



# 5th Lyophilisation

Optimising technologies & techniques for stability, delivery and longevity of pharmaceuticals and biologics

7th - 9th September 2011, Visiongain Conference Centre, London, UK

**BOOK NOW!**

## Key Speakers

Rashmi Shah, Senior Clinical Assessor, **Food and Drug Administration (FDA)**

Akhilesh Bhambhani, Senior Research Chemist, **Merck**

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

Mark Morton, Process Analytical Technology Scientist, **Abbott Laboratories**

Vinciane De Cupere, Scientist, Immunostimulants Industrialisation, **GSK Biologicals**

Jörg Lümekemann, Resp. Implementation New Technologies Parenterals, **F.Hoffmann-La Roche**

Romain Veillon, Vision Technology Specialist, **GSK Biologicals**

Kevin Ward, Director of Research and Development, **Biopharma Technology**

Paul Matejtschuk, Principal Scientist, Standardisation Science, **National Institute for Biological Standards and Control**

Yitzchak Grant, Formulation Scientist, **Medimmune**

Andrew Ingham, Lecturer in Pharmacy / Pharmaceutical delivery, **Aston University**

Maik Guttzeit, Quality Assurance, **GEA Pharma Systems**

Afzal R Mohammed, Lecturer in Pharmaceutics School of Life and Health Sciences, **Aston University**

Enric Jo, PhD, Director Planta RJ SJD / RJ SJD Plant Manager, **Reig Jofré Group**

Pre-conference Workshop, Wednesday 7th September, 2011

**Lyophilisation cycle development - formulation characteristics and cycle development**

**Led by:** Asa Bergenholtz, Consultant, **LyoTech AB**

**Cutting edge analytical technologies for application before, during and after freeze**

**Led by:** Kevin Ward, Director of R&D, **Biopharma Technology**

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# Conference Introduction

## 5th Lyophilisation

### 7th - 9th September 2011, London, UK

#### Dear Colleague,

Lyophilisation is one of the fastest growing markets, with estimated revenue of \$1.77bn (for products and services) in 2009, total revenues in this market is expected to reach \$3.25bn in 2015 and \$6.15bn by 2025<sup>1</sup>. This growth will be driven primarily by the introduction of new products, specifically biologics such as monoclonal antibodies (mAbs) and recombinant proteins.

Visiongain's 5th Lyophilisation conference will gather professionals from around the world to address important issues on development of an optimised lyophilisation cycle, scale-up of the lyophilisation cycle from a laboratory to a pilot- or production-scale unit and help you understand the characteristics of the product successful freeze-drying.

It is a three day strategic conference lead by experts to provide participants with a thorough review of every aspect of lyophilisation processes through workshop, sessions, case studies and panel discussions.

#### Whether your interests lie in drug formulation, process engineering, manufacturing or strategic partnering; attending this 3 day conference will enable you to:

- Find out critical aspects of freeze-drying of pharmaceuticals and biologicals
- Hear about latest developments in process analytical technologies (PAT) in freeze-drying of parenteral products
- Learn about practical formulation and process development of freeze-dried products
- Examine freeze drying biologicals: achieve product consistency both within a batch and between batches
- Explore best practices in cGMP, QbD, QC and QA to ensure that the product meets the desired quality attributes
- Implement engineering trends and developments in lyophilisation
- Understand design of freeze-drying processes for pharmaceuticals
- Improve drying method selection for protein pharmaceuticals: product quality implications
- Review new developments in excipients selection, sterilisation, freeze dryer cleaning
- Stay ahead by learning latest engineering trends to ensure durability
- Overcome challenges in lyophilisation by computer modelling of the freeze drying process; to facilitate process design and scale up
- Characterise the final dried formulation
- Develop new strategies to remain competitive
- Meet manufacturers showcasing their leading products

I look forward to meeting you at the conference

Best regards

Sonia Tomar  
Conference Producer

#### Who should attend?

Presidents, Chief Executive Officers, Vice Presidents, Chief Scientific Officers, Directors, Business Development Managers, and Principal Scientists of:

