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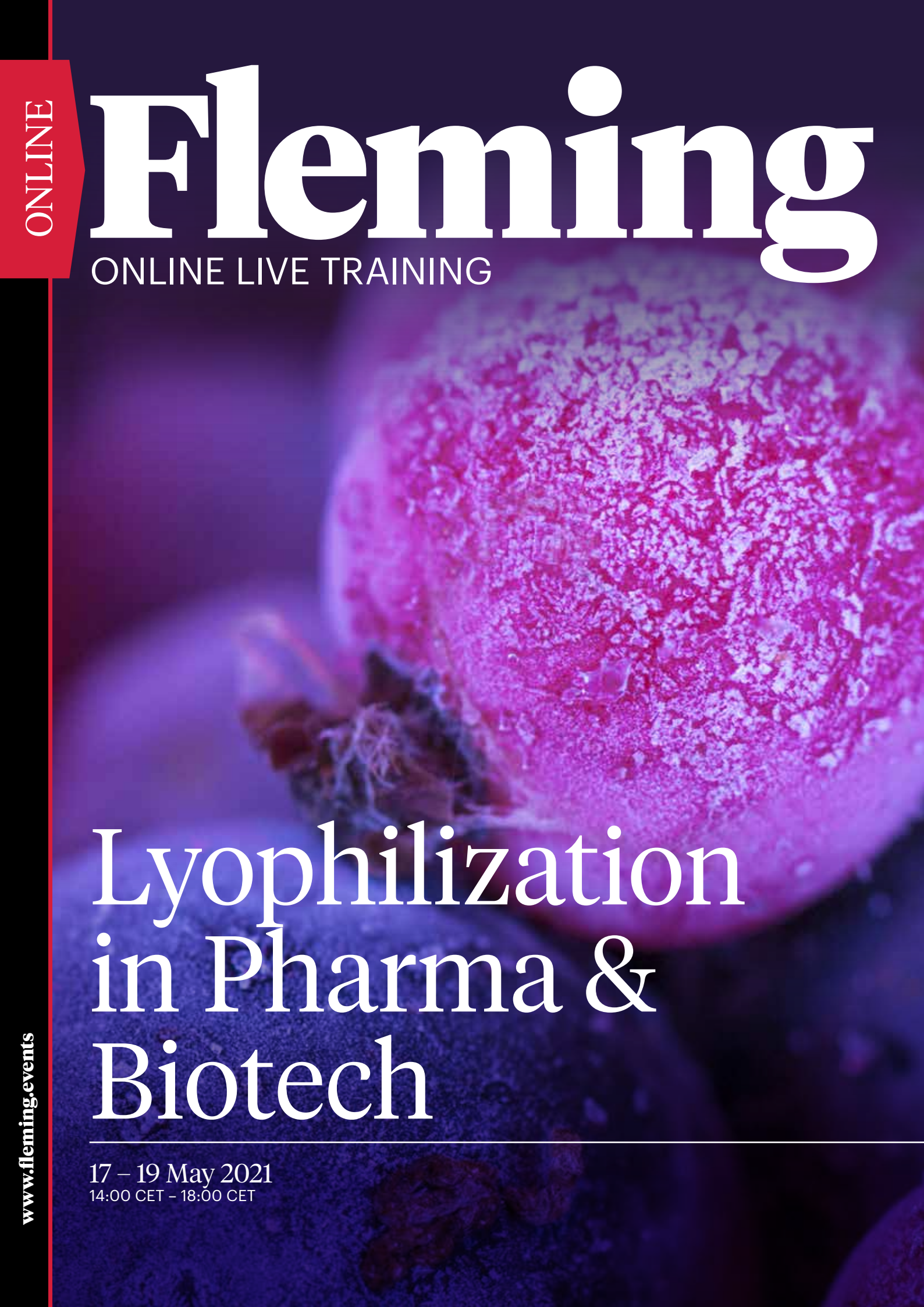

Lyophilization in Pharma & Biotech

17 – 19 May 2021
14:00 CET - 18:00 CET

www.fleming.events

Key topics:

