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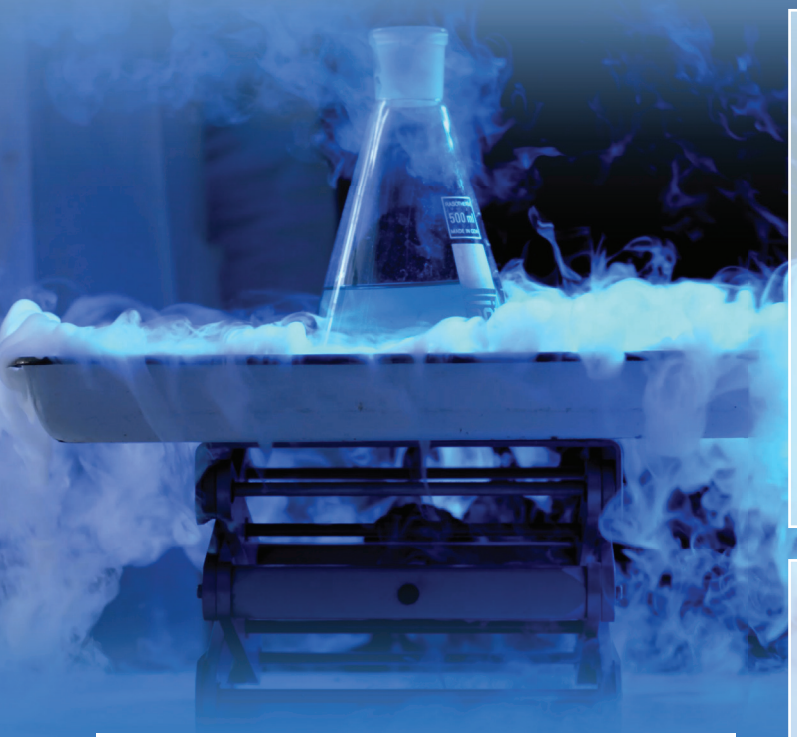
SMi Presents the 6th Annual Conference on...

Pharmaceutical Freeze Drying Technology

Optimising pharmaceutical technology through innovations and novel approaches in freeze drying

Holiday Inn Kensington Forum, London, UK

WORKSHOPS: 12TH
CONFERENCE: 13TH - 14TH
JUNE 2018



CHAIR FOR 2018:

- **Sune Klint Anderson,** Principal Scientist, **Janssen**

FEATURED SPEAKERS 2018:

- **Paul Matejtschuk,** Principal Scientist, **NIBSC – MHRA**
- **Mostafa Nakach,** Head of Pharmaceutical Engineering, **Sanofi**
- **Erwan Bourles,** Expert Scientist, Head Filling Drying Device, **GlaxoSmithKline**
- **Miguela Vieru,** Senior Scientist, **Janssen**
- **Eric Munson,** Patrick Deluca Endowed Professor of Pharmaceutical Technology, **University of Kentucky**
- **Patrick Garidel,** Bioprocess and Pharmaceutical Development Biologicals, **Boehringer Ingelheim**
- **Daryl Williams,** Reader in Particle Science, **Imperial College London**

FEATURED HIGHLIGHTS IN 2018:

- Discuss the use of old and new methods in terms of the optimisation of freeze drying cycles
- Learn about case studies which delve into the processes through which cycles can be refined to the utmost efficiency
- Hear about a new PAT for freeze drying cycle development through vial impedance spectroscopy
- Discover ways in which water activity measurement and mathematical modelling can be used to evaluate the stability of freeze dried vaccines
- Evaluate quality-by-design strategies, applied to spray drying, versus lyophilisation

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PLUS TWO INTERACTIVE HALF-DAY PRE-CONFERENCE WORKSHOPS
TUESDAY 12TH JUNE 2018, HOLIDAY INN KENSINGTON FORUM, LONDON, UK

A: From Physical Properties to Lyophilised Product

Workshop Leaders:
Paul Matejtschuk, Principal Scientist, **NIBSC - MHRA**
Robert Forbes, Professor of Clinical Pharmaceutics, **University of Central Lancashire**
08.30 - 12.30

B: Critical Assessment of Lyophilised Products Using Analytical, Visual and Mechanistic Approaches

Workshop Leader: **Edmond Ekenlebie,** Principal Scientist, **Biopharma Process Systems Ltd**
Andrew Bright, Senior Scientist, **Biopharma Process Systems Ltd**
13.30 - 17.00

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Pharmaceutical Freeze Drying Technology

