

INSIGHTS IN LYOPHILISATION



SP SCIENTIFIC



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SCIENCE TOUR
2018**

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and partners proudly presents

INSIGHTS in LYOPHILIZATION

SCIENCE TOUR 2018

The Combined Decades of Experience Seminar – Friday, September 7th

📍 **DUBLIN** Ireland – The National Institute for Bioprocessing Research and Training (NIBRT)

SEMINAR AGENDA

08:30 – 08:45 ● **Welcome Address and Opening Remarks**

Ian Whitehall
SP Scientific

Session I: Fundamentals Of Freeze Drying

08:45 – 09:30 ● **Fundamentals, Part 1**
Introduction to freeze drying; physical concept; general design of a freeze dryer; formulation basics; introduction of physicochemical properties of materials, etc.

Henning Gieseler
GILYOS GmbH

09:30 – 09:45 ● **Questions & Answers, Coffee Break**

09:45 – 10:30 ● **Fundamentals, Part 2**
Introduction to the concept of freezing / the freezing step; primary drying, incl. heat and mass transfer principles; secondary drying step; physics of secondary drying; etc.

Kevin Ward
Biopharma UK

10:30 – 10:45 ● **Questions and Answers, Coffee Break**

Session II: Special Topics

10:45 – 11:30 ● **The World of Thermal Analysis: Paving the Way to a Comprehensive Product Understanding**
Introduction to formulation characterization using various state of art techniques (LT-FDM, DTA / impedance measurements, mDSC, etc.); definition of critical formulation temperatures; interpretation of results; use of information for subsequent freeze drying cycle design; etc.

Thomas Codd
Biopharma UK

11:30 – 12:15 ● **Miniaturization of Freeze Drying to Optimize Product and Process Development**
Introduction to the Freeze Drying Vial System (FDVS) and LyoCapsule™ mini freeze dryer; complementary use in product and process optimization; examples, benefits and potential challenges; etc.

Alexandra Braun
GILYOS GmbH

12:15 – 13:30 ● **Questions & Answers, Lunch Break**

13:30 – 14:00 ● **Establishing a Baseline Inspection Capability for Difficult to Inspect Freeze Dried Drug Product**

Adrian Bennis
AMGEN

14:00 – 14:45 ● **Process Analytical Technology (PAT) for the Design and Optimization of Freeze Drying Cycles**
Currently available PAT tools for freeze drying process monitoring (e.g. MTM / SMART™ Freeze Dryer, TEMPRIIS, TDLAS, others); use of PAT to define process Design Space (DS); etc.

Henning Gieseler
GILYOS GmbH

14:45 – 15:30 ● **Nucleation Control 2018: Primary Nucleation Tools and the Challenge to Control Secondary Nucleation**
Technology update and review; application examples ControlLyo™ and SynchroFreeze™; merits and demerits; role of secondary nucleation to avoid batch heterogeneity; physics of ice crystal growth; etc.

Tim Wenzel
GILYOS GmbH

15:30 – 16:00 ● **Questions & Answers, Coffee Break**

16:00 – 16:30 ● **Scale-Up of Freeze Drying Cycles**
Relevant scales in freeze drying; performance tests; placebo and partial loads; technical batches; step-by-step approach for successful scale-up.

Kevin Ward
Biopharma UK

16:30 – 17:00 ● **Freeze Drying of Organic Co-Solvent Systems**
Thermal analysis of co-solvent systems; appropriate concepts for process design; observations in process performance and product quality.

Julia Kosan
Freeze Drying Focus Group (FDG)

17:00 – 17:30 ● **A Preliminary Test of Two Novel Sealing Solutions for Vial Freeze Drying**
Performance of LyoSeal® and PLASCAP® sealing solutions during vial freeze drying using amorphous and crystalline formulations; nested vial configurations; discussion of pros and cons; etc.

Tim Wenzel
GILYOS GmbH

17:30 ● **Wrap Up & End of Seminar**