- Vaccine/antibody/cell manufacturing
- Bioprocess research and development
- Chemical Engineering
- Process implementation and process engineering
- Stability testing
- Sterile production
- Quality assurance and quality control
- Standardisation science
- Drug formulation
- Active pharmaceutical ingredients
- Pharmaceutical production
- Manufacturing and engineering
- Licensing
- Product development
- Outsourcing/contract manufacturing
- Dried technology
- Packaging and labelling
- Pilot plant operations

#### Associate Sponsor:



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#### Poster Presentation

At a busy conference it is hard to make sure everyone who shares your interests knows what you are doing. Maximise your time at Visiongain's 5th Lyophilisation meeting by sharing your results in a poster presentation. With a plethora of key decision makers, take advantage of this senior networking opportunity.

Please send your 200 word abstract, in English, to: [info@visiongainglobal.com](mailto:info@visiongainglobal.com) for approval. The deadline for submissions is Monday 22nd August, 2011. Please include contact details for the corresponding author(s).

Academic institutions will not be charged a fee if booked as full-price delegates. Posters submitted by pharmaceutical and biotechnology firms will be charged a fee of £199.

Posters submitted by service providers / vendors are welcome and will be subject to evaluation. Upon approval a fee of £500 will apply. Two delegates from your organisation must be booked at full price to present a poster.

Please note that all posters will be displayed at the discretion of Visiongain Ltd and are subject to approval. Due to limited space, please register your interest early.

#### Sponsorship and exhibition opportunities

This event offers a unique opportunity to meet and do business with some of the key players in the pharmaceutical and biotech industries. If you have a service or product to promote, you can do so at this event by:

- Hosting a networking drinks reception
- Taking an exhibition space at the conference
- Advertising in the delegate documentation pack
- Providing branded bags, pens, gifts, etc.

If you would like more information on the range of sponsorship or exhibition possibilities for visiongain's 5th Lyophilisation Conference, please contact us:

Ronald Magali, +44 (0)20 7549 9934  
[ronald.magali@visiongainglobal.com](mailto:ronald.magali@visiongainglobal.com)

# Pre-Conference Interactive Workshop

## 5th Lyophilisation

### Wednesday 7th September 2011

## Lyophilisation cycle development - formulation characteristics and cycle development

### Cutting edge analytical technologies for application before, during and after freeze-drying

**Led by:** **Asa Bergenholtz**  
Consultant  
**LyoTech AB**

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

**Timings:** 09:30 - 10:00 Coffee & Registration  
10:00 - 12:00 Morning Session  
14:00 - 16:00 Afternoon Session  
Timing includes lunch and refreshment breaks

### Morning Session:

Lyophilisation cycle development - principles and practice for Biologicals

Led by: Asa Bergenholtz

- Basic concepts and introduction to formulation development for lyophilisation
- Solute/solvent behaviour, crystalline/amorphous mixtures, formulation design for lyophilisation, some examples
- Formulation and process relationship: The lyo-cycle, freezing and primary/secondary drying. The relevance of the Tg and collapse temperature.
- Optimising the process, how and for what reason?
- Lyophilisation of pharmaceutical - vs. probiotic (living cell) products

### Afternoon Session:

Cutting edge analytical technologies for application before, during and after freeze-drying

Led by: Kevin Ward

- Characterisation of materials to enable freeze-drying cycle development: Freeze-Drying Microscopy (FDM); Electrical impedance (Zsinφ) analysis; Thermo-analytical methods.
- Process Analytical Technology: technologies available to aid the understanding of the freeze-drying process while it's happening.
- Analysis of the Freeze-Dried Product: can product appearance be quantified?; Destructive and non-destructive methods for residual moisture analysis; Thermo-analytical methods; Examining and predicting important changes in the dried product in relation to structure and stability.

