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SMi Group Proudly Present the 7th Annual Conference...

Lyophilisation

*Exploring Novel Technologies and Bolstering
Lyophilisation Strategies for Freeze Drying Optimisation*

HOLIDAY INN KENSINGTON FORUM, LONDON, UK

CONFERENCE: 3RD-4TH
WORKSHOPS: 5TH

JUNE 2019



HIGHLIGHTS IN 2019:

- **EXPLORE** the recent advances in lyophilisation methods and technologies from Biopharma Technology
- **DISCUSS** the novel methods that characterise complex pharmaceutical products to aid formulation design from **NIBSC**
- **GAIN** insight into the approaches to avoid cross contamination during lyophilisation from **SKAN AG**
- **DISCOVER** a new approach towards process design through the use of micro freeze dryers by **Politecnico di Torino**
- **EXAMINE** multiple tools and methods to determine primary drying endpoint from **Pfizer**

CHAIRS FOR 2019:



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



Xiaodong Chen, Senior Research Investigator, **Bristol-Myers Squibb**

FEATURED 2019 SPEAKERS INCLUDE:

- **Paul Matejtschuk**, Principal Scientist & Section Head, Standardisation Science, **NIBSC**
- **Bert Van Meervenne**, Senior Principal Scientist, **Pfizer**
- **Mostafa Nakach**, Head of Pharmaceutical Engineering Group, **Sanofi-Aventis R&D**
- **Kevin Ward**, Director of R&D, **Biopharma Technology**
- **Paul Barry**, Development Scientist, **Genzyme Ireland Ltd/Sanofi**
- **Anthony Cannon**, Regional Director, ExM, GTO Bio/ Sterile European Region, **MSD**

PLUS TWO INTERACTIVE HALF DAY POST CONFERENCE WORKSHOPS | WEDNESDAY 5TH JUNE 2019, HOLIDAY INN KENSINGTON FORUM, LONDON, UK

A: From Physical Properties to Lyophilised Product

Workshop Leader:

Paul Matejtschuk, Principal Scientist & Section Head, Standardisation Science, **NIBSC**
08.30 - 12.30

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

Workshop Leader:

Andrew Bright, Senior Scientist, **Biopharma Process Systems Ltd**
13.30 - 17.00



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www.lyophilisation-europe.com

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8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**

Xiaodong Chen, Senior Research Investigator, **Bristol-Myers Squibb**

OPENING ADDRESS

9.10 **Recent advances in technologies and approaches in freeze-drying: a quick tour**

- Formulation characterisation – freeze-drying microscopy and thermal analysis
- Process monitoring and control – PAT and controlled nucleation methods
- Approaches, limitations and practicalities in scaling up the freeze-drying process
- Post-lyophilisation testing – new technologies for understanding the final product

Kevin Ward, Director of R&D, **Biopharma Technology**

9.50 **Anatomy of the Lyophilisation Process: Considerations for a Successful Tech Transfer**

- Tech transfer of a lyophilised product
- Overview of the Lyophilisation process and the critical process parameters
- Specific focus on the technical considerations with analysis of the impact on the Lyophilisation recipe
- Impact of deviations to the CPPs on the product quality during transfer activities

Anthony Cannon, Regional Director, ExM, GTO Bio/Sterile European Region, **MSD**

10.30 **Morning Coffee**

SPOTLIGHT PRESENTATION

11.00 **Representative Scale-down Lyophilisation Cycle Development Using a Micro Freeze-Dryer**



A scale-down lyophiliser was used to simulate at-scale Lyophilisation development and optimisation. Equivalent Lyophilisation performance between the scale-down lyophiliser and a laboratory lyophiliser were demonstrated for placebo and mAb drug products. By changing the MicroFD® Kv, laboratory, and potentially manufacturing cycles, may be simulated using this lyophiliser for tremendous API savings:

- The MicroFD® is designed with precision machined, temperature controlled aluminium blocks that make direct contact with the outer vials. These blocks are designed to mimic vial-to-vial contacts that control inter vial heat transfer
- Demonstrated the ability to fine-tune the MicroFD® heat transfer coefficient (Kv) to match the Kv of vials in a Lyostar III laboratory scale unit
- The resulting performance between scales results in equivalent product primary drying times, product temperature profiles, and critical quality attributes (CQAs)
- A workflow is proposed using the scale-down lyophiliser to simulate at-scale lyophilisation development and optimisation

Xiaodong Chen, Senior Research Investigator, **Bristol-Myers Squibb**

11.40 **Preventing Cross Contamination during Lyophilisation**

- What are highly potent/toxic Biopharmaceutical Products
- What are the GMP and Occupational Safety Requirements
- How to prevent Product Contamination during loading the Lyo
- Cleaning Requirements and Occupational Safety Requirements

