2nd Lyophilization Americas

Successful formulation strategies, optimising technologies & techniques for stability, cycle development, regulatory compliance, validation and scale-up

March 6th - 8th, 2012, Boston, USA

BOOK NOW!

Key Speakers

Sebastian Schneider, Pharmaceutical Engineering and New Technologies, F.Hoffman La Roche
Venkat Koganti, Senior Scientist, Pfizer
Alessandro Gianfrancesco, Agglomération & Drying Network Deputy Leader, Nestle Research Center
Sandhya Buchanan, Boehringer Ingelheim Vetmedica
Yitzchak Grant, Senior Engineer, Kraft
Marion Molina, Ph.D./Principal Development Scientist, Pharmalucence, Inc
Prakash Sundaramurthi, Ph.D., Sr Scientist II, Scientific Affairs, Teva Parenteral Medicines, Inc.
Deepak Bahl, Senior Scientist, Catalent
Kevin Ward, Director of Research and Development, Biopharma Technology
Maik Guttzeit, Quality Assurance, GEA Pharma Systems
Ulrike Pohl, Division of Pharmaceuticals, University of Erlangen
James Drinkwater, Chairman, Pharmaceutical and Healthcare Sciences Society
Renaud Janssen, Global Director of Scientific Affairs, Datwyler Pharma Packaging
Mark Shon, Vice President, Sales & Marketing, SP Scientific

Pre-conference Workshop, Tuesday March 6th, 2012
Cutting edge analytical technologies to apply before, during and after freeze-drying
Led by: Kevin Ward, Director of Research and Development, Biopharma Technology

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Dear Colleague,

With over 130 products on the market worth $50bn, biologicals and biopharmaceuticals remain the fastest growing segment amongst novel pharmaceutical entities today. Mirroring this trend the market for lyophilizing compounds such as biologicals and biopharmaceuticals is currently approaching 200 million units and it is set to continue its year-on-year double digit growth.

Without lyophilization, 60% of biotherapeutics including recombinant proteins, plasma, vaccines and antibodies could not be commercially available. Freeze-drying has become increasingly efficient in recent years, easier to use, more cost-effective and extremely accurate. It imparts higher stability, broader temperature tolerance, and longer shelf life to pharmaceutical formulations unstable in aqueous solution.

Visiongain’s lyophilization conference will gather professionals from around the world to address important issues on development of an optimised lyophilization cycle and scale-up of the lyophilization cycle from a laboratory to a production-scale unit. The conference will be a three day strategic conference lead by experts to provide participants with a thorough review of every aspect of the lyophilization process through workshop, sessions, case studies and panel discussions.

Lyophilization is one of the hot topics in the industry today and it will continue to grow as the need for freeze dried formulations will be fuelled by the fact that many of the compounds currently in development are biologicals — complex chemical molecules that need complex vehicles to enable targeting in the body.

Why you should attend this conference

- Discover 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 lyophilization
- 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 lyophilization 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

Carrie Lancaster
Conference Manager

Who should attend this conference?

- Presidents, Chief Executive Officers, Vice Presidents, Chief Scientific Officers, Directors, Business Development Managers, and Principal Scientists of:
  - Freeze drying technology
  - 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 labeling
  - Pilot plant operations
Cutting edge analytical technologies to apply before, during and after freeze-drying

Led by: Kevin Ward
Director of Research and Development
Biopharma Technology

Timings:
09:30 - 10:00 Coffee & Registration
10:00 - 15:00 Workshop
Timing includes lunch and refreshment breaks

About the workshop:
Cutting edge analytical technologies for application before, during and after freeze-drying

- Characterisation of materials to enable freeze-drying cycle development: Freeze-Drying Microscopy (FDM); Electrical impedance (Zsin) 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: Destructive and non-destructive methods for residual moisture analysis; Thermo-analytical methods and predicting changes in the dried product in relation to structure and stability.

About BTL:

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.

www.biopharma.co.uk
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Registration and refreshments</td>
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<tr>
<td>09:30</td>
<td>Opening address from the Chair</td>
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<tr>
<td>09:40</td>
<td>Impact of scale on heat transfer during lyophilisation</td>
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<td></td>
<td>• Heat transfer to the product is important to ensure consistent drying</td>
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<td>• Well understood in food industry due to scale of drying containers</td>
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<td>• Solutions/learnings can be applied in biotech to encourage homogeneity within the dryer</td>
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<td>Yitzchak Grant</td>
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<td>Senior Engineer, Kraft</td>
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<tr>
<td>10:20</td>
<td>Ensuring container/closure seal integrity in lyophilization applications</td>
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<td>• Standards for lyophilization vials and closures</td>
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<td>• Container/closure integrity in uncapped condition</td>
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<td>• Detecting closure imperfections by camera inspection</td>
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<td>• Container/closure integrity after capping</td>
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<td>Renaud Janssen</td>
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<td>Global Director of Scientific Affairs, Datwyler Pharma Packaging</td>
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<tr>
<td>11:00</td>
<td>Morning refreshments</td>
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<tr>
<td>11:20</td>
<td>A scientific approach to optimal freeze drying of food products</td>
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<td>• Why to freeze dry food? Specific needs and constraints for the food industry</td>
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<td>• Freeze drying as a structuring process: Link between drying kinetics and material properties</td>
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<td>• Sustainability and possible alternatives to conventional freeze drying</td>
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<td></td>
<td>Alessandro Gianfranco</td>
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<td>Agglomération &amp; Drying Network Deputy Leader, Nestle</td>
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<td>12:00</td>
<td>Formulation of orally disintegrating tablets containing a non water-soluble drug-delivery system</td>
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<td>• What are orally disintegrating tablets?</td>
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<td>• Review of actual literature dealing with formulation of orally disintegrating tablets</td>
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<td>• Factors of influence when formulating orally disintegrating tablets</td>
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<td>• Taste masking of naproxen sodium as a drug delivery system (own research, presentation of experiments and results)</td>
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<td>• Formulation of orally disintegrating tablets consisting of different excipients and containing particles of different sizes</td>
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<td></td>
<td>Ulrike Pohl</td>
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<td>Division of Pharmaceuticals, University of Erlangen</td>
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<td>12:40</td>
<td>Networking lunch</td>
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<td>13:40</td>
<td>Lyophilization process modeling: from process design to design space</td>
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<td>• Overview of modeling approaches</td>
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<td>• Utilizing models through different phases of product development</td>
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<td>• Building design space using minimal experimentation</td>
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<td></td>
<td>Venkat Koganti</td>
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<td>Senior Scientist, Pfizer</td>
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<td>14:20</td>
<td>Characterization of Lyophilized Protein Formulations: Challenges and Opportunities</td>
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<td>• Practical formulation development of freeze-dried products</td>
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<td>• New tools to characterize the final dried formulations</td>
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<td>• Mechanism of protein stabilization by lyoprotectant</td>
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<td>• Prediction of long-term stability from solid state characteristics</td>
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<td>• Development of room temperature stable formulation</td>
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<td>Bingquan Wang</td>
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<td>Process Development Manager, Genzyme</td>
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<td>15:00</td>
<td>Afternoon Refreshments</td>
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<tr>
<td>15:20</td>
<td>Presentation to be announced</td>
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<td>15:40</td>
<td>Risk-Based Design in Lyophilizer Projects</td>
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<td>• Current situation and actual discussions</td>
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<td>• Opportunities and benefit</td>
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<td>• Evaluation of risks and possibilities of risk reduction</td>
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<td>• Risk management as part of project management</td>
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<td>• Project focus on “real” process requirements</td>
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<td>• To avoid “dead paper” within validation and documentation</td>
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<td>• Organisation of lyophilizer projects in accordance with a risk-based approach</td>
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<td>• Influence to life cycle phases like planning, design, manufacturing, testing and operation</td>
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<td>Maik Guttzeit</td>
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<td>Quality Assurance, GEA Pharma Systems</td>
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<td>16:20</td>
<td>Closing remarks from the Chair</td>
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<td>16:30</td>
<td>Networking Drinks</td>
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<td>Take your discussions further and build new relationships in a relaxed and informal setting</td>
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Day 2
2nd Lyophilization Americas
Thursday March 8th, 2012

09:00 Registration and refreshments

09:30 Opening address from the chair

09:40 Characterization and Quantification of Lyophilized Product Appearance and Structure
- Problems associated with the determination of visual (macroscopic and microscopic) appearance of lyophiles
- Technologies that may help characterize various aspects of cake appearance and mechanical properties
- The role of adsorption methods to find RHg and total surface area, and FMS to indicate residual water location

Kevin Ward
Director of Research and Development
Biopharma Technology

10:20 Development of Freeze dryer (FD) Bio-decontamination using vaporized hydrogen peroxide (HPV) - vH₂O₂
- Overview of the advantages and challenges of using vH₂O₂ as a method of FD decontamination
- Applying Gaseous Vapour Phase (GVP) decontamination for surface sterilization in Freeze dryers
- Regulatory considerations and references
- Considering application of FD decontamination at Lab scale, production scale and in retrofit
- Analytical methods of H₂O₂ residual testing for Freeze dried biological products

James Drinkwater
Chairman
Pharmaceutical and Healthcare Sciences Society

11:00 Morning refreshments

11:20 The Importance of Controlling Nucleation during the Freezing Step
- Using a Lyostar 3 freeze dryer equipped with both ControllyoTM and MTM (Manometric Temperature Measurement) technologies, the effect of controlling nucleation on critical product and process parameters was investigated
- Comparing cycle times, Rp (product resistance), and dm/dt (sublimation rates) in uncontrolled runs and in cycles where the nucleation was controlled at various temperatures
- Automatic cycle optimization using SMARTTM Technology, following nucleation, demonstrates the difference in shelf temperature selection in controlled vs. uncontrolled runs

Mark Shon
Vice President, Sales & Marketing
SP Scientific

12:00 Nucleic Acid-based Therapeutics: Stabilization as dehydrated formulations
- Preservation of “naked” nucleic acids (e.g., DNA) in the dried state
- Challenges of lyophilizing non-viral gene delivery systems (e.g., lipid-based)

Marion Molina
Ph.D./Principal Development Scientist
Pharmalucence, Inc

12:40 Networking lunch

13:40 Application of laser spectroscopy to control freeze drying cycles
- Control of freeze drying cycles – current techniques and requirements
- Physical basics of Tunable Diode Laser Spectroscopy (TDLAS)
- Technical realization on the freeze dryer
- Proof of concept experiments
- Concepts to control freeze drying cycles by TDLAS
- Cycle control experiments
- QBD/PAT

Sebastian Schneider
Pharmaceutical Engineering and New Technologies
F.Hoffman La Roche

14:20 Mechanistic Study on Loss of Clonogenic Potential of a Lyophilized CD34+ Cell Line during Processing and Following Ambient Storage

Sandhya Buchanan
Boehringer Ingelheim Vetmedica

15:00 Afternoon refreshments

15:20 Physical characterization during freeze-drying: relevance to the development of stable lyophilized product - a case study
- The different physical forms (polymorphs, state of solvation, noncrystalline form) of an active pharmaceutical ingredient (API) can exhibit differences, sometimes pronounced, in their physicochemical properties including stability
- However, this issue has not received adequate attention in lyophilized products. One exception is pentamidine isethionate (PI), wherein the stability dependence on physical form has been documented. Upon product storage, the amorphous PI undergoes discoloration, while the crystalline PI is resistant to color change. Hence in this work, the phase behavior of pentamidine isethionate (PI) was monitored during all the stages of freeze-drying.

Prakash Sundaramurthi, Ph.D.
Sr Scientist II, Scientific Affairs
Teva Parenteral Medicines, Inc.

16:00 Presentation to be announced

Deepak Bahl
Senior Scientist
Catalent

16:40 Chair’s closing remarks

16:50 End of Conference
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Damian Gorman, +44 (0)20 7549 9934
damian.gorman@visiongaininglobal.com

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