  - Alternative technologies
  - Challenges of new modalities
  - Process modelling
- 16:50 **WRAP-UP AND CLOSING REMARKS**
- 17:00 END OF TRAINING



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- ✓ We find a trainer, draft topics, and then find the premises and dates which match your needs.
- ✓ Provide your employees a unique learning experience without having to leave the office.

*"Knowledge is important,  
but implementation is crucial."*



# THE TEAM BEHIND:

We are delighted to bring you the

## **FREEZE DRYING FOR BIOLOGICS/PHARMACEUTICS**

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Or write to

[event.inquiries@fleming.events](mailto:event.inquiries@fleming.events)  
to get in touch with a member of  
our team

### **DASA JANOSIKOVA**

Production Manager - Life Sciences

### **MONICA JONES**

Marketing manager



## **VIENNA**

The iconic French croissant originates from Vienna. These buttery and soft delights are based on an Austrian pastry called Kipferl (meaning 'crescent' in German). They were made by Viennese bakers to commemorate the Austrian victory over the Ottoman Turks in 1683. The shape of the pastry was based on the crescents that adorned the uniforms of their enemy. When Marie Antoinette married King Louis XVI, she introduced her favorite pastry to France, few changes were made, and the croissant was introduced to the world.



## REGISTRATION

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