Richard Denk, Head Sales Containment, **SKAN AG**

12.20 **Networking lunch**

13.20 **A proposed scientific rationale for the establishment of acceptance criteria for leak rates in pharmaceutical freeze dryers**

- A methodology has been developed to determine the theoretical quantity of air that could leak into a pharmaceutical freeze dryer based on vacuum pressure increase
 - Based on the potential maximum bioburden and particulate level of the leaked air from potentially unclassified areas, simple calculations can be undertaken to determine the maximum allowable leak rate that will still maintain Class 100 / Grade A conditions for the duration of the lyophilisation cycle
 - It will be shown that the 2 x 10⁻² mbar-litre/sec specification, that is frequently quoted as the acceptable leak rate for modern pharmaceutical freeze dryers may not be appropriate to maintain Grade A conditions for freeze dryers of differing volumes with lyophilisation cycles of differing lengths
 - This methodology can then be used as a justification for the setting of leak rate limits for new cycles or freeze dryers based on potential microbial risk rather than equipment process capability
- Aled Jones**, Manufacturing Tech Support Manager, **Ipsen**

14.00 **Application of Infrared Thermography and Multivariate Image Analysis for the on-line Monitoring of a Freeze-Drying Process**

- Infrared camera, placed inside a freeze-dryer, can be used to monitor product temperature in several vials, in different positions
- Product temperature measurement may be used to infer the residual amount of ice in the primary drying stage, as well as the parameters of a simple one-dimensional model of the process
- The system may be used also to track the evolution of the product in the freezing stage
- Using Multivariate Image Analysis (MIA) it becomes possible to extract additional information about process dynamics
- The proposed MIA-based PAT system is able to efficiently detect undesired events occurring during the process
- Information obtained through a standard RGB camera may be also include in the PAT system

Daive Fissore, Associate Professor, **Politecnico di Torino**

14.40 **Afternoon Tea**

15.10 **Optimisation of industrial freeze-drying cycle - Two real life examples**

- Comparing two dated lyophilised products (60's) with historical cycles that exhibit distinct complications
- Development and optimisation of manufacturing processes to overcome the lack of physical chemistry data from dated products
- Applying product knowledge, new freeze dryer knowledge, simulation and process modelling

Mostafa Nakach, Head of Pharmaceutical Engineering Group, **Sanofi-Aventis R&D**

15.50 **Analysing current strategies in vaccine formulation design to achieve improved stability for long term storage and distribution**

- Due to the intrinsic instability of vaccines in aqueous solution, there is a pressing need for improved lyophilisation strategies that tackle stability for successful transfer and storage in warmer climates where they are needed most. This session will delve into the design of vaccine formulations through modelling by Design of Experiments (DoE) that ultimately provide a statistical approach to excipient selection. These will be presented through a case study to better showcase the strategic approach.
- Assessing the challenges of handling labile vaccines
 - Utilising DoE approach to provide statistical analysis for better formulation design
 - Case study: Validation of DoE approach through field testing
- Speaker TBC: **Pharmaceutical Company**

16.30 **Chairman's Closing Remarks and Close of Day One**

Register online at www.lyophilisation-europe.com

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8.30 Registration & Coffee

9.00 Chairman's Opening Remarks

Sune Klint Andersen, Principal Scientist Spray Drying,
Janssen Pharmaceuticals

OPENING ADDRESS

9.10 Low Temperature Drying Processes for Biopharmaceuticals

- Challenges in drying of biopharmaceuticals
- Drying process landscape and trends
- Emerging low temperature drying processes

Sune Klint Andersen, Principal Scientist Spray Drying,
Janssen Pharmaceuticals

9.50 Primary Drying endpoint determination

- Overview & discussion of different tools to determine primary drying endpoint
- Pros and Cons of each method
- Touching briefly additional potential of these tools

Bert Van Meerven, Senior Principal Scientist, **Pfizer**

10.30 Morning Coffee

11.00 Applications for Impedance Spectroscopy in the Determination of In-Vial Phase Behaviour

- Through Vial Impedance Spectroscopy – An Introduction
- Dielectric loss mechanisms in frozen solutions
- Measurement frequency selection for different facets of the freezing process (ice nucleation to solidification end point)
- Determination of in-vial glass transitions and collapse phenomena

Geoff Smith, Professor of Pharmaceutical Process Analytical Technology, **De Montfort University**

11.40 Formulation for freeze drying, development and applicability

Increasing complexities of myriad pharmaceutical products and materials demand improved and novel methods that characterise and consequently provide essential information to support formulation design.

