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# PHARMACEUTICALS AND BIOPHARMACEUTICALS: LYOPHILISATION

7th - 8th  
JULY  
2014

Marriott Regents Park | LONDON, UK

## KEY SPEAKERS

- **Andrea Weiland**, CEO, **Explicat Pharma**
- **Professor Dr Thomas de Beer**, Laboratory of Process Analytical Technology, **Ghent University**
- **Patrick Garidel**, Associate Director, Protein Science, **Boehringer Ingelheim**
- **Mark Yang**, Director of Fill Finish Development, **Genzyme**
- **Sune Andersen**, Principal Scientist, **Novo Nordisk**
- **Jason Gray**, Consultant, **Allembis (ex-Merck)**
- **Dr Rongjun Chen**, Lecturer in Chemical Engineering, **Imperial College London**
- **Bertie Daly**, Associate Director, **Alexion Pharmaceuticals**
- **Jamie Biddlecombe**, Formulation Development Scientist, **MedImmune**
- **Julie Pagenaud**, Sterile Product Manufacturing Manager, **Ipsen**
- **Massimo Rastelli**, Project Leader Biopharm, **GSK**

## KEY TOPIC INSIGHTS

- Hear detailed insight into critical parameters through Lyorobustness
- Key case study from MedImmune on advancements in lyophilised drug product development and scale-up
- Discuss the costs versus benefits of optimising the lyophilisation process
- Case study from Genzyme on mitigation strategies to minimise fogging in glass vials
- Evaluate mathematical modelling in freeze drying
- Gain insight into imaging analysis as a support tool for your freeze drying cycle
- Analyse process analytical techniques for product visualisation during freeze drying

**PLUS AN INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOP**  
Wednesday 9th July, Marriott Regents Park Hotel, London, UK

## Getting the most out of your Physical Characterisation Analysis

Workshop Leader: **Jason Gray**, Director, **Allembis**

8.30am - 12.30pm

[www.lyophilisation-conference.com](http://www.lyophilisation-conference.com)

Register online or fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711

ACADEMIC & GROUPS DISCOUNTS AVAILABLE



**8.30 Registration & Coffee**

**9.00 Chairman's Opening Remarks**  
**Patrick Garidel**, Associate Director, Protein Science,  
**Boehringer Ingelheim**

**OVERVIEW OF FREEZE-DRYING**

**KEYNOTE ADDRESS**

**9.10 The essentials in freeze-drying**

- 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**, Associate Director, Protein Science,  
**Boehringer Ingelheim**

**9.50 The Importance of Physical Properties Analysis When Developing a Lyophilised Formulation**

- The critical nature of the glass transition temperature
- Ensuring fit for purpose analytical techniques
- Listening to the probes

**Jason Gray**, Director, **Allembis**

**10.30 Morning Coffee**

**11.00 The real time wireless validation of lyophilisation processes**

- Current real time lyophiliser temperature validation issues
- TrackSense Pro Sky -80C wireless data-logger system
- Reproducible results including industry examples

**Jesper Møgelvang**, Director, Sales and Marketing, **Ellab**

**USING PAT AND ROBUSTNESS**

**11.40 Lyocycle Development: the journey from lab scale to production scale – assessment of the critical process parameters through Lyorobustness testing to establishing the process boundaries and the process design space – a case study**

- Linking critical quality attributes to process parameters – the development lyocycle
- Risk assessment to establish the critical process parameters for transfer
- Lyocyclerobustness testing on lab scale to establish process boundaries
- Use of PAT (TEMPRIS®) to mitigate the risk when transferring from lab scale to production scale

**Dr Andrea Weiland**, Managing Director, Heading CMC Development and Project Management, **Explicat Pharma GmbH**

**12.20 Networking lunch**

**1.40 Advancements in Lyophilised Drug Product Development and Scale-up**

- Characterisation of lab-scale to manufacturing scale freeze-dryers for robust scale-up
- Reducing cycle time - effect of drying above Tg'
- PAT tools for lyophilisation