- Freeze drying-process overview
- Primary & secondary drying
- Formulation design of freeze dried products
- Microscopy and thermal analysis in formulation characterisation
- Cycle development & scale-up
- PAT in freeze-drying process
- Regulatory submissions
- Analysing the freeze-dried product

Course Overview:

A successfully optimized freeze-drying cycle will provide reliable, safe processing in an efficient manner. Each stage of the process – freezing, primary drying and secondary drying – poses its own challenges. Many factors influence the design of the cycle, including the specific thermal characteristics of the product, the type and amount of product per batch or container, and the capabilities of the processing equipment to be used. This training course provides an overview of how to develop an optimized freeze-drying process, from freezing, primary and secondary drying to what is required to successfully move the cycle to scale-up for production. It will go through each critical stage required to optimize a cycle including: an overview of the freeze drying process, formulation design of freeze dried products, characterization of the formulation in the frozen state prior to freeze drying, cycle development and scale up for freeze drying process (including the iterative approach and also the use of "new" SMART software), and the use of PAT (Process Analytical Technology) for monitoring the process. We will be including a presentation of how to approach the submissions to regulatory authorities.

Key takeaways:

Gain
a basic understanding of 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 a formulation

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

Learn
how to develop a freeze-drying process using the traditional iterative (stepwise) approach and how this compares to the use of SMART software

Discover
some suggestions that can help any regulatory submission be more readily accepted (e. g. what data to be included and how to lay out the information)

Gain
a basic understanding of typical Process Analytical Technology (PAT) to monitor the freeze-drying process and when primary drying is complete.

Training audience:

This Training Course is of particular interest to:

- ✓ R&D Scientists
- ✓ Formulation Scientists
- ✓ Product & Process Scientists/ Managers
- ✓ Quality Control departments
- ✓ Regulatory Affairs
- ✓ Process Engineering
- ✓ Plant Operation/Production

Online Live Training Features:

- Real-time, instructor-led course
- Live discussions
- Chat with participants
- Gallery view to see all participants in video meeting at one time
- Comprehensive digital course documentation
- Case studies
- Certificate of completion issued by the trainer

Click Here & REGISTER ONLINE

Meet the Training Leaders:

Kevin Smith

Kevin joined Biopharma in 1993 as senior service engineer, later becoming Technical Director, before retiring in 2018. Over those years he helped build a strong service department responsible for the installation, site acceptance testing and qualification, together with the ongoing technical support of a wide range of machines, ranging from the small bench-top laboratory machines to very large fully automated production equipment. Most of the customary documentation, maintenance and qualification protocols were written by Kevin in association with Biopharma's previous Technical Director, Richard Wood. He also updated the ISO9001: Quality Management System for Biopharma Process Systems Ltd.

Kevin Ward

After graduating with a BSc in Chemistry and being attracted by an advertisement for a PhD studentship in pharmaceutical freeze-drying at Aston University in the UK, Kevin Ward began his career in lyophilisation in 1993. His PhD included studies on protein stabilisation; the preparation, loading and preservation of "stealth liposomes"; and the thermal properties of lyophilised amorphous and crystalline mixtures. Following his PhD, Kevin worked in the pharmaceutical industry and in vaccine development, before joining the Biopharma Group in 2000 and, as Director of R&D, he has built up a team of dedicated freeze-drying scientists. Since that time, Kevin and his team have had experience of more than 2,500 unique projects for over 500 client companies worldwide, developed 3 analytical instruments, run more than 400 training courses, and successfully secured EU- and UK- government funding for 15 novel research projects. He has appeared on BBC television for his team's work on the preservation of red blood cells and been an advisor to the BBC for one of their popular science shows. Kevin is a Fellow of the Royal Society of Chemistry and a member of the Academy of Pharmaceutical Sciences. From 2000-2014, he was part of a not-for-profit focus group that produced a large number of technical monographs to support users of freeze-dryers, and he chaired the group from 2007-2014. He has been industrial supervisor to two doctoral students, an external examiner and a Visiting Lecturer at University College London and University of Sussex Pharmacy Schools in the UK. An author of numerous papers, book chapters and patents, Kevin continues to lecture on the international stage and co-edited a text book on technological advances in freeze-drying that was published in January 2019.

