

LYOPHILIZATION 2005

May 18-20, 2005 • Washington Marriott • Washington, DC

Barnett International's Annual Conference on Freeze-Drying

LYOPHILIZATION 2005

Strategies for Successful Formulation, Cycle Development and Optimization, Regulatory Compliance, Validation, and Scale-Up

May 18-20, 2005 • Washington Marriott • Washington, DC

Learn from the Real World Experience of Industry Members Working in Formulation, Cycle Development, and Manufacturing!

*Eli Lilly and Company
Chiron Corporation
Regeneron Pharmaceuticals, Inc.
Lyophilization Technology, Inc.
BOC Edwards Pharmaceutical Systems
Sublimation Science
FTS Systems, Inc.
Baxter Pharmaceutical Solutions, LLC
US Food and Drug Administration, CBER*

*Sanofi Pasteur
GlaxoSmithKline Biologicals
KBI BioPharma, Inc.
QLT USA, Inc.
SP Industries-VirTis & Hull Brands
Microbiological Consulting
TELSTAR Industrial, S.L.
Genentech, Inc.*

In-Depth Industry Case Studies and Workshops:

An Empirical Approach to Developing an Optimized Lyophilization Cycle: Formulation and Process Strategies
*J. Jeff Schwegman, PhD,
Baxter Pharmaceutical Solutions, LLC*

Being Prepared for FDA Inspections of Lyophilized Products
*Robert Darius,
US FDA, CBER*

Comprehensive Process Validation & Use of Microbalance to Develop a Freeze-Drying Cycle
Yves Mayeresse, GlaxoSmithKline Biologicals

Successful Scale-Up from Pilot Scale to Production Scale & Selecting a Contract Site
Samir U. Sane, PhD, Genentech, Inc.

Knowing and Fully Utilizing Your Freeze-Dryer's Maximum Throughput Capability
Jim Searles, PhD, Eli Lilly and Company

Developing a Scientifically Sound Formulation and Optimizing the Lyophilization Process
Agnieszka Banbula, PhD, KBI BioPharma, Inc.

*An Interactive Tutorial and Closing Workshop on:
Risk Assessment and Root Cause Analysis in the Lyophilization Process*
Edward H. Trappler, Lyophilization Technology, Inc.

— Wednesday, May 18, 2005 —

Plus: Special Pre-Conference Summit with Two Workshops!
Lyophilization 101 – Understanding the Basic Concepts and Processes
Microbiological Issues in Aseptic Filling and Sterile Lyophilization

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Wednesday, May 18, 2005

Attend One or Both of These In-Depth Presentations

8:00 Workshop Registration and Coffee

8:45 Workshop A Begins

Workshop A

Lyophilization Fundamentals – Understanding the Basic Concepts and Processes

Successful freeze-drying cycle development and problem analysis comes from a fundamental understanding of classical theory. This workshop is designed to introduce the basic concepts at an elementary level, and provide a foundation for independent learning. Information to be presented is essential to those who might participate in cycle development or product failure investigation. The course content will focus on the big three — freezing, primary drying, and secondary drying — but will not ignore the importance of surrounding confounding variables such as chemical formula, equipment mechanical competence, sterilization, stoppering, components, moisture testing, and a myriad of other issues which influence final product quality.

- Historical Overview of Classical Theory Leading to Lyophilization
 - Kinetic theory of gasses
- Freezing
 - Water – it's all about water
 - Crystallization of water
 - Supercooling and latent heat
 - Freezing rates and why they matter
- Primary Drying
 - Collision theory and mean free path
 - Diffusion
 - Pressure units – why pressure matters
 - Sublimation – Clausius Clapeyron
 - Product collapse – thermal analysis
 - Shelf temperature vs. product temperature(s)
 - Zero order kinetics
 - Predicting sublimation rates
 - Problems (also issues and challenges)
- Secondary Drying
 - Langmuir model for desorption
 - Discussion of isotherms
 - Shelf and product temperature
 - Monitoring dryness
- Problem Solving

About the Workshop Leader:

Narlin Beaty, PhD, is a principal in Sublimation Science, a service organization to the parenteral pharmaceutical industry specializing in lyophilization commissioning, cycle development, and both machine and product cycle validation. He is also a founder of Qualification Process Solutions, an engineering firm that performs large equipment and utility commissioning, as well as managing production shutdown activities. He retired from a career as the Chief Science Officer at Chesapeake Biological Laboratories, Inc. in Baltimore, Maryland. Dr. Beaty has 22 years of experience in diverse areas of sterile manufacturing, engineering related to fill and finish of pharmaceuticals, sales, and contracts. Over the past two decades, he has been closely involved in the transfer of scores of processes from the development lab to commercialization. In addition to lyophilization projects, Dr. Beaty is knowledgeable in test method development and testing validation; sterile process design and manufacturing validations; preparation of clinical trial materials; container-closure system design; and accelerated and ongoing stability studies. He holds BS and MS degrees from the University of Texas at Austin, and a PhD in Biological Chemistry from the University of Michigan at Ann Arbor. His current professional associations include the American Association for the Advancement of Science, and the American Chemical Society.

12:00 Luncheon

1:30 Workshop B Begins

Workshop B

Microbiological Issues in Aseptic Filling and Sterile Lyophilization

Critical to aseptic filling and lyophilization is an effective environmental monitoring and control program. This half-day workshop is designed to provide background to formulators, plant engineers, and production and quality assurance personnel on successful strategies to exclude microorganisms from lyophilized products.

Areas covered in the workshop include:

- An overview of aseptic processing
- Key regulatory and compendial documents
- Prospects for harmonized standards
- Product requirements for aseptic filling and terminal sterilization
- The impact of clean room design and operation on microbial control
- Implementation of barrier systems on microbial control
- Validation of sterile filtration operations
- Equipment and packaging component sterilization
- Process simulation or media fills
- Disinfectant effectiveness
- Non-viable particulate monitoring
- Microbial monitoring of air, surfaces, and personnel
- Alert and action level setting
- Sterility testing
- Rapid microbial methods
- Microbial contamination investigations
- Implementation of the 2004 FDA Aseptic Processing Guide
- Recent inspectional trends

About the Workshop Leader:

Tony Cundell, PhD, formerly Director, Microbiological Development and Statistics in the Wyeth Pharmaceutical Global Quality Technology group, and now a consultant, is an expert in pharmaceutical microbiology. He chaired the PDA Task Force responsible for the publication of Technical Report #33 "Evaluation, Validation and Implementation of the New Microbiological Testing Methods." He has published articles on the role of water activity determination in microbial control and testing of non-sterile pharmaceutical products, autoclave validation, environmental monitoring, the role of rapid microbial methods in PAT, microbial identification, and aseptic processing. He is a member of the 2000-2005 USP Analytical Microbiology Committee of Experts.

5:00 Close of Pre-Conference Workshops

D I S T I N G U I S H E D F A C U L T Y

Edward H. Trappler
President
Lyophilization Technology, Inc.

Yves Mayeresse
Freeze-Drying Manager
GlaxoSmithKline Biologicals

Agnieszka Banbula, PhD
Senior Scientist
KBI BioPharma, Inc.

Samir U. Sane, PhD
Senior Process Engineer
Genentech, Inc.

Nicole McKenna
Process Development Engineer
QLT USA, Inc.

Dr. Paul Stewart
Director of Technology
BOC Edwards Pharmaceutical Systems

Karen A. Bossert, PhD
Senior Director of Finished Goods
Regeneron Pharmaceuticals, Inc.

Robert Darius
US Food and Drug Administration, CBER

Jim Searles, PhD
Senior Research Scientist, Global Parenteral
Commercialization Technology Center
Eli Lilly and Company

Narlin B. Beaty, PhD
Principal
Sublimation Science

Miquel Galan
R&D and Innovation Director
TELSTAR Industrial, S.L.