- How does freeze drying impact bio activity?
- Role of Design of Experiments in formulation development
- Using PAT tools - through vial impedance as an example

Paul Matejtschuk, Principal Scientist & Section Head,
Standardisation Science, **NIBSC**

12.20 Networking lunch

13.20 Long-Term Storage Stability and Effect of Moisture Content on Freeze-Dried Immunoglobulin G (IgG)

- High protein concentration products for targeted therapeutic use are commonly manufactured by freeze-drying
- The long-term storage stability of freeze-dried plasma derived Immunoglobulin G (IgG) from moderate to high concentrations (1, 5, 10 and 20 % w/v) was assessed for -20°C, 20°C, 45°C
- At -20°C < 1% of monomer loss, 20°C <5% monomer loss, whilst 45°C a 15%-39% decrease in monomer concentration
- Moisture content in vial effected formulation stability

Daryl Williams, Professor of Particle Science and Director of Discovery Space, **Imperial College London**

14.00 Assessment of Aggregation in Lyophilised Biologics

- Using large data sets to identify common cause(s) for aggregation occurrence
- Analytical assessment of aggregation

Paul Barry, Development Scientist, **Sanofi**

14.40 Afternoon Tea

15.10 Current state of MTM – True PAT with high future potential

- Current state of MTM Technology
- Operating principle
- Future potential & Limitations

Georg Frinke, Facility and Process Engineer,
Bayer Pharmaceuticals

15.50 Evaluating the challenges of highly concentrated biological formulations to minimise issues

Pharmaceutical products presented as highly concentrated biologicals often confer inherent instability issues that result in complications in long term storage and reduced therapeutic potential. Complete understanding of the product's parameters, formulation design and cycle optimisation remain ongoing challenges.

- Considerations in formulation design of highly concentrated lyophilisation products
- Achieving protein stability and the analysis of cake appearance and how this affects product performance
- Optimising reconstitution outcome and long-term storage stability

Speaker TBC: **Pharmaceutical Company**

16.30 Chairman's Closing Remarks and Close of Day Two

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TECHNOLOGY NETWORKS

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Wednesday 5th June 2019

Holiday Inn Kensington Forum, London, UK

8.30 - 12.30

From Physical Properties to Lyophilised Product

Workshop Leader:

Paul Matejtschuk, Principal Scientist & Section Head,
Standardisation Science, **NIBSC**

Workshop overview:

From this workshop you should expect to learn details of the nature of the amorphous and crystalline state, how formulations influence the freeze drying of proteins and how you can through analytical methodology (freeze drying microscopy, thermal analysis) arrive at a freeze drying cycle which should deliver a successful freeze dried end product.

Why You Should Attend this Workshop:

- 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

8.30 Registration & Coffee

9.00 Chairman's Opening Remarks

9.10 Principles of Formulation for Freeze drying

- The basics of freeze drying process
- The importance of water/ice
- The impact of formulation on delivering a well-dried product

9.50 Analytical measurements and their implementation

- What do I measure? T_g' and T_c
- How do I measure it? FDM, DSC and more...
- How do I interpret the data

10.30 Morning Coffee

11.00 From analytical data to cycle design

- From critical temperature to a FD cycle
- Cycle design – freezing primary and secondary drying steps
- Cycle optimisation & Process Analytical Techniques

12.30 Closing Remarks and End of Workshop

About the Workshop Leader:

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.

About the Organisation:

The National Institute for Biological Standards and Control (NIBSC) is a global leader in the characterisation, standardisation and control of biological medicines. NIBSC plays a major role in assuring the quality of biological medicines worldwide through the provision of biological reference materials, by testing products and carrying out research. Our expert scientists also provide advice on a routine basis and in response to emergencies.

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

Workshop Leader:

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 this Workshop:

- Learn about the fundamentals of 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 Overview of Critical Quality Attributes (CQAs) of Lyophilised Products and analytical Methods

- What are typical CQAs?
- Analytical approaches and methods for reconstituted and dry state analysis – using techniques including DSC, DVS, Raman, IR, XRD, DLS

15.10 Case Studies

- Sample case studies and discussion on how to use these techniques to answer specific questions

15.40 Afternoon Tea

16.00 Assessing Structural Properties of Lyophilised Materials

- Visual quantitative methods, including in situ vial quantification of mechanical properties
- Practical exercise assessing typical structural patterns in freeze dried products

17.00 Closing Remarks and End of Workshop

About the Workshop Leader:

Dr Andrew Bright 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.

LYOPHILISATION

Conference: 3rd – 4th June, 2019, Holiday Inn Kensington Forum, London, UK Workshops: 5th June 2019, Holiday Inn Kensington Forum, London, UK

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