Day One | Wednesday 13th June 2018

www.pharmafreezedrying.com

08.30 Registration & Coffee

09.00 Chairman's Opening Remarks

Sune Klint Andersen, Principal Scientist Spray Drying, **Janssen**

BIOLOGICS FREEZE-DRYING AND OPTIMISATION OF CYCLES

KEYNOTE ADDRESS:

09.10 Freeze drying of biologics: The essentials

- Short introduction to the freeze-drying process
- Freeze-dried market products
- Biologics in the dry state: what to consider?
- Formulation principles for freeze-dried products
- Process development of freeze-dried products
- Primary packaging for freeze-dried products
- Analytics for the characterisation of lyophilizates
- Stability issues

Patrick Garidel, Bioprocess and Pharmaceutical Development Biologicals, **Boehringer-Ingelheim**

09.50 Use of old and new methods in optimising freeze drying cycles

- Illustrate how existing technologies can be used
- New and experimental methods are adding to our capabilities
- Off-line dynamic mechanical analysis
- On-line impedance analysis

Paul Matejtschuk, Principal Scientist, **NIBSC-MHRA**

10.30 Morning Coffee

KEYNOTE:

11.00 Optimisation of industrial freeze drying cycle

- Two "old" products of the 60's (called "A" and B") performed with historical cycles exhibit aspects issues. The manufacturing of both products was intended to be carried out using a new and stated art freeze dryer. Due to the age of the products, very few process or physical chemistry data was available
- Therefore the manufacturing process was developed and optimized based on product knowledge, new freeze dryer knowledge, simulation and process modeling
- The objective of the presentation is to share how the methodology was applied and to outline the concrete benefit for both products

Mostafa Nakach, Head of Pharmaceutical Engineering, **Sanofi**

STABILITY OF FREEZE-DRIED PHARMACEUTICALS AND MATHAMATICAL MODELLING

11.40 Predicting stability of freeze dried pharmaceuticals

- Tools currently used to predict stability
- Challenges associated and errors
- Reducing errors in the predicted stability value

Eric Munson, Professor, Pharmaceutical Sciences, **University of Kentucky**

12.20 Networking Lunch

KEYNOTE:

13.30 How to use water activity measurement and mathematical modelling to evaluate the stability of freeze-dried vaccines

- Definition of water activity
- Examples of stability evaluation using water activity measurement
- Case study on a vaccine formulation

Erwan Bourles, Expert Scientist Head Filling, Drying & Device, **GSK**

14.10 Long term storage stability of FD biologics: Effects of storage temperature

- Challenge of drying high protein content materials
- Stress thermal stability studies on model IgG formulation
- Physicochemical and bioactivity analysis
- Novel mechanical/ structural analytical methods

Daryl Williams, Reader in Particle Science, **Imperial College London**

14.50 Afternoon Tea

FORMULATION CONSIDERATIONS

15.20 Formulation considerations in the development of liposomes in a freeze-dried format

- Considerations of the advantages and challenges to freeze-drying of liposomes and nanomedicines
- Strategies to formulate these systems as stable freeze-dried products
- Methods to rapidly screen and identify suitable freeze-dried formats

Maryam Hussain, Research Assistant/ PhD Student, **University of Strathclyde**

16.00 Freeze-Dried product appearance: Looking at the material and the immaterial

- Macroscopic parameters: shape, uniformity, skin formation, shrinkage, defects in gross morphology and root causes
- Micro-collapse: is it acceptable?
- What effects might micro-collapse have on the product?
- How can it be detected and predicted?

Kevin Ward, Director of R&D, **BioPharma Process Systems Ltd**

16.40 Chairman's Closing Remarks and Close of Day One

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08.30 Registration & Coffee

09.00 **Chairman's Opening Remarks**
Sune Klint Andersen, Principal Scientist Spray Drying, **Janssen**

SPRAY DRYING

KEYNOTE ADDRESS:

09.10 **QbD in spray drying vs lyophilisation**
- Quality-by-Design strategies for drying processes
- Typical sources of variation for lyophilization and spray drying processes
- Timing/conditions for initiating QbD for drying processes
- Applying PAT in drying process QbD

Sune Klint Andersen, Principal Scientist Spray Drying, **Janssen**

KEYNOTE:

09.50 **Detection of silicone oil leaks in lyo-installation with standard equipment**
Georg Frinke, Process Engineer, Bayer*

10.30 **Morning Coffee**

CASE STUDIES OF LYOPHILISATION, CYCLE DEVELOPMENT AND NOVEL APPROACHES

KEYNOTE:

11.00 **Lyophilization of a synthetic small molecule with antiviral activity for oral delivery (case study)**
- Formulation development for an antiviral agent with low aqueous solubility
- Lyophilization of a formulation containing cyclodextrin
- Freeze dried product characterization
- Spray drying as an alternative technique to stabilize the drug product formulation

Miguela Vieru, Research & Development, PDMS - Parenterals & Liquids, **Janssen**

11.40 **Through Vial Impedance Spectroscopy - A new PAT for freeze-drying cycle development**
- Description of the system and the measurement principles
- Characterization of ice and the unfrozen fraction
- Determination of single vial product temperature and drying rates
- Applications for process parameter determination (Kv, Rp)

Geoff Smith, Professor of Pharmaceutical Process Analytical Technology, **DeMontford University**

12.20 **Networking Lunch**

13.30 **Novel approaches to reducing subjectivity and enhancing quantification in characterisation methods pre- and post-lyophilisation**
- Applications of Thermal Analysis by Structural Characterisation (TASC) in freeze-drying microscopy (FDM)
- Training operators to recognise the onset of collapse and reducing operator-to-operator variation
- Quantification of the effect and impact of annealing at different temperatures
- The use of quantitative Young's Modulus (elasticity) measurements to provide a better understanding of:
- The significance of temperature gradients across shelves in freezing and drying for different formulations
- The robustness of different formulations to different lyophilisation conditions

Kevin Ward, Director of R&D, **BioPharma Process Systems Ltd**

14.10 **In silico approaches to aid rational design of freeze dried formulations**
- Importance of intermolecular interactions between excipients and actives for their stability and/or solubility
- In silico freeze drying of pharmaceutical formulations
- Case studies: from a small molecule to protein therapeutics
- Perspectives on applications of in silico tools in rational design of formulations

Mire Zloh, Professor Emeritus, **University of Hertfordshire**

14.50 **Afternoon Tea**

FUTURE DIRECTIONS OF THE FIELD

15.20 **PANEL - The future of novel technology for predicting cycles within the lyophilisation field**
- The current novel technologies which have been recently introduced into the market
- The benefits of these technologies over existing technologies
- Barriers to entry into implementation e.g. regulations, pricing etc
- How can technologies be further developed?

Paul Matejtschuk, Principal Scientist, **NIBSC**
Sune Klint Andersen, Principal Scientist Spray Drying, **Janssen**
Kevin Ward, Director of R&D, **BioPharma Process Systems Ltd**
Mostafa Nakach, Head of Pharmaceutical Engineering Group, **Sanofi-Aventis R&D**

16.00 **Electrospin drying for pharmaceutical application**
- The development of electrospinning in continuous manufacturing
- Freeze drying in combination with electrospinning and the advantages of nanofibres
- The challenges of spinning and achieving a high throughput
- What might the future hold for electrospinning in a scale- up pharmaceutical setting?

Speaker to be confirmed

16.40 **Chairman's Closing Remarks and Close of Day Two**

* Subject to final confirmation

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HALF-DAY PRE-CONFERENCE WORKSHOP
Tuesday 12th June 2018
08.30 – 12.30
Holiday Inn Kensington Forum, London, UK

A: From Physical Properties to Lyophilised Product

Workshop Leaders:
Paul Matejtschuk, Principal Scientist, **NIBSC - MHRA**
Rob Forbes, Professor of Clinical Pharmaceutics,
University of Central Lancaster

Workshop Overview:

The workshop will address fundamental approaches to formulation of biologics for freeze drying, look at modern predictive methods to optimise formulation, offer practical advice and worked examples of how formulation challenges can be overcome and highlight the pitfalls to avoid on scaling up.

Why you should attend:

- Basic training in fundamentals of freeze drying formulation
- Gain experience of DoE approach to biologics formulation
- Learn how to transfer knowledge from lab to pilot scale

Agenda:

08.30 **Registration and Coffee**

09.00 **Opening Remarks and Introductions**

09.10 **Session 1: Principles of formulation and freeze drying**
- Basic principles of freeze drying
- What makes a good formulation?
- Designing a freeze drying cycle

09.50 **Session 2: Principles of DoE in pharmaceutics and biopharma**
- What is Design of Experiments and how can it be applied in formulation?
- DoE in formulation – screening and optimisation
- Impact of DoE over classical approaches

10.30 **Morning Coffee**

11.00 **Session 3: Examples of formulation optimisation by both classic and DoE routes**
- Example of One Factor At Time formulation
- Example of DoE in Vaccine formulation (published study)
- Cost effective use of DoE

11.40 **Session 4: From trial to scale-up**
- Principles of scale up in freeze drying
- Hardware considerations
- Examples

12.20 **Closing Remarks**

12.30 **End of Workshop**

About the workshop leaders:

Dr Paul Matejtschuk leads a team in the development of formulation and freeze drying processes for the International Standards and other reference materials produced by NIBSC. He has broad experience across downstream processing including lyophilisation, analytical and preparative chromatography, ultrafiltration, glycan analysis, peptide mapping and protein chemistry.