Mark E. Chin, BS
Scientist,
Manufacturing Process Science Group
Chiron Corporation

Lawrence Ulfik
Director of Sales, Laboratory Products
SP Industries-VirTis & Hull Brands

J. Jeff Schwegman, PhD
Research Scientist
Baxter Pharmaceutical Solutions, LLC

Ernesto Renzi
Business Manager Americas
BOC Edwards Pharmaceutical Systems

Tony Cundell, PhD
Consultant
Microbiological Consulting
*former Director, Microbiological
Development and Statistics,
Pharmaceutical Global Quality
Technology Group
Wyeth*

Joseph F. Brendle
Director,
Technology and Business Development
FTS Systems, Inc.

Peter Hanscome
Development Scientist
Sanofi Pasteur

M A I N C O N F E R E N C E

Thursday, May 19, 2005

7:30 *Conference Registration and Morning Coffee*

8:00 *Co-Chairperson's Welcome and Opening Comments*
Edward H. Trappler, President, Lyophilization Technology, Inc.

8:15 **Developing a Scientifically Sound Formulation, and Optimizing the Lyophilization Process**
Agnieszka Banbula, PhD, Senior Scientist, KBI BioPharma, Inc.
The presentation will address important issues to be considered when developing a lyophilization process for a biological formulation. The advantages and disadvantages of various excipients and their effect on product integrity will be discussed. Common mistakes in developing such products will also be addressed. A case study will be presented.

- What important factors to consider when developing a lyophilized biotech product
- How to avoid committing common mistakes
- Understand the use of biophysical characterization tools in developing lyophilized biological products
- How to maximize success in the development of lyophilized products

9:00 **Freeze-Drying Potent Drugs**
Ernesto Renzi, Business Manager Americas, BOC Edwards Pharmaceutical Systems
There is a trend in the market to go from traditional forms of drugs produced in large volume towards a new generation of drugs dedicated to oncology, which are therefore potent. The design of the production facility needs to be adapted to a number of issues: protection of the operators, protection of the equipment (decontamination), and protection of the environment. The presentation covers adapted solutions in vial handling, containment of the vial path, neutralization of effluent, and protection of the components to allow the manufacturing of these drugs in safe conditions.

9:45 **Modeling Lyophilization: "Mathematical Modeling for Dummies"**
Narlin B. Beaty, PhD, Principal, Sublimation Science

As a beginner's guide to mathematical models for lyophilization, this presentation will assist in developing a foundation for sophisticated analysis of your lyophilization data. Focusing primarily on the sublimation event, we will go through the simplest possible math models and show how they are derived. Mathphobes can follow along. The purpose of models is to better understand the physical world and to have a new tool, which may permit asking new questions. If you consider "math" to be a four-letter word, you might find this talk refreshing.

- Zero order kinetics for phase change
- Phase change graphs look like lyo traces
- Determine energy input from a lyo trace
- Microwave model
- Lyophilization of a sphere

10:30 *Mid-Morning Break*

10:45 **Understanding and Controlling the Nucleation Step in Lyophilization**
Miquel Galan, R&D and Innovation Director, TELSTAR Industrial, S.L.

The freezing step is of paramount importance in freeze-drying: it dictates ice morphology and size distribution, influencing the extent of product crystallinity, surface area, drying rate, protein aggregation, etc. It is fatally accepted that nucleation is an "uncontrolled step" during freezing. This session focus on the experimental results obtained with a new method to control nucleation and crystal growth of ice during the freezing processes in a pilot lyophilizer. Control of the freezing conditions is possible and the loss of freeze labile components may be minimized. The presentation specifically covers:

- Spontaneous nucleation and ice morphology
- Historical attempts to control nucleation
- New method to control nucleation and crystal growth
- Porosity of the solid matrix
- Advantages: minimizing variability and dramatic drying time reduction

- 11:30 **Use of Microbalance to Develop a Freeze-Drying Cycle**
Yves Mayeresse, Freeze-Drying Manager, GlaxoSmithKline Biologicals
 Sublimation rate is a key parameter to develop and optimize a freeze-drying cycle. For instance, product probes are classically used to estimate end point of the primary drying during a cycle; now the microbalance can give the precise value. Moreover, the drying rate can be followed and interpreted during the whole primary drying. The desorption phase can be started with a known quantity of residual moisture avoiding collapse due to a not adapted heat input. By varying the parameters of your cycle and formulation, you can evaluate the impact on each of them on the optimization of your cycle. During the presentation, the following points are addressed:
- Principle of a microbalance *in situ* measurement
 - Influence of pressure, temperature, and concentration of excipients on freeze-drying rate for a model formulation
 - Statistical analysis of the obtained curves
 - Interpretation of the values obtained in respect of freeze-drying theory