### About visiongain:

Visiongain is a specialist business information company focused on providing cutting edge products and services across the Pharmaceutical/Biotech, Telecommunications, Defence and Finance sectors, which include reports, conferences, online daily news and offline news analysis and bespoke consultancy. With a commitment to innovation and excellence, visiongain offers flexible solutions to meet our clients' business intelligence needs, providing the right information at the right time to facilitate the commercial decision-making process. Our pharmaceutical products include Pharma Business Daily, the leading daily email newsletter for the pharmaceutical, biotech and healthcare industries, and a range of independent, high-quality, in-depth reports covering focused and topical areas of concern. Our pharmaceutical conferences address the hottest commercial, regulatory and technical topics and provide an ideal forum for debate and networking for pharmaceutical professionals from around the world.

For further information, please visit: [www.visiongain.com](http://www.visiongain.com)

### About your workshop leaders:



Kevin Ward

Kevin is Director of Research and Development at BTL, leading collaborative research activity and overseeing the delivery of client projects. After graduating in Applied Chemistry in 1993, he undertook a Ph.D. studying the freeze-drying of pharmaceutical formulations and drug/vaccine delivery systems. In the past 11 years at BTL, he has had direct involvement in the freeze-drying R&D of a diverse range of over 700 materials, from small molecules to proteins, antibodies, liposomes, particulates, gels, slurries, nanoparticles, bacteria, vaccines and blood products. Since 2007, Kevin has also chaired the PHSS Freeze-Drying Special Interest Group, an international working group that produces monographs on practical aspects of freeze-drying technology.



BTL was founded in 1997 and is a contract R&D and consulting company specialising in freeze-drying formulation and process development. During the past 14 years, BTL has worked with over 700 products and compounds, including small drug molecules, biopharmaceuticals, proteins, vaccines, drug delivery systems, PCR reagents, medical devices, whole organisms and blood components. Its client base includes more than 300 companies worldwide. BTL has also developed and markets internationally two analytical instruments specifically designed for the characterisation of materials prior to freeze-drying, which enables tailor-made efficient and robust freeze-drying cycles to be developed on a product-specific basis. BTL runs training courses in lyophilisation technology and has trained more than 2,500 people in the past 10 years. Since 2009, BTL has been successful in obtaining 6 grants from the Technology Strategy Board to support a number of fundamental R&D programmes examining novel applications of freeze-drying. Working with academic partners such as Cambridge University, Imperial College London, Durham University and Southampton University, as well as other small businesses, BTL has achieved success in the freeze-drying of a wide range of materials, including red blood cells, probiotic bacteria, medical implants and crop protection agents.



Asa Bergenholtz

Welcome to LyoTech - Specialists in Biotechnology!

- LyoTech is a privately owned consulting company established in 2003.
- LyoTech offer consultants with experience of biotechnology.
- Our consultants have experience of R&D, pilot scale fermentation, formulation development, lab- to pilot scale freeze-drying, cycle optimizations, and up-scaling.
- We offer to help in various stages of production or to help you with your outsourcing, such as to increase your procurement skills.
- We are specialized on DP development and manufacture, and take on for example laboratory work, project management and documentation work.

[www.lyotech.se](http://www.lyotech.se)