Edmond Ekenlebie

Edmond is a principal Scientist at Biopharma. He joined BTL in 2014 after a PhD from Aston University in Birmingham, UK. His PhD focused on the optimisation of 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. A Pharmacist since 2006, Edmond previously held managerial roles as both Locum and Superintendent Pharmacist. Dr Ekenlebie currently offers his expertise in consultancy to BTL's worldwide clientele base and remains heavily involved in research work. His current research collaboration is focused on recombinant vaccine formulation development to break the cold chain. He is extremely passionate about freeze drying and maintains an interest in intellectual property across the freeze drying patent landscape.

All you need is  or  with  and  ***It`s easy as that!***

Recommended ***Required***

Day 1

17 May 2021

13:45 Online meeting room opens

14:00 Welcome note from Fleming

- Instructions by a Fleming member
- Opening remarks from the trainer

14:10 Speed networking (all participants)

Join with your camera turned on to meet & greet the trainers and participants, as well as to share your expectations on this course and what you would like to learn

14:30 **Introduction to Lyophilisation**

This module begins by providing an overview of the process, and briefly introduces the concepts and fundamental aspects of modern freeze-drying equipment

15:30 **The Basics of Freezing and Annealing**

Freezing is a very important part of the freeze-drying process, defining the ice crystal structure and ensuring that solute components are fully rigid prior to removal of the solvent. The module will continue by describing the process in detail and how freezing conditions can be adjusted according to formulation.

16:30 Break

16:50 **Primary and Secondary Drying**

This module will introduce the concepts and practicalities of Primary drying (sublimation) - the central part of the freeze-drying cycle where the goal is to remove ice efficiently yet with minimal risk to the product itself - and Secondary drying, which is used to reduce residual moisture for better stability.

17:50 **Q&A**

18:00 End of Day 1

Day 2

18 May 2021

13:45 Online meeting room opens

14:00 **Formulation Fundamentals**

This lecture will highlight what ingredients are typically used in freeze-dried pharmaceutical formulation, the roles of excipients, and what features of a formulation are important in freeze-drying; it will then cover the use of thermal analysis to establish critical temperatures and thermal events in the frozen state.

15:00 **Microscopy and Thermal Analysis in Formulation Characterisation**

This module will discuss in greater detail the use of Freeze-Drying Microscopy and other advanced techniques in the determination of gross morphological events that may occur for a particular formulation during the lyophilisation process.

16:00 Break

16:10 **Cycle Development: The Classical Iterative Method**

In order to achieve a safe yet efficient cycle, the critical temperature of a formulation must be taken into account, and appropriate freeze-drying conditions used accordingly. This presentation will explain how this can be done in a stepwise manner, using the relevant formulation information.

17:10 **Process Analytical Technology (PAT) in Freeze-Drying**

There are a number of traditional and more novel methods of monitoring the freeze-drying process, including simple temperature measuring devices to batch monitoring technologies and endpoint detection techniques. This section of the module will introduce concepts and practicalities of PAT methods.

18:00 End of Day 2

Day 3

19 May 2021

13:45 Online meeting room opens

14:00 **Scale-Up Parameters and Cycle Robustness**

Scaling up a cycle from laboratory R&D scale to full manufacturing scale involves an appreciation of the differences in equipment design and performance, upstream processes and the working environment. The first part of this module will highlight some of the more important factors and how to take them into account.

15:00 **Regulatory Submission Principles**

Some tips and suggestions to help make the submission process a less problematic experience.

16:00 Break

16:10 **Analysing the Freeze-Dried Product**

Residual water, thermal properties and mechanical structure can all be particularly important factors in determining the physical, chemical and biological activity of a pharmaceutical or biotechnology product. The main part of this module will explore a range of methods employed to quantify aspects of the dried material.

17:10 **Q&A**

17:40 End of Training

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"Knowledge is important, but implementation is crucial."

