

# Development of a Freeze-Drying Process

Bring your own samples  
for discussion

## Overview

This workshop will give a thorough introduction into the Physics and Thermodynamics of Freeze-Drying. This seminar comes with an additional overview about technical aspects to be considered and gives an overview about current technologies available on the market. It is created to introduce all people who are professionally linked to Freeze-Drying and might be of special interest for cycle developers (R&D), upscale & transfer specialists, project managers & engineers, process & site engineers, qualification & validation specialists. Open problem examination allows you to bring in a current problem linked to Freeze-Drying. The group will discuss and evaluate possible approaches for troubleshooting.

## Who Should Attend:

This course is designed specifically for

- Cycle Developers (R&D)
- Upscale & Transfer Specialists
- Project Managers & Engineers
- Process & Site Engineers
- Qualification & Validation Specialists
- Members of Parenteral Production Teams

## Learning Objectives:

Upon completion of this course participants will know the basic principles of all Freeze Drying aspects:

- Physical / Thermodynamic Theory of Nucleation, Sublimation and Desorption
- Technical & Technological Solutions to accomplish a standard process
- Based on the prior theory, several hands-on-sessions provide practical knowledge to design a Freeze-Drying process
- Basics of qualification of a freeze dryer



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Georg holds a degree in Engineering from UAS, Cologne, Germany. He is Process Engineer at Bayer Pharma and responsible for the technical operation of the parenteral facility. Previously, he worked as Process Engineer for Optima (Klee) and GEA Lyophil / Steris. Among others, he is specialized in the development of customized Freeze-Drying processes (particularly upscaling with PAT) and in the qualification (FAT, SAT, IQ, OQ, PQ) of pharmaceutical freeze dryers.

## Thursday, 29 November 2018 9:00 – 18:30

### THEORY

#### 9:00 Introduction

- Introduction to Drying Technologies
- Overview of the Freeze Drying Process
- Properties of Water
- Properties of Heat Transfer during Lyophilization

#### 10:00 Nucleation (with Parallel Hands-on)

- Scientific Basics
- Freezing Process
- Sensors & PAT

#### 11:00 Coffee Break

#### 11:30 Nucleation (Cont.)

- Hands-on: Freezing of Sucrose in a Lyo with integrated thermo-resistant measurement

#### 12:45 Lunch Break

#### 13:45 Sublimation

- Scientific Basics
- Drying Process
- Sensors & PAT
- Hands-on: Ice-temperature calculation based on manometric temperature measurement

#### 16:00 Coffee Break

#### 16:30 Desorption

- Scientific Basics
- Residual Moisture
- Sensors & PAT
- Hands-on: Preparation and start of a lyo-process

#### Bring in your Questions:

**Real problems of Freeze Drying can be presented and will be discussed in the group**

#### 18:30 End of Day 1

## Friday, 30 November 2018 8:30 – 17:00

### TECHNOLOGIES & PRACTICE

#### 8:30 Repetition of Previous Day Theory

#### 9:00 Hands-On: Recipe Development

#### 11:00 Coffee Break

#### 11:30 Process Design

Derive design requirements from process requirements

- Process requirements
- Process steps of Lyo-cycle
- Auxiliary processes for parenteral production

#### 12:30 Lunch Break

#### 13:30 Design of a Lyophilizer - From Engineering to Qualification

- Vessel system
  - Shelf system
  - chamber system
  - condenser system)
- CIP / SIP-Equipment
- Qualification procedures
  - CIP-Process
  - SIP-Process
  - Leak Test

#### 15:30 Auxiliary Systems of a Lyophilizer

- Aeration System with Filter test
- Sensor Equipment / PAT Methods
- Vacuum System
- Heat Transfer System
- Refrigeration System

#### 15:00 Coffee Break

#### 16:30 Hands-on:

- Evaluation of the Lyo experiment & samples of collapsed probe

#### 17:00 End of Training Course