- 09:00 Registration and refreshments
- 09:30 Opening address from the chair  
 **Patrick Garidel**  
 Head of Pharmaceutical Basic Development  
**Boehringer Ingelheim Pharma**
- 09:40 Freeze-drying/lyophilisation of biological products: an overview  
  - Brief introduction to lyophilisation
  - Lyophilised market products
  - Biologics in the dry state: what to consider?
  - Formulation principles for lyo products
  - Analytics for the characterisation of lyophilisates
  - Stability issues **Patrick Garidel**  
 Head of Pharmaceutical Basic Development  
**Boehringer Ingelheim Pharma**
- 10:20 Development of concentrated lyophilised antibody formulations: tech transfer from laboratory to pilot scale  
  - Motivation
  - Lyophilisation development at high mAb concentration: what to consider?
  - Case Study
 Reconstitution time  
 Container/Closure  
 Other practical considerations  
  - Conclusion **Akhilesh Bhambhani**  
 Senior Research Chemist  
**Merck**
- 11:00 Morning refreshments
- 11:20 First approach applying QbD in a scale-up of a lyophilisation cycle for an antiviral product  
  - Case study to show the experimental design to determine limit values for the critical parameters of a lyophilisation process.
  - These limits applied to the lyophilisation cycle in a pilot plant provide outputs, in aesthetical and physical specifications, to evaluate the tested cycles.
  - The case study can lead the process to determine which the limitations are when we carry out transference between equipments that might have different performance related on the heat and mass transfer.
  - The data are treated by means a chemiometric tool.
  - The criterion applied for design includes several situations, from the most conservative one up to the most aggressive one. **Dr. Enric Jo, PhD**  
 Director Planta RJ SJD / RJ SJD Plant Manager  
**Reig Jofré Group**
- 11:50 Lyo product characterisation & control  
  - Lyo cake final state, impact of earlier stages (formulation, freezing, sublimation, secondary drying)
  - Lyo cakes visual inspection, current and new technologies
  - Closure integrity testing
  - Near Infra Red perspectives **Romain Veillon**  
 Vision Technology Specialist  
**GSK Biologicals**
- 12:00 Networking lunch
- 13:30 Lyophilisation and use of reference materials for the control testing of biological medicines  
  - The need for stable reference materials
  - Formulation & processing considerations for reference material manufacture
  - Establishment process
  - Examples from the haematological and vaccine testing arena **Paul Matejtschuk**  
 Principal Scientist, Standardisation Science  
**National Institute for Biological Standards and Control**
- 14:10 Considerations for transferring a bulk freeze-drying process from a glass container to a tray  
 **Vinciane De Cupere**  
 Scientist, Immunostimulants Industrialisation  
**GSK Biologicals**
- 14:50 Afternoon Refreshments
- 15:10 Risk based lyophiliser design and related supplier involvement  
  - Fundamentals of ICH Q9 (quality risk management)
  - The risk based approach as design tool
  - Cost and time saving potential by using risk management
  - Shared responsibilities in GMP projects?
  - Possibilities of supplier involvement
  - Required controls for beneficial leverage of supplier activities **Maik Guttzeit**  
 Quality Assurance  
**GEA Pharma Systems**
- 15:50 Short cycle times for cost efficient processing of lyophilised formulations  
  - High solid content freeze drying a strategy for pharmaceutical processing
  - Product resistance interesting ways to avoid it
  - Monitoring primary drying, can you always believe your sensor? **Andrew Ingham**  
 Lecturer in Pharmacy/ Pharmaceutical delivery  
**Aston University**
- 16:30 Closing remarks from the chair
- 16:50 Networking Drinks  
 Take your discussions further and build new relationships in a relaxed and informal setting.