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The team behind:

We are delighted to bring you the

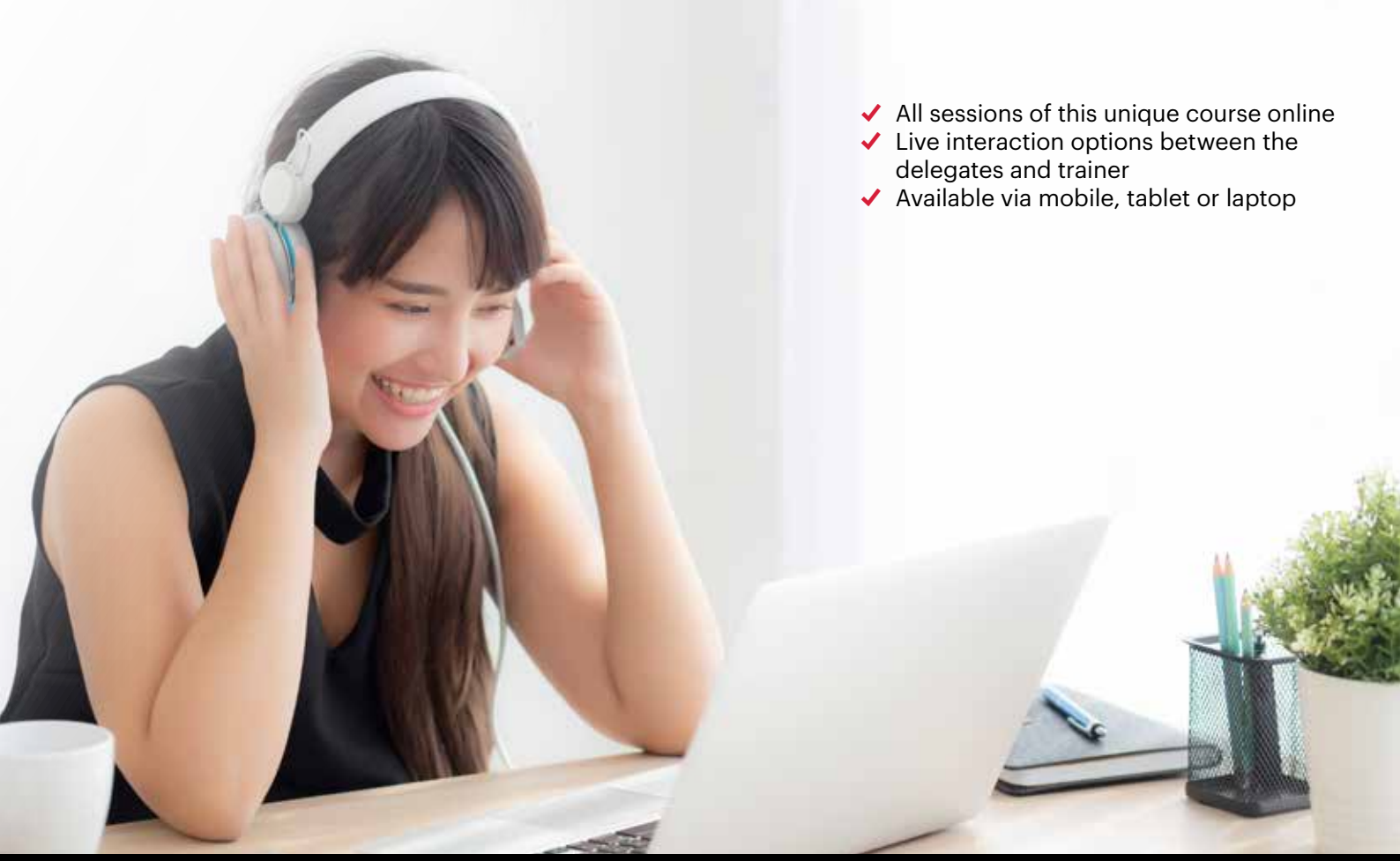
Lyophilization in Pharma & Biotech

Click on the ticket below to sign up

Or write to
event.inquiries@fleming.events
to get in touch with a member of our team

Dasa Janosikova
Production Manager - Life Sciences

Monica Jones
Marketing manager



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