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SMi Presents the 4th Annual Conference and Exhibition on...

Lyophilisation Europe

4 - 5 JULY 2016

Holiday Inn Kensington Forum, London, UK

Design a cost efficient freeze-drying process without compromising drug quality

CHAIR FOR 2016:

- **Sune Klint Andersen**, Principal Scientist, **Novo Nordisk A/S**

KEYNOTE SPEAKERS INCLUDE:

- **Patrick Garidel**, Head of Pharmaceutical Basic Development, **Boehringer Ingelheim**
- **Mostafa Nakach**, Head of Pharmaceutical Engineering, **Sanofi**
- **Paul Matejtschuk**, Principal Scientist, **NIBSC**
- **Erwan Bourles**, Freeze Drying Scientist, **GSK**
- **Daniela Stranges**, Senior Scientist, **GSK Vaccines**
- **Geoff Smith**, Professor, **Leicester School of Pharmacy**

HIGHLIGHTS FOR 2016:

- Control the impact of process variables and managing risk
- Ensure product quality and compliance through regulatory guidance
- Optimise spray drying process and formulation development for complex dosage forms
- Integrate risk-based approaches into QbD principles
- Hear cutting edge advancements on PAT tools to optimise parameters for scale-up

PLUS INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 6th July 2016, Holiday Inn Kensington Forum, London, UK

Design and scale up of a freeze drying process

Workshop Leaders:
Paul Matejtschuk, Principal Scientist and Section Head, **NIBSC** and **Kevin Ward**, Director of R&D, **Biopharma Process Systems Ltd**
08.30 – 12.30

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Lyophilisation Europe

Day One | Monday 4th July 2016

08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**
Sune Klint Andersen, Principle Scientist, **Novo Nordisk A/S**

OPENING ADDRESS

09.10 **Application of QbD principles to design lyophilisation process robustness studies in support tech transfer of a freeze-dried vaccine component**

- Introduction: General overview of QbD principles and tools applied to vaccines development
- Case study is related to combination vaccine in which one component is a freeze-dried product in order to confirm process parameters set points and define PAR for lyophilisation step the following approach has been pursued: Definition of QTPP and product CQAs for lyophilisation process step: Risk assessment performed to determine possible interaction between PPs and product CQAs
- Set up of down scale model representative of manufacturing scale; experimental plan design: Results analysis for identification of Proven Acceptable Ranges for CPPs
- Manufacturing control strategy confirmed through execution of confirmatory runs

Daniela Stranges, Senior Scientist, **GSK Vaccines**
Emanuele Tomba, Scientist, **GSK Vaccines**

NEW EXCIPIENT AND LYOPHILISATION PROCESS

9.50 **Constructing a robust design space based on product and process limitations**

- The basics of constructing and using a design space using Prior Knowledge and experimental data
- The balance between desktop research and practical studies
- Finding more quantitative aspects of lyophile analysis to include in QbD – structural and mechanical properties

Kevin Ward, Director of Research & Development, **Biopharma**

10.30 **Morning Coffee**

11.00 **Process scale up of nanoparticles: Spray drying of nanoparticles**

- A viable alternative to achieving continuous production
- Optimising solution/suspension properties to maintain critical quality attributes
- Challenges with atomisation

Session reserved for sponsor

11.40 **Freeze-drying protein and vaccine formulations**

- Formulation development approaches
- Impact of formulation on freeze drying cycle
- Forced degradation to support long term storage

Paul Matejtschuk, Principal Scientist, **NIBSC**

12.20 **Networking Lunch**

13.30 **Through vial impedance spectroscopy: A process analytical technology (PAT) to develop a rational lyophilisation cycle**

- What are the challenges inherent in preformulation and phase transitions during lyophilisation?
- What should be classed as critical process parameters?
- What happens on microscale-down and scale-up?
- Developing the toolbox – overlapping (multiplexed) PAT from single vial to batch monitoring?