12:15 *Luncheon*

- 1:15 **Container Closure Systems for Lyophilized Products**
Mark E. Chin, BS, Scientist, Manufacturing Process Science Group, Chiron Corporation
 The selection of the container closure (stopper) for a lyophilized product is critical to product stability and the timely completion of the product development. Not understanding the requirements for a given project can lead to a difficult and frustrating experience in selecting a stopper and determining the proper process conditions. This talk will present some methods and information that can be helpful in evaluation and implementation of a container closure to meet the needs of a project.
- Learning how to evaluate container closure options – formulation, design, manufacturers, ready-to-sterilize
 - Identifying the key issues – cost, machinability, drying time, container closure validation
 - Stopper quality and inspection – know what effect this can have and how to address it
 - Working with stopper manufacturers to reduce quality problems

A Two-Part In-Depth Case Study Presentation

- 2:00 **An Empirical Approach to Developing an Optimized Lyophilization Cycle: Formulation and Process Strategies**
J. Jeff Schwegman, PhD, Research Scientist, Baxter Pharmaceutical Solutions, LLC
 The goal of the formulation/process development scientist when designing a lyophilization cycle is to produce a stable, safe product in the shortest amount of time using the most robust cycle. By taking an empirical approach to freeze-drying through thermal analysis studies and targeted pilot studies, it is possible to significantly reduce overall cycle time by eliminating the number of pilot runs, and by maximizing the sublimation rate by working closer to the critical temperatures. Specifically:
- Part I – Pre Lyophilization: Formulation and Thermal Analysis Techniques**
- Understand how to use, and the importance of using, thermal analysis techniques to characterize the properties of a frozen system
 - Understand the technique of annealing, how it can benefit/stabilize formulations, and how to determine if your formulation requires an annealing step
 - Learn about the common excipients added to lyophilized formulations and how to choose them
 - Evaluate case studies in failed products/cycles, and learn how to diagnose and prevent these problems in the future
- Part II – Lyophilization Cycle Development, Dried Solids Characterization, and Stabilization of Problematic Formulations**
- Understand how to use targeted pilot studies in a lab-scale dryer to develop an optimized freezing, primary drying, and secondary drying protocol
 - Understand the various techniques used to characterize the final freeze-dried solids and why these techniques are important in development
 - Learn formulation tips and techniques that can be used to help stabilize problematic formulations (specifically biological formulations)
 - Evaluate case studies in failed products/cycles and how to diagnose and prevent these problems in the future

3:00 *Afternoon Break*

- 3:15 **Examining Current Trends in Lyophilization Cycle Control: Vapor Pressure Induced Pressure Rise, Product Temperature Profiles, Case Study Implementation of PV/CM and BE in Freeze-Drying**
Lawrence Ulfik, Director of Sales, Laboratory Products, SP Industries-VirTis & Hull Brands

Case Study

This session looks at current trends in lyophilization cycle control, and how and when the various methods can be used to maintain consistency in lyophilization cycles. The presenter explores the benefits and drawbacks of each technique, and offers strategies and a case history describing pitfalls and successes. Your instructor provides an understanding of how barometric endpoint and Pirani/Capacitance differential can be used during primary and secondary drying to assist in endpoint determination. In addition, the presentation covers regulatory/cGMP guidelines as they apply to lyophilization and cycle control.

- Exploring the role of shelf surface temperature and shelf inlet temperature in the freeze-drying cycle
- Learning how a temperature sensor reacts in product during freeze-drying, and use of special TC probes
- Knowing how shelf edge effects can be minimized using thermal-guard trays and chamber wall heating and cooling to minimize edge effects
- Understanding how time-based controls function in some lyophilization control systems

- 4:00 **Successful Scale-Up from Pilot Scale to Production Scale**
Samir U. Sane, PhD, Senior Process Engineer, Genentech, Inc.

Case Study

Implementing a robust lyophilization process on production scale is a critical step to ensure reliable manufacture of a product for clinical or commercial supply. The implementation can be especially challenging if it is performed at a contract site. This session will discuss the key considerations involved in scaling up lyophilization processes from pilot-scale freeze-dryers to production-scale freeze-dryers. For example:

- Approaches to process characterization and development studies
- Selection of surrogate formulation
- Impact of equipment and facility differences
- Selection of process tolerances
- Process monitoring – pressure rise testing

The presentation will also include a case study describing lyophilization process scale-up for a pharmaceutical protein at a contract site. Considerations involved in selecting a contract site will also be discussed.

- 4:45 **Using Smart Freeze-Dryer™ Technology as a Process Analytical Technology (PAT) Tool**
Joseph F. Brendle, Director, Technology and Business Development, FTS Systems, Inc.

Smart Freeze-Dryer Technology provides process information not previously available to those involved in developing and troubleshooting freeze-drying processes. This session will present an overview of Smart Freeze-Dryer Technology, and show how the data available from the system may be used to better understand the effect of process parameters and process parameter changes on the freeze-drying process. The data and analysis can be applied as a part of a company's overall PAT initiative.

- Become familiar with the fundamentals of Smart Freeze-Dryer Technology
- Understand the data available from Smart Freeze-Dryer Technology
- Learn examples of how to apply Smart Freeze-Dryer Technology as a PAT tool

5:30 *End of Day One Main Sessions*

Friday, May 20, 2005

7:30 *Morning Coffee*

- 7:45 *Chairperson's Welcome and Opening Comments*
Karen A. Bossert, PhD, Senior Director of Finished Goods, Regeneron Pharmaceuticals, Inc.

- 8:00 **Knowing and Fully Utilizing Your Freeze-Dryer's Maximum Throughput Capability**

Featured Case Study

Jim Searles, PhD, Senior Research Scientist, Global Parenteral Commercialization Technology Center, Eli Lilly and Company
 The throughput of a freeze-dryer can be defined as the number of vials of a given product that it will produce in a year. Higher throughput represents a more effective use of this capital asset, and provides for more medicine manufactured at a lower cost. This enables more patients to receive the

medicine, and frees up capital for use in discovering and developing new pharmaceuticals. Your session leader will present the results of a comprehensive effort at Eli Lilly to characterize the maximum drying rate capability of all of our freeze-dryers as a function of chamber pressure, and show how these findings provided critical input into a freeze-drying cycle optimization project that was taking place at the same time. The dryer capability and cycle optimization projects will significantly improve our freeze-drying throughput worldwide. Your presenter will also cover the factors controlling the maximum drying rate capability, including Lilly's recent discovery of choked water vapor flow in freeze-drying. This session will feature an extended opportunity for Q&A.

9:00 **Design of a Pilot Scale Freeze-Dryer Connected to a Barrier Isolator**
Peter Hanscome, Development Scientist, Sanofi Pasteur

Case Study

In this session you will see the process of design and integration of a pilot-scale freeze-dryer to a barrier isolator and filling line. Learn the complexities of integration of different manufacturers of equipment and how this company resolved them. The problems incurred will be discussed in the actual case study.

- Design specifications
- Final selection criteria
- Installation
- Room layout

9:45 *Mid-Morning Break*

10:00 **Case Study in Lyophile Physical Defects**

Case Study

Nicole McKenna, Process Development Engineer, QLT USA, Inc.

Often, "real-world" problems do not present themselves like the ones in the textbooks. Your session leader will present a case study in just such a problem. Using lyophilization cycle data, differential scanning thermal analysis, and pictures, she will walk the participants through the problem and solutions, giving them opportunities to think through and apply some of their own ideas.

- How to determine sublimation rates from lyophilization data, and predict rates for a modified cycle
- Why it is important to obtain thermal analysis of your product prior to cycle development
- When it can be beneficial to "think outside of the box" in terms of solutions

10:45 **NCCW: In-Line Non-Contact Inspection with NMR Presents New Opportunities & Challenges in Process Control**

Dr. Paul Stewart, Director of Technology, BOC Edwards Pharmaceutical Systems

BOC Edwards develops in-line measurement equipment to determine the product quality of every single product dosage. This fit well within the PAT framework as defined by FDA. One of the first deliverables of this development is the Non-Contact Check Weigher (NCCW) based upon NMR. Besides 100% weight measurement, it is clear that with a filling system the feedback of the measured results improves the filling accuracy significantly. The session will illustrate some of the background, and will identify

potential other applications, especially on moisture determination of the freeze-dried product.

- Understand the working principle of this new measurement technique
- Identify the applicability of the technique for product quality improvement
- Define next steps to implement this technology in the production environment

11:30 **Determining Product Performance – Strategies for Stability Testing**
Karen A. Bossert, PhD, Senior Director of Finished Goods, Regeneron Pharmaceuticals, Inc.

The process of lyophilization is done specifically to stabilize a compound and/or a product. However, how do you really know that the product is stable? And how long will it remain stable? This session examines the regulatory requirements for stability of lyophilized products and provides training on the tools and techniques available for assessing stability.

- Examining stability requirements worldwide
- Characteristics of lyophilized products monitored on stability
- Analytical techniques for assessing stability

12:15 *Luncheon*

1:15 **Comprehensive Process Validation**

Yves Mayeresse, Freeze-Drying Manager, GlaxoSmithKline Biologicals
Three parameters need to be optimized to obtain a successful product: the formulation, the freeze-drying cycle, and the freeze-dryer. This session focuses on the last one. A deep knowledge of the freeze-dryer obtained through validation helps you to better interpret your results at R&D level, to easily scale-up your product, and to implement it in production freeze-dryers. Specifically, this presentation covers the following topics:

- Strategies for validation of the freeze-dryer from the DQ to the PQ
- Establishing the link between product, freeze-dryer, and freeze-drying cycle
- Adding value to your process with a rational validation approach
- Increasing your knowledge of the freeze-dryer to better improve your freeze-drying cycle

IN-DEPTH SESSION

FDA Perspective

2:15 **Being Prepared for FDA Inspections of Lyophilized Products**
Robert Darius, US Food and Drug Administration, CBER

- Understand the general injectable product requirements applicable in the U.S.
- Demonstrate that your product meets the applicable standards
- Prepare for an FDA inspection: When is FDA most likely to inspect? What does the FDA consider to be red flags? How should you communicate with the FDA before, during, and after an inspection?
- Discuss issues raised in FDA complete response letters and 483 inspection observations: Learn how to channel this information in order to improve your processes and speed up regulatory approvals

3:15 *Afternoon Break*

RISK ASSESSMENT AND ROOT CAUSE ANALYSIS IN THE LYOPHILIZATION PROCESS

WORKSHOP

3:30 *Workshop Begins*

Process excursions of critical process parameters warrant a deviation investigation as to the root cause and an assessment of the impact on finished product qualities. Consideration of excursions includes relative magnitude compared to a proven acceptable range (PAR) of processing parameters. This session will review establishing such ranges for PAR during development. Events that can occur outside a PAR will also be discussed relative to the risk assessment and impact on finished product quality. Illustrations of abhorrent processing conditions and product abnormalities will be used during this interactive workshop to develop possible root causes and assessment of the impact on finished product qualities. Examples of events and observations include:

- Examining potential issues in freeze-drying – Critical versus non-critical excursions
- Understanding what is and is not a problem – What constitutes a cycle deviation? How conservative do you need to be?
- Using PAR to minimize cycle deviations
- Variations in finished product attributes – What causes them and what can be done? i.e., physical appearance (melt back, collapse, etc.) and residual moisture
- Strategies for reviewing cycle data to identify potential root causes of the problem

About the Workshop Leader

Edward H. Trappler is President and Founder of Lyophilization Technology, Inc., a contract research and technical services firm dedicated to freeze-drying. He has over 25 years experience in lyophilization that ranges from product development to equipment application engineering. He received his Bachelor of Science degree in Chemistry at The College of New Jersey. His experience in the pharmaceutical industry includes product development, toxicology supply preparation, clinical manufacturing, and parenteral production.

5:00 *Close of Conference*

LYOPHILIZATION 2005

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