ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers


Anthony Cannon
MSD


Maik Guttzeit
Bayer


Kristien Janssen
Pfizer


Dr Benjamin Ledermann
GEA


Dr Bernhard Luy
Meridion Technologies


Heide Nagel
Novartis Pharma Stein


Prof Dr Luis Padrela
University of Limerick


Dr Frank Sielaff
Hessian State Office of Health and Care, Darmstadt, Germany


Dr Andrea Weiland-Waibel
Explicat

Lyophilization 2025

Opportunities and Challenges for the Pharmaceutical Industry

21 - 23 October 2025 | Cologne, Germany

Image: GEA, Germany

Includes Workshops at GEA

Highlights

- Fundamentals of freeze drying
- Formulation & process development
- Atmospheric freeze drying
- Lyo-cycle development and improvement
- Scale-up and validation of freeze drying processes
- Freeze drying of highly potent and sensitive biological material
- Media Fill
- Lyophilizer in aseptic production lines
- 100% inspection
- Workshops:
  - Fundamentals, cycle development and scale-up
  - Hands on demonstration of production scale freeze dryer design and functions
  - Automated loading and unloading systems
  - Innovations in freeze drying applications

Objectives

Take advantage of the opportunity to **focus on freeze drying technologies and processes** and get a first-hand demonstration of solutions for diverse requirements. Further, benefit from the **workshop** where you can get a **hands-on experience in freeze drying yourself**. In small groups, you will learn how the freeze drying output is affected by different equipment, parameter changes, solvents, etc.

Background

Lyophilization (or freeze drying) is one of the most exciting technologies in the pharmaceutical industry, although it is a very old process for the preservation of unstable materials. Trends are growing towards using non-aqueous systems.

Additionally, Process Analytical Technology (PAT) / RTRT (Real Time Release Testing, Annex 17 of the EU GMP Guide) systems for in-line process monitoring are used to control and determine critical processing parameters. PAT plays also an important role in continuous lyophilization processes. According to ICH´s new guideline Q13 *"continuous manufacturing (CM) has potential for improving the efficiency, agility, and flexibility of drug substance and drug product manufacturing"*. Regulatory agencies have seen more companies engaged in the development and implementation of CM in recent years than in the past.

Modern QbD (Quality by Design) development following ICH Q8, Q9 and Q10 is based on the objective to design a lyophilization cycle applying a systematic and scientific approach instead of trial and error. Sufficient process understanding is essential to achieve a robust production process and efficient handling of post-approval changes (life cycle management according to ICH Q12) of a freeze drying process.

There is an increasing trend in aseptically produced lyophilized products, including peptides and proteins. Owing to the nature of these biological products, the lyo-cycle is more complicated and, in most cases, even longer than for other medicinal products.

The utility of lyophilization goes far beyond the vial. Principles of low temperature, low pressure can be applied to stabilize substances ranging from high potent APIs, novel medical devices, biologics and nanomaterials, freeze drying offers multiple opportunities.

Target Audience

This conference addresses specialists and executives working in the fields of pharmaceutical manufacture, research and development and quality control, as well as engineers, project/facility engineers, especially those involved in the implementation of new monitoring methods for controlled nucleation, risk-based scale-up models and process technology for freeze drying processes. The conference is also of interest for participants working in the areas of container development and manufacturing process/packaging.

Programme

Fundamentals of Lyophilization
(Dr Benjamin Ledermann)

- Introduction and historical review
- Advantages and disadvantages of freeze drying
- Structure and function of a freeze dryer
- The three phases of freeze-drying process
- Process monitoring and optimisation

Increased Efficiency through Optimisation of Lyophilisation Cycles and PAT
(Dr Andrea Weiland-Waibel)

- CQA and critical process parameters
- Freeze drying: scale-up and validation
- Process control strategies

Impact of the new Annex 1
(Dr Frank Sielaff)

- EU GMP Annex 1 - Effects on Lyo products
- GMP questions during inspections
- Experiences from the perspective of an inspector

Simulation of Lyophilization & CCIT
(Dr Andrea Weiland-Waibel)

- Simulation techniques and models for the optimisation of lyophilisation
- Introduction to Container Closure Integrity Testing (CCIT) methods and their importance
- Integration of CCIT in quality control and quality assurance

Lyophilization Technology- Design Requirements and Technical Solutions
(Anthony J Cannon)

- Main components of a lyo (chamber, condenser, refrigeration skid, vacuum skid, shelves, etc.)
- Purpose of these components
- Design criteria of these components (temperature homogeneity, cooling and heating capacity, sublimation capacity and gas flow, etc.)

Lyophilizer in Aseptic Production Lines - Challenges and Chances
(Kristien Janssen)

- Automatic Loading and Unloading of Freeze Dryers
- FD cycles: monitoring and challenges
- Turn-over times
- Lyoplus
- Steps towards higher sustainability

Aseptic Process Simulation (Media Fill)
(Heide Nagel)

- Media Fill Design
- Worst Case Parameter for Media Fill
- Validation of lyophilisation processes with Media Fill
- Requirements for Media Fill

Spray Freeze Drying
(Bernhard Luy)

- Aseptic generation of homogenous, free-flowing lyophilized bulk material
- Spray freezing and dynamic rotary freeze drying
- Process characteristics and product properties
- Case Studies and industrial applications for parenterals

Qualification and Testing of Freeze Dryers
(Maik Guttzeit)

- QbD requirements for successful freeze dryer projects
- Qualification strategies and critical test requirements
- Involvement of suppliers in the qualification process

Supercritical CO_2 Technology as an enabling Approach for the Drying of Biopharmaceuticals
(Luis Padrela)

- Drying of biomolecules
- Atomization
- Supercritical CO_2-based methods
- Particle size control
- Stabilization
- Economic and aseptic considerations

Moderators

Clemens Mundo, Concept Heidelberg & Thomas Beutler, GEA

Workshops

On the third conference day, you will have the opportunity to **take part in several parallel workshops.** For that purpose, several lyophilizers will be available at GEA. Experienced GEA experts will lead you in small groups, providing an intensive experience and directly applicable know-how.

- **Hands-on demonstration of production scale freeze dryer design and functions**
  This workshop will provide each participant with an overview of a state-of-the-art production-scale freeze drying system, including system configuration. Also, a small scale production freeze dryer that is applicable to be integrated into the VARIOSYS® Platform will be demonstrated.

- **Fundamentals of freeze drying, cycle development and scale-up**
  For effective freeze drying, each product requires a unique recipe (formulation); these formulations are initially developed on a laboratory or pilot-scale unit and it is imperative that formulation development takes both product characteristics and the limitations of pilot and production machines into account. This workshop will examine the procedures and consequences of process development and scale-up.

- **Live demonstration of automated loading and unloading systems**
  Demonstration of fully operational fixed and robotic load/unload system. Additionally, it will be possible to look at a system with special features, including online moisture control.

- **Workshop tour**
  including visit of shelf manufacturing area, freeze dryer testing as well as simulation and system integration.

- **Innovations in freeze drying applications**
  This workshop will focus on processing Microwave Freeze Drying, as well as the use of environmentally friendly cooling systems and technologies for controlled nucleation and continuous freeze drying.

It is highly recommended that you bring your own safety shoes, if available!

Free transfers on 23 October 2025
A shuttle bus will bring you to Cologne Central Station at approximately 15:15 h. From Cologne Central Station, frequent airport connections are available.

Speakers

Anthony J. Cannon
MSD

Tony is currently Director, External Manufacturing, Technical Operations, for SM Sterile Products at MSD located in Lucerne, Switzerland. He is responsible for technical support of both the Sterile SM drug products and the End to End Antibiotics Supply platform. He has held various positions throughout his career ranging from Drug Product development through commercial manufacturing with a focus on formulation and process development of both liquid and lyophilized parenterals, final container development and optimization, medical devices and drug delivery.

Maik Guttzeit
Bayer

Maik Guttzeit holds a Dipl.-Ing. degree in general process engineering. For almost 20 years Maik was Team Leader Validation at GEA which provides customized GMP Lyophilizer systems. He is member of the GAMP® D-A-CH committee, of ASME BPE Subcommittee on System Design and also of the ECA validation group. Since 2018 he is with Bayer AG, first as Global Technology Manager Aseptic and Sterile and in his current role as principle expert for C&Q concepts.

Kristien Janssen
Pfizer

Very early in her career, Kristien became involved with lyophilization as she was part of a project to purchase, install, and validate three 20