

# Insights in Lyophilisation

## Current Best Practices & New Research Trends

SP Scientific ♦ University of Connecticut ♦ GILYOS GmbH

Dates  
&  
Locations

Wednesday, 9 May, Basel, Switzerland  
Friday, 11 May, Stockholm, Sweden  
Monday, 14 May, Antwerp, Belgium

08:30 – 08:45	Welcome Address & Opening Remarks	Mark Shon <i>SP Scientific</i>
<b>Morning Session: Basic Principles of Freeze-Drying</b>		
08:45 – 10:00	<b>Basic Principles, Part 1</b> General Introduction; Physical Concept Behind Freeze-Drying; Formulation Basics; Physicochemical Properties of Materials; Thermal Analysis Techniques to Analyse Material Characteristics (e.g. DSC, Freeze-Dry Microscopy).	Henning Gieseler <i>GILYOS GmbH</i>
10:00 – 10:15	<b>Morning Break</b>	
10:15 – 11:30	<b>Basic Principles, Part 2</b> The Freezing Stage in Freeze-Drying; Primary Drying: Heat and Mass Transfer; Design of a Primary Drying Process; Possibilities for Endpoint Detection; Secondary Drying Stage.	Michael Pikal <i>University of Connecticut</i>
11:30 – 11:45	<b>Questions and Answers (Morning Session)</b>	
11:45 – 13:00	<b>Lunch Break</b>	
<b>Afternoon Session: Special Topics</b>		
13:00 – 13:30	<b>Optical Coherence Tomography (OCT) Based Freeze Drying Microscopy: The New Generation of Collapse Temperature Measurement?</b> Introduction to OCT for Imaging the 3D Structure of Product Formulations Freeze-Dried in Standard Vials.	Michael Pikal <i>University of Connecticut</i>
13:30 – 14:00	<b>Recent Advancements in Specific Surface Area Measurements of Freeze-Dried Products to Assess Final Product Quality Attributes</b> SSA Methodology to Reliably Determine the Cake Inner Morphology and Subsequent Correlation of Such Data to the Final Product Quality Attributes.	Margit Gieseler <i>GILYOS GmbH</i>
14:00 – 14:30	<b>The Current State of Controlled Nucleation: ControLyo™ vs. Ice Fog Technique</b> Controlled Nucleation Techniques in Freeze-Drying with Focus on ControLyo™ (Praxair) and Ice Fog. Use of Such Concepts in Laboratory and Production Scale Freeze-Drying Equipment; Benefits and Limitations.	Michael Pikal <i>University of Connecticut</i>  Henning Gieseler <i>GILYOS GmbH</i>
14:30 – 15:00	<b>Afternoon Break</b>	
15:00 – 15:45	<b>Quality by Design (QbD) in Process Development of Freeze-Dried Products</b> General Regulatory Definitions, Robustness Testing Protocols; Case Study: Building a Process Design Space.	Peter Stärtzel <i>GILYOS GmbH</i>
15:45 – 16:15	<b>New Insights Into Heat Transfer Characteristics of Tubing and Moulded Vials</b> Comparison of Recent Tubing and Moulded Vial Designs; Heat Transfer Characteristics; Subsequent Application to Product Freeze-Drying; etc.	Henning Gieseler <i>GILYOS GmbH</i>
16:15 – 16:45	<b>Pilot Scale: A Review of Recent Advancements and Principles of Scale-Up</b> Review of Recent Technical Innovations in Pilot Scale Equipment; Principles for Successful Scale-up from Laboratory to Pilot Scale; OQ-Testing; etc.	Margit Gieseler <i>GILYOS GmbH</i>
16:45 – 17:00	<b>Questions and Answers (Afternoon Session)</b>	