His most recent experience has been in the biological application of thermal analysis, formulation and lyophilisation of biologicals, high throughput screening methods, application of Design of Experiments (DoE) and Process Analytical Technology (PAT) in freeze drying as well as the measurement of residual water and its impact on the stability of biologics

Rob Forbes has a degree in Pharmacy, and a PhD in Pharmaceutical Technology from the University of Bradford. Prior to my appointment at UCLan, he held a Chair in Biophysical Pharmaceutics within the School of Pharmacy, Faculty of Life Sciences, at the University of Bradford. Before joining the faculty at Bradford, Rob spent some time within the Pharmaceutical Industry. A PhD background in the pharmaceutics of salt form selection under the supervision of Prof Peter York and Dr James Wells was applied in practice in Industry when he worked for Astra in Sweden. Rob conducted post-doctoral work in the formulation of depot injections and went on to lead a pre-formulation team. His responsibilities included optimising physical form selection e.g. salt selection, polymorph, amorphous forms. Aspects of the work contributed to patents and intellectual property. Since moving to academia Rob's industrial background and expertise has been useful in progressing many collaborative research projects. Particular highlights include the supervision of over 20 PhD students to completion, his involvement in Innovate UK R&D grants, and his time leading the speciality research Biopharmaceutical Formulation Group at the University of Bradford.

HALF-DAY PRE-CONFERENCE WORKSHOP
Tuesday 12th June 2018
13.30 – 17.00
Holiday Inn Kensington Forum, London, UK

B: Critical Assessment of Lyophilised Products Using Analytical, Visual and Mechanistic Approaches

Workshop Leaders:
Edmond Ekenlebie, Principal Scientist,
Biopharma Process Systems Ltd
Andrew Bright, Senior Scientist, **Biopharma Process Systems Ltd**

Workshop Overview:

The workshop provides an overview of the critical quality attributes of lyophilised products and delves further into analytical, visual and mechanical methods typically used in industry. Using practical exercises and case studies, techniques will be explored to cover typical problem solving and how these can inform the overall freeze drying process.

Why you should attend:

- Learn about the fundamentals of lyophilised cake characterisation
- Obtain an understanding into the different approaches and their capabilities
- Gain practical insight and advice from experienced practitioners
- Enjoy the informal interactive nature of the structured sessions

Agenda:

13.30 **Registration and Coffee**

14.00 **Opening Remarks and Introductions**

14.10 **Session 1: Overview of Critical Quality Attributes (CQAs) of Lyophilised Products and Analytical Methods**
- What are the typical CQAs?
- Analytical approaches and methods for reconstituted and dry state analysis- using techniques including DSC, DVS, Raman, IR, XRD, DLS

15.10 **Session 2: Case studies**
- Sample case studies and discussion on how to use these techniques to answer specific questions

15.40 **Afternoon Tea**

16.00 **Session 3: Assessing structural properties of lyophilised materials**
- Visual and quantitative methods, including in situ vial quantification of mechanical properties
- Practical exercise assessing typical structural patterns in freeze dried products

17.00 **End of Workshop**

About the workshop leaders:

Dr Edmond Ekenlebie Edmond is a principal Scientist at Biopharma. He joined BTL joined 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.

Dr Andrew Bright Andrew joined BTL in January 2018 as Senior Scientist after receiving his Ph.D. from the University of Bradford. There, he was investigating freeze dried vaccine formulations with the thesis title "Mechanistic Insights into the Stabilisation of Biopharmaceutical Using Glycine Derivatives" and also holds a MChem in Chemistry with Pharmaceutical and Forensic Science. Andrew previously worked for 2 years as a Senior Scientist at Pfizer within liquid formulations specialising in freeze dried formulation design, process development, and scale up.

About the organisation:

Biopharma Process Systems started in 1989 as a family business supplying freeze-dryers and related equipment. It has since grown and its offerings expanded to providing formulation design, characterisation and lyo cycle development, specialist analytical instruments, training courses, and troubleshooting for clients worldwide on their equipment, products and processes. During the past 28 years, Biopharma has arguably become Europe's leading freeze-drying company.

PHARMACEUTICAL FREEZE DRYING TECHNOLOGY

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Workshops: Tuesday 12th June 2018, Holiday Inn Kensington Forum, London, UK

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