- 09:00 Registration and refreshments
- 09:30 Opening address from the chair
- 09:40 Application of PAT, six-sigma and Qbd strategies to lyophilisation
- Potential opportunities for Process Analytical Technology in lyophilisation
  - Combination of PAT, six-sigma and Qbd strategies
  - Practical examples
- Mark Morton**  
Process Analytical Technology Scientist  
**Abbott Laboratories**
- 10:20 Concepts to use Laserspectroscopy to control freeze drying cycles
- Control of freeze drying cycles – current techniques
  - Control of freeze drying cycles – idealised requirements
  - Physical basics of Tunable Diode Laser Absorption Spectroscopy (TDLAS)
  - Technical realisation on the freeze dryer
- “Proof of concept” experiments for the TDLAS measurement technique
- Concepts for the control of freeze drying cycles by TDLAS
  - Experiments for cycle control
  - Qbd / PAT Philosophy
  - Summary / Outlook
- Jörg Lümekemann**  
Resp. Implementation New Technologies, Parenterals  
**F.Hoffmann-La Roche**
- 11:00 Morning refreshments
- 11:20 Sponsor Spotlight Session
- Take this unique opportunity to be a part of the conference theme, network, share ideas and provide an overview of your product/ services to the audience. For more information please contact [ronald.magali@visiongainglobal.com](mailto:ronald.magali@visiongainglobal.com)
- 12:00 Formulation and process development of lyophilised orally disintegrating tablet
- Orally disintegrating tablets; proline; serine
  - Lyophilisation; annealing; sublimation rate
  - Lyophilised orally disintegrating tablets (ODTs)
  - Thermal analysis and formation of intact tablets
- Afzal R Mohammed**  
Lecturer in Pharmaceutics School of Life and Health Sciences  
**Aston University**
- 12:40 Networking lunch
- 13:40 Presentation to be announced
- Yitzchak Grant**  
Formulation Scientist  
**Medimmune**
- 14:10 Co-Crystals and physical mixtures
- Preparation of co-crystals and physical mixtures by lyophilisation
  - Investigation of the physical properties of co-crystals and physical mixtures by lyophilisation
- Victor Diaz**  
Projects Director  
**Sigma-Alrich**
- 15:00 Afternoon refreshments
- 15:20 The importance of moisture assessment for robust cycle development and scale up
- Importance of moisture for product stability
  - Factors affecting moisture variability
  - Methods used for moisture analysis
  - Scale up/robustness issues
- Isobel Cook**  
Principal Research Scientist  
**Biopharma Technology**
- 16:00 Role of quality by design in biopharmaceutical manufacturing
- Quality by end product testing versus quality by design
  - Quality target product profile
  - Implementation and Integration of Qbd with ICH guidance
    - Quality risk management
    - Process analytical technology
    - Design of experiments
    - Design space
  - Mock case study for applying Qbd for lyophilisation
  - Conclusions
- Rashmi Shah**  
Senior Clinical Assessor  
**Food and Drug Administration (FDA)**
- 16:40 Chair's closing remarks
- 16:50 End of Conference

# Registration Form

## 5th Lyophilisation

### 7th - 9th September 2011, London, UK

Conf. code **3#3**

#### Standard Prices

Conference and workshop	Fee: £1699	VAT: £339.80	Total: £2038.80	<input type="checkbox"/>
Conference only	Fee: £1299	VAT: £259.80	Total: £1558.80	<input type="checkbox"/>
Workshop only	Fee: £599	VAT: £119.80	Total: £718.80	<input type="checkbox"/>
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 Fee: £999 VAT: £199.80 Total: £1198.80

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I confirm that I have read and agree to the terms and conditions of booking

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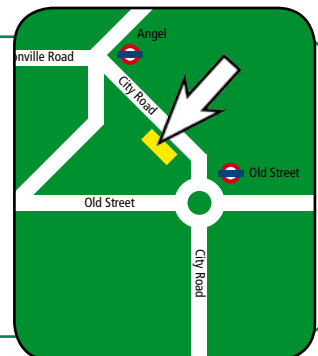
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### 5th Lyophilisation

7th - 9th September 2011

**Location:** Visiongain Conference Centre

**Address:**  
 230 City Road  
 London  
 EC1V 2TT  
 UK



#### How to book

**Email:** conferences@visiongainglobal.com  
**Web:** http://www.visiongain.com/lyophilisation

#### UK Office:

**Tel:** +44(0) 20 7336 6100  
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Visiongain Ltd  
 230 City Road  
 London  
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 UK

#### General information

**Venue:** Venue: Directions: Visiongain Conference Centre 230 City Road, London, EC1V 2TT. United Kingdom. Closest tube station is Old Street (Northern Line).  
**Accommodation:** Thistle City Barbican, Central Street, Clerkenwell, London, EC1V 8DS, Phone: 0871 376 9004 / +44 845 305 8304, Fax: 0871 376 9104 / +44 845 305 8343  
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