**Jamie Biddlecombe**, Formulation Development Scientist, **MedImmune**

**2.20 Real-time evaluation of protection ability of stabilizers for protein formulations by vibrational spectroscopic measurements during pharmaceutical freeze-drying**

- In-process visualization of protein-stabilizer interactions during freezing and drying
- Comparison of stabilizing ability of different cryo- and lyoprotectants for protein formulations by in-process visualization
- Evaluation of process analytical techniques for product visualization during freeze-drying

**Professor Dr Thomas de Beer**, Laboratory of Pharmaceutical Process Analytical Technology, **Ghent University**

**3.00 Afternoon Tea**

**3.30 Porous and nanofibrous polymeric structures by freeze-drying and some relevant applications**

- Ice-templating and freeze-drying: a versatile route for preparation of porous materials
- Combining emulsion-templating and freeze-drying: a systemic tuning of material porosity
- Drug nanocrystals by emulsion-freeze-drying and solvent evaporation within porous polymers
- Instantly forming emulsions by hand shaking with the freeze-dried porous polymers

**Dr Haifei Zhang**, Lecturer, Department of Chemistry, **University of Liverpool**

**4.10 Experience with PAT implementation in pharmaceutical spray drying**

- Types of PAT used in spray drying
- Practical considerations in implementation of PAT
- Case study: PAT applicability in a small scale spray dryer
- Case study: PAT implementation and results in a production scale spray dryer

**Dr Sune Klint Andersen**, Principal Scientist, **Novo Nordisk**

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

**WHO SHOULD ATTEND? This event is for professionals in the fields of:**

- Pharmaceutical and biologicals storage
- Freeze-drying and lyophilisation
- Research and development
- Chemical engineering
- Sterility Product development
- Outsourcing Business development
- Quality assurance and quality control
- Protein stabilisation
- Cold chain distribution
- Freeze-dryer manufacturers
- Pharmaceutical packaging & labelling
- Pre-filled syringes
- Quality by design
- Up-scaling
- Vaccine storage
- Formulation
- Clinical trial logistics

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8.30 Registration & Coffee

9.00 Chairman's Opening Remarks  
Andrea Weiland, Managing Director, **Explicat Pharma GmbH**

### OVERCOMING CHALLENGES IN LYOPHILISATION

#### KEYNOTE ADDRESS

9.10 **Mathematical modelling, design and scale-up of freeze-drying cycles**

- Mathematical models in freeze-drying science
- Mathematical modelling for rapid cycle development: the strength and weakness of in-line and off-line methods, determination of model parameters, application to industrial equipment
- Mathematical modelling for process transfer and scale-up: overview of benefits and drawbacks within model-based approaches, methodologies used to characterise heat and mass transfer in industrial apparatus, examples of scale-up of freeze-drying cycles

**Dr Roberto Pisano**, Assistant Professor, **Politecnico di Torino**

9.50 **Studying Lyophilisation Kinetics Using Freeze Drying Microscopy**

- Using freeze drying microscopy to accurately measure collapse temperatures
- Measuring sublimation kinetics from direct visualisation of sublimation front movement
- Furthering our understanding of the factors affecting sublimation kinetics in vial based (and other) systems
- Discussion of results for a model lactose system and comparisons with vial drying experiments

**Andy Stapley**, Senior Lecturer, Chemical Engineering, **Loughborough University**

10.30 Morning Coffee

### ADVANCES IN LYOPHILISATION FIELD

11.00 **3-stage validation approach for Lyophilized Products**

- Evaluating technology transfer of an existing commercial product
- Developing a new lyophilised product
- Discussion of advances in the lyophilisation field

**Massimo Rastelli**, Project Leader Biopharm, **GSK**

11.40 **Fogging in glass vials and new container systems for lyophilisation development**

- Fogging in DP vials is fairly common and can lead to product loss
- Multiple factors attribute to fogging
- Mitigation strategies to minimise fogging in glass vials
- Novel coating and container systems for lyophilisation

**Mark Yang**, Director of Fill Finish Development, Late Stage Process Development, **Genzyme**

12.20 Networking lunch

### OPTIMISATION AND VALIDATION

1.40 **Fill finish lyophilisation**

- Increasing stability / shelf life
- Lyophilisation cycle time and running sequence
- Proposals for lyophilisation optimisation: costs versus benefits of optimising the lyophilisation process

**Mr Bertie Daly**, Associate Director, Sterile Fill Finish, **Alexion Pharmaceuticals**

2.20 **Cryopreservation of mammalian cells via intracellular trehalose delivery – one step towards cell lyophilisation**

- Overviewing the challenges in cryopreservation and lyophilisation of mammalian cells
- Discussing the role of trehalose in cell cryopreservation / lyophilisation
- Introducing a novel technology for intracellular loading of trehalose based on a non-toxic, membrane-permeating polymer
- Demonstrating the application of the technology in cryopreservation of live cells

**Dr Rongjun Chen**, Lecturer, Department of Chemical Engineering, **Imperial College London**

3.00 Afternoon Tea

3.30 **How to handle all freeze drying manufacturing equipment**

- Challenge of investment: new machine vs retrofitting / revamping
- Qualification & validation strategies based on risk analysis approach
- Project case study: from user requirements to manufacturing

**Julie Pagenaud**, Sterile Product Manufacturing Manager, **Ipsen**

4.10 **Imaging analysis as a support tool for freeze drying cycle design**

- Frequency domain imaging analysis: overview of main potentialities in the quality control of freeze dried products and in the design of industrial cycles
- Imaging analysis for the prediction of the mass transfer resistance: laboratory results and transfer to industrial applications
- Cycle design and industrial scale-up: benefits and drawbacks of the imaging approach in the optimisation of the cycle parameters

**Dr Sabrina Grassini**, Assistant Professor, **Politecnico di Torino**

4.50 Chairman's Closing Remarks and Close of Day Two

Supported by



## HALF-DAY POST-CONFERENCE WORKSHOP A

Wednesday 9th July 2014 | 8.30am – 12.30pm

Marriott Regents Park, London, UK

### Getting the most out of your Physical Characterisation Analysis

Workshop Leader:

**Jason Gray**, Director, **Allembis**

#### Overview of workshop:

The workshop will provide advice and training on the latest analytical techniques and how to get the best out of them for the physical characterization of lyophilised products.

#### Programme:

- 8.30 Registration and coffee**
- 9.00 Welcome and introduction**
- 9.20 Case study identifying the key physical properties and analytical techniques**
  - Thermal Analysis
  - Spectroscopy
  - XRD
  - Vapour sorption
  - SEM
- 10.10 Hints and tips for choosing the right techniques and method**
- 11.00 Morning coffee**
- 11.15 Making the data work for you - a case study**
- 12.15 Conclusions and close of workshop**

#### About the workshop host:

Jason Gray has over 20 years' experience in characterisation and formulation development of (bio)pharmaceuticals within industry and academia. Having studied several hundred molecules, managing global research/analytical facilities and project managing multi-site and multi-country development projects through to regulatory approval, Jason has now set up Allembis to provide expert advice, project management and training around characterisation and formulation development of (bio)pharmaceuticals. He is also currently a visiting Lecturer at the University of Sunderland.

**Want to know how you can get involved?**

**Interested in promoting your services to this market?**

Contact **Daniel Lee**, SMI Marketing on  
**+44 20 7827 6078**,  
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24 – 25 March 2014, London

#### **Paediatric Clinical Trials**

31 March – 1 April 2014, London

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2 – 3 April 2014, London

#### **Biosimilars USA**

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12 – 13 May 2014, London

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#### **BioBanking**

23 – 24 June 2014, London

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### JULY

#### **Lyophilisation**

7 – 8 July 2014, London

#### **BioNetworks**

7 – 8 July 2014, London

#### **Allergies**

9 – 10 July 2014, London

#### **Immunogenicity**

14 – 15 July 2014, London

# PHARMACEUTICALS AND BIOPHARMACEUTICALS: LYOPHILISATION

CONFERENCE: 7TH – 8TH JULY 2014, MARRIOTT REGENTS PARK, LONDON, UK | WORKSHOP: 9TH JULY 2014, LONDON

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