



**2018 PDA Europe**  
**Freeze Drying in Practice**

**23-27 April 2018 | Training Course**

Register by  
30 November 2017  
and SAVE!

**23-27 April 2018**

Martin Christ Gefriertrocknungsanlagen GmbH  
Osterode (Harz) | Germany

## Overview

Freeze drying, also termed lyophilization or sublimation drying, is a gentle drying technique. It has been used in the pharmaceutical industry for many years to improve the stability of medications.

Biopharmaceuticals in particular require an especially gentle manufacturing process due to their complex and thermosensitive molecular structure. In this regard, freeze drying represents the method of choice for improving storage stability of biopharmaceuticals, which is insufficient in the liquid formulation. While presently already approx. 60% of these products are freeze dried, a further increase in this percentage is to be expected in the coming years.

A freeze drying process is divided into three stages: freezing process, primary drying and secondary drying. The freeze dryers necessary for this are complex, computer-controlled systems. The main components are a vacuum chamber with vacuum pump and ports for attaching the product as well as the cooled condenser, where deposit of the subliming steam from the product occurs on its surfaces. Automated cleaning and sterilization units complete the range of functions. Production freeze dryers are integrated into process lines and equipped with automatic loading and unloading systems to satisfy both aseptic requirements and higher product throughput while at the same time decreasing error rates.

## Learning Objectives

You will be thoroughly familiarized with the freeze drying process. The structure and operating principle of freeze dryers are introduced and the interaction of the different functional groups is explained.

You will get to know the regulatory requirements of the freeze drying process. Fulfillment of these requirements and the sequential process steps will be introduced by means of examples.

Emphasis is placed on technical support, calibration of the most important sensors, qualification of the system and preventative maintenance. You will learn how to identify and remedy the most frequently occurring system malfunctions. Understanding the maintenance plan rounds off your skills of servicing a freeze drying system.

Cleaning and sterilization requirements are discussed intensively and their technical application will be demonstrated on the freeze dryer. Technical concepts are introduced for automatic loading and unloading.

Interactive training elements, exercises and experiments in the laboratory and production areas constitute a large part of the course. After you have been familiarized with the theoretical background, you will carry out a freeze drying process to completion under the guidance of experienced experts. The results are examined, potential errors and their avoidance are discussed thoroughly. You will obtain insight into the procedures for cleaning and sterilization and will also carry out these processes yourself.

The practical character of the meeting is furthermore supported by the fact that you may pose questions from your everyday work, which will then be discussed collectively. You will receive advice from the experts and have the opportunity to exchange with the other course participants.

## Who Should Attend

This training course is geared to operators of pharmaceutical freeze drying systems. It particularly addresses employees in the areas of

- Production
- Technology
- Qualification/Validation
- Quality Assurance

who are responsible for the planning, purchasing, operation, usage and qualification/validation of freeze drying systems.

## Monday, 23 April 2018

**12:00** Reception and Welcome Snack

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**12:30** INTRODUCTION

- **Collection and clustering of the questions contributed by the participants**
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**13:00** THEORY 1 - OBJECTIVE AND RATIONALE FOR FREEZE DRYING

- **History and development of freeze drying**
  - **Introduction to the different phases of a freeze drying process (three basic principles of freeze drying)**
  - **Examples of use of freeze drying in daily routine and pharmaceutical production**
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**14:15** Coffee Break

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**14:30** THEORY 2 - PRINCIPLES OF THE FREEZE DRYING PROCESS

- **Physical correlation between basic principles and acceptance criteria**
  - **Measured parameters and their technical implementation**
  - **Development and composition of a formulation**
  - **Packaging for freeze drying**
- 

**15:30** PRACTICE 1 - PREPARATION OF SOLUTIONS

- **Different concentrations**
  - **Weighing out**
  - **Pipetting into vials**
  - **Stoppering**
  - **Freezing experiment with distilled water under vacuum to develop a general understanding of the critical temperature**
- 

**17:45** Transfer to the Networking Dinner

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**18:00** Networking Dinner

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**21:00** Return to the recommended Hotels

## Tuesday, 24 April 2018

**08:30**     **Transfer from the recommended hotels to Martin Christ facility**

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**09:00**     **Recapitulation and Summary of Day 1**