Geoff Smith, Professor, **Leicester School of Pharmacy**

IMPROVING MODELING PROCESS

14.10 **Optimisation of industrial freeze drying cycle: Two case studies**

- Redevelop a freeze drying process for internal manufacturing of two "old" products of the 60's (called "A" and B") performed with historical cycles
- Methodology is based on the product knowledge, the equipment knowledge, modeling and simulation
- Study outcomes: Validation batches with full rational leading to compliant product and Optimized productivity

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

14.50 **Afternoon Tea**

15.20 **Continuous Freeze Drying of (Bio-)pharmaceuticals**

- Model based design
- PAT – latest development
- Fundamentals of system design
- Challenges with continuous freeze drying and how to overcome

Jos Corver, Owner, **Rheavita BV**

PANEL DISCUSSION

16.00 **Designing formulations for lyophilised products**

- Identify the right formulation
- Characterising the amorphous and crystalline structure of ice per individual vial in a cluster within the dryer
- Correlating porous structure with rehydration kinetics to optimise drying processes

Erwan Bourles, Freeze Drying Scientist, **GSK**
Mostafa Nakach, Head of Pharmaceutical Engineering, **Sanofi**
Jos Corver, Owner, **Rheavita BV**

16.40 **Chair's Closing Remarks and Close of Day One**

WHO SHOULD ATTEND:

VPs, Directors, Chiefs, Heads, Principals, Managers and Analysts of:

- Lyophilisation
- Formulation Scientist
- Bioprocessing
- Process Development
- Sterile/ Fill-Finish
- Production
- PAT
- CMC
- Chemistry
- Manufacturing
- Quality Assurance/QA
- Freeze-Drying

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08.30 Registration and Coffee

09.00 **Chairman's Opening Remarks**
Sune Klint Andersen, Principle Scientist, **Novo Nordisk A/S**

OPTIMISING DRUG FORMULATION

OPENING ADDRESS

09.10 **Challenges in spray drying process and formulation development**
- Benchmarking lyophilisation with spray drying
- A viable alternative for achieving continuous production
- Maintaining product critical quality attributes across scales

Sune Klint Andersen, Principal Scientist, **Novo Nordisk A/S**

9.50 **ATEX regulation applied to a manufacturing workshop of high potent injectables**
- The ATEX regulation
- Process review
- Validation activities

Franck Pavan, Injectable Business Manager, **Pierre Fabre**

10.30 **Morning Coffee**

11.00 **Establishing the correct safety margins to prevent temperature collapse**
- Translating the scalability and freezing rate of small vials from early development to industrial scale
- Optimising PAT principles in API development
- Trouble shoot analysis and risk management

Session reserved for sponsor

11.40 **On the use of PAT tools and statistical analysis to determine optimal freeze drying cycle parameters for scale-up**
- Design of experiment approach in order to select the accurate process parameters to preserve product from collapse
- Surface response analysis to create a process acceptable range for the selected freeze drying cycle
- Validation of the process acceptable range with experimental trials using PAT tools

Erwan Bourles, Freeze Drying Scientist, **GSK**

12.20 **Networking Lunch**

PANEL DISCUSSION

13.30 **Challenges of optimising filling processes and maintaining freeze dryers**
- Maintaining continuous process validation and control of process parameters
- Case study on material flow
- Integrating risk-based approaches into QbD principles

Erwan Bourles, Freeze Drying Scientist, **GSK**
Moderate by Sune Klint Andersen, Principal Scientist, **Novo Nordisk A/S**

ACHIEVING THE RIGHT FORMULATION

14.10 **Freeze-drying of highly concentrated biologics at specific formulation conditions**
- Freeze-drying of highly concentrated protein formulations
- Buffer-free formulations
- Impact on stability
- Case study with a monoclonal antibody

Patrick Garidel, Head of Pharmaceutical Basic Development, **Boehringer Ingelheim**

14.50 **Afternoon Tea**

15.20 **Modern process of lyophilisation**
- Evaluation of current lyophilisation approach
- Real time PAT control
- How to modernise your process?

Andrea Weiland, Managing Director, **Explicat Pharma**

16.00 **Developing a solid design space**
- Assessing variable factors in construction that impact on the homogeneity of the final product appearance
- Defining the level of risk and margins of failure
- Methodology for developing a design and excursion space for lyophilisation

Thomas de Beer, Professor, **Ghent University**

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

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HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 6th July 2016
08.30 – 12.30
Holiday Inn Kensington Forum, London, UK

Design and scale up of a freeze drying process

Workshop Leaders:
Paul Matejtschuk, Principal Scientist and Section Head, **NIBSC** and **Kevin Ward,** Director of R&D
Biopharma Process Systems Ltd

Overview of workshop:

This workshop will start by covering the basics of freeze-drying cycle development, from the data required to start the R&D process to the data gained and decision-making that happen along the way. It will then provide more detail on different approaches including QbD, software-based cycle development, and the importance of understanding scale-up factors and strategies for reducing risk.

Why should you attend this workshop?

- Learn the fundamentals of lyo cycle development
- Understand the different approaches available to the R&D scientist
- Gain practical tips and advice from experienced practitioners
- Enjoy the informal interactive nature of the structured sessions!

Programme:

08.30 **Registration and Coffee**

09.00 **Session 1: Approaches to cycle development**
- Classic iterative approach
- Alternative approaches, including automated systems
- Pros and cons of each approach

09.30 **Session 2: Classic iterative approach**
- What information is needed prior to cycle development?
- Integrating formulation design with cycle development
- How can we maximise data generation from each run?
- Practical tips for planning cycles and analysing the outcome

10.30 **Coffee Break**

11.00 **Session 3: Alternative approaches to cycle development**
- The use of software-based algorithms
- Integrating QbD into the cycle development process

11.30 **Session 4: Robustness testing and scale-up**
- Practical constraints of robustness testing
- The use of DoE in robustness testing
- Scale-Up factors, including differences in equipment, formulation and upstream processing parameters

12.30 **End of Workshop**

About the Organisations:

Biopharma Process Systems started in 1989 as a family business supplying freeze-dryers and related equipment. It has since grown into a company of 25 people 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 27 years, Biopharma has arguably become Europe's leading freeze-drying company.

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. Further details please **www.nibsc.org**

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16th - 17th March
Holiday Inn Kensington Forum, London, UK

Paediatric Clinical Trials
16th - 17th March
Holiday Inn Kensington Forum, London, UK

APRIL

Asthma & COPD
11th - 12th April
Holiday Inn Kensington Forum, London, UK

Controlled Release
18th - 19th April
Holiday Inn Regents Park, London, UK

Adaptive Designs
18th - 19th April
Holiday Inn Regents Park, London, UK

Pre-Filled Syringes East Coast
25th - 26th April
Renaissance Woodbridge, New Jersey, USA

Lyophilization USA
27th - 28th April
Renaissance Woodbridge, New Jersey, USA

MAY

Alzheimer's
10th - 11th May
Holiday Inn Kensington Forum, London, UK

Clinical Trial Logistics
18th - 19th May
Holiday Inn Kensington Forum, London, UK

Pain Therapeutics
23rd - 24th May
Holiday Inn Kensington Forum, London, UK

ADC Summit 2016
23rd - 24th May
Holiday Inn Kensington Forum, London, UK

JUNE

Pre-Filled Syringes West Coast
6th - 7th June
Hyatt Regency Mission Bay, San Diego, USA

ADMET
13th - 14th June
Holiday Inn Kensington Forum, London, UK

Immunogenicity
13th - 14th June
Holiday Inn Kensington Forum, London, UK

BioBanking
20th - 21st June
Holiday Inn Kensington Forum, London, UK

JULY

Lyophilisation Europe
4th - 5th July
Holiday Inn Kensington Forum, London, UK

Allergies
6th - 7th July
Holiday Inn Kensington Forum, London, UK

Peptides
6th - 7th July
Holiday Inn Kensington Forum, London, UK

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