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**09:10**     THEORY 3 - DEVELOPMENT OF A FREEZE DRYING PROCESS

- **Introduction of the simulation tool**
- **What are the important parameters?**
- **How can the parameters be set?**
- **What happens, if the parameters were selected inappropriately?**

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**10:30**     **Coffee Break**

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**10:45**     THEORY 4 - PROCESS CONTROL TOOLS

- **Thermal resistance measurement (Lyo-RX)**
- **Comparative pressure measurement (Pirani/capacitive pressure measurement)**
- **Barometric temperature measurement (BTM/MTM)**
- **Wireless temperature measurement (WTM)**
- **Desorption rate measurement (DRM)**
- **Conductance sensor**
- **Inline camera (LyoCam)**

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**11:45**     PRACTICE 2: PROGRAMMING

- **Programming the freeze dryer with the programs developed in Theory 3**

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**12:45**     **Lunch Break**

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**13:45**     PRACTICE 3: FREEZING BEHAVIOR

- **Determination of the critical temperature**
- **Loading the freeze dryer**
- **Placing of wired and wireless product sensors**
- **Starting the freeze drying process**
- **Introduction to the lycam technology**

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**15:15**     **Coffee Break**

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**15:30**     THEORY 5 - OPERATING PRINCIPLES OF THE FREEZE DRYER

- **Overview of different operating and construction principles of freeze dryers**
- **Construction principle of the freeze dryer and its device modules**
- **Performance figures (port sizes, condenser sizes, evacuation times)**
- **Chamber system**
- **Cooling & vacuum systems**
- **Filter systems**
- **CIP/SIP**
- **Interaction of the device modules in the freeze drying process**

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- 16:30** PRACTICE 4 - TOUR OF THE PRODUCTION ROOMS OF MARTIN CHRIST
- **Introduction to the different size classes of freeze dryers**
  - **Introduction to the functional modules of the freeze dryer**
  - **Visualization of the basic analogy of the functional modules across the size classes**
  - **Explanation of the step-by-step production process for freeze dryers**

- 17:45** PRACTICE 6 - A GLANCE AT FREEZE DRYERS
- **Discussion of the current status of the process**
  - **What is evident/what is not yet evident**

**18:15** **Transfer from Martin Christ facility to the recommended hotels**

## Wednesday, 25 April 2018

**8:30** **Transfer from the recommended hotels to Martin Christ facility**

**9:00** **Recapitulation of Key Learnings from Day 2**

- 9:10** THEORY 6 - LYO QUALIFICATION
- **Explanation of the sequence DQ-RA-IQ-OQ-PQ**
  - **Measures for maintaining the qualified state**

- 09:55** PRACTICE 7 - INTRODUCTION TO THE GENERAL ORDER OF EVENTS IN OPERATION
- **Brief explanation of all workstations**
  - **Explanation and instruction on the logistics**

- 10:25** PRACTICE 8
- **Discussion of the current status of the process in the freeze dryer**

- 10:55** PRACTICE 9: WORKSTATION OPERATION SEQUENCE 1
- **Calibration of pressure sensor/vacuum sensor**
  - **Calibration of temperature sensor**
  - **Shelf temperature mapping**
  - **Roughness measurement**

- 11:40** CONTINUATION PRACTICE 9: WORKSTATION OPERATION SEQUENCE 2
- **Calibration of pressure sensor/vacuum sensor**
  - **Calibration of temperature sensor**
  - **Shelf temperature mapping**
  - **Roughness measurement**

**12:25** **Lunch Break**

- 13:25** CONTINUATION PRACTICE 9: WORKSTATION OPERATION SEQUENCE 3
- **Calibration of pressure sensor/vacuum sensor**
  - **Calibration of temperature sensor**
  - **Shelf temperature mapping**
  - **Roughness measurement**

# TRAINING COURSE AGENDA

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**14:10** CONTINUATION PRACTICE 9: WORKSTATION OPERATION SEQUENCE 4

- **Calibration of pressure sensor/vacuum sensor**
  - **Calibration of temperature sensor**
  - **Shelf temperature mapping**
  - **Roughness measurement**
- 

**14:55** PRACTICE 10 - MAINTENANCE AND FAULT CORRECTION

- **Introduction to the most frequently occurring faults**
    - Diagnosis
    - Most probable causes
    - Correction
  - **Introduction to a preventative maintenance concept**
  - **Presentation of examples of defective components with explanation of the causes**
- 

**15:55** **Coffee Break**

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**16:10** THEORY 7 - CIP & SIP

- **Inspection of CIP & SIP systems**
  - **Cleaning validation**
  - **Sterilization qualification**
  - **Turn-around concept**
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**16:55** THEORY 8 - LOADING/UNLOADING

- **Loading/Unloading**
    - Frames/Trays
    - Carts
    - Robots
    - Frameless
  - **Introduction to different loading/unloading layouts with several freeze dryers in conjunction with filling and capping**
  - **Introduction to the technical concept solutions with different freeze dryers (products from different suppliers)**
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**17:55** PRACTICE 11

- **Discussion of the current status of the process in the freeze dryer**
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**18:40** **Transfer from Martin Christ facility to the recommended hotels**

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## Thursday, 26 April 2018

**8:30**      **Transfer from the recommended hotels to Martin Christ facility**

**9:00**      **Recapitulation of Key Learnings from Day 3**

**9:20**      PRACTICE 12

- **Simulation of major faults with freeze driers**
- **Diagnosis (and simulation) of the correction of major faults**

**10:20**      **Coffee Break**

**10:40**      PRACTICE 13

- **Explanation of conductance sensor**
- **Inspection and explanation of the CIP/SIP-functional modules in an industrial freeze dryer**
- **“Contamination” of a freeze dryer with riboflavin solution**
- **Start of the CIP cycle**

**13:00**      **Lunch Break**

**14:00**      THEORY 9

- **Introduction to the functioning and operation of the RM measuring instrument**
- **Presentation of theory, function and purpose of the most important analysis techniques for lyophilizates**
- **Introduction to the measurement of residual moisture**
- **Demonstration of the Karl-Fischer measuring instrument**

**15:00**      **Coffee Break**

**15:20**      PRACTICE 14

- **Discussion of the current status of the process in the freeze dryer**

**15:50**      PRACTICE 15

- **Examination of the cleaning result with a UV lamp**
- **Discussion of the cleaning result**
- **Start of the SIP cycle**
- **Discussion of the process sequence**

**17:20**      **Transfer from Martin Christ to dinner location**

**18:00**      **Farewell Dinner**

**21:00**      **Transfer from dinner location to the recommended hotels**



## Friday, 27 April 2018

**8:30**      **Transfer from the recommended hotels to Martin Christ facility**

- 9:00**      PRACTICE 16
- **Unloading the freeze dryer**
  - **Evaluation of the process chart**
  - **Determination of reconstitution time**
  - **Visual Inspection**

- 10:00**     PRACTICE 17
- **Assessment of the different results**  
-Measurement of residual moisture in the vials
  - **Questions & answers and conclusion**

**12:00**     **End of Course**

## Faculty



**Andrea Allmendinger**, *PhD, Senior Scientist, Hoffmann-La Roche Basel*

Andrea Allmendinger is a pharmacist by training and conducted her studies at the University of Heidelberg in Germany and at the University College London. She holds a PhD in Pharmaceutical Technology from the University of Basel. Andrea joined Hoffmann-La-Roche Basel in 2010, where she currently holds the position as Senior Scientist in the Late-stage Pharmaceutical and Processing Development Department for parenteral products. Andrea is specialized in highly concentrated monoclonal antibody formulations and in particular in the development of freeze dried, parenteral formulations, as well as process development, optimization and transfer of lyophilization cycles. In addition to her role at Roche, she is lecturer at the University of Freiburg in the department of Pharmaceutical Technology and Biopharmacy since 2015.



**Klaus Hudel**, *PhD, Business Development Manager, Martin Christ GmbH*

After his studies of chemical engineering at the University of Dortmund, Klaus held a position as test engineer in a public water and waste association. His following position at the well-known German RWTH Aachen University consisted in practical industrial projects. After achieving his PhD in engineering about a thermal treatment topic, he moved to the appropriate industry where he worked as project engineer for big scale drying equipment. For almost 20 years now, Klaus works for in Martin Christ Gefriertrocknungsanlagen GmbH. In his current position as business development manager he is not only responsible for market perspectives and key customer relations, but is also busy in seminars and workshops about freeze drying.



**Sascha Pfeiffer**, *Managing Director, Lyo Engineering*

Sascha Pfeiffer is a Pharma Quality Engineer with over 10 years of experience in Pharma Engineering in the area of API Fill Finish. Sascha founded Lyo Engineering in 2013 and holds the role as Managing Director. Lyo Engineering is a Consulting Company in the Areas Management, Freeze Dryer Process Engineering and Quality Issues (Quality Assurance, Qualification and Validation). Sascha is specialized in Quality Assurance Engineering and in technical Transfers, as well as plant process optimization.

Additional employees of Martin Christ Gefriertrocknungsanlagen GmbH are operating as trainers and supporting staff for the practical exercises.



## CONTACT INFORMATION

### Elke von Laufenberg

Manager Training & Education

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**Faculty Management**

**General Event Information**

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**Registration**

**Membership Management**

## ORGANIZER

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## VENUE

### Martin Christ

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## HOTEL RECCOMENDATION

### HOTEL SAUERBREY \*\*\*\*

Friedrich-Ebert-Str. 129

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Tel.: +49/ (0)5522-5093-0

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Please bring flat and solid shoes for hands-on sessions.



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- 1 **ONLINE:** [pda.org/eu/fdp2018](http://pda.org/eu/fdp2018)
- 2 **FAX:** +49 30 436 55 08-66
- 3 **EMAIL:** [registration-europe@pda.org](mailto:registration-europe@pda.org)

This PDF-file provides an automatic fill-in function. Your signature, however, is needed in writing.

### 1 Your Contact Information

If this form is an update to a previously submitted form, please check here.

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(Check only if you are substituting for a previously enrolled colleague; a nonmember substituting for member must pay the membership fee.)

\* This information will be published in the conference attendee list. Should you not wish us to publish these details, please contact us.

### Information about Visa Matters

- All registrations which will involve visa matters will have to be submitted to PDA EU four weeks prior to the start of the event at the latest. For later registrations, PDA Europe will be unable to assist participants in any visa affairs.
- All costs incurring in connection with visa affairs shall be borne by registrants. (This applies in particular to costs for submitting documents by courier.)
- Potential participants must be clients of UPS shipping agency and submit their UPS customer reference number to PDA EU (together with their registration).

### 2 Registration

**EARLY BIRD DISCOUNT**  Book by 30 November 2017 to receive € 300 off

All fees given in Euro and excluding VAT (7 %)

**Training Course (23–27 April)**  
 Freeze Drying in Practice  
 All Participants

**2990**

The fee includes course documentation as well as mid-session refreshments and lunch. Excellent networking opportunities with snacks and drinks will be given. The fee does not include the hotel accommodation.

### 3 Payment Options

**By Credit Card**

American Express

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VISA

**For your credit card information safety:**

**Please send your details by fax only (+49 30 4365508-66) or register online.**

**By Bank Transfer**

**Beneficiary:** PDA Europe gGmbH

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**BIC (SWIFT-Code):** DEUTDE33

**Bank Address:** Deutsche Bank, Welfenallee 3-7, D-13465 Berlin, Germany

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# 2017 PDA EUROPE CONFERENCES

19 – 20 September **Pharmaceutical Freeze Drying Technology** ★ **Cologne, Germany**

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26 – 27 September **Particles in Injectables** ★ **Berlin, Germany**

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26 – 27 September **10<sup>th</sup> Workshop on Monoclonal Antibodies** ★ **Berlin, Germany**

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10 – 11 October **Pharmaceutical Cold & Supply Chain Logistics** ★ **Prague, Czech Republic**

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7 – 8 November **The Universe of Pre-filled Syringes and Injection Devices** ★ **Vienna, Austria**

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21 – 22 November **Outsourcing & Contract Manufacturing** ★ **Munich, Germany**

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Subject to change

For latest info: [pda.org/pda-europe](http://pda.org/pda-europe)

Shortlist 25 Aug 2017

★ Events with additional Education Program. More information – <http://t1p.de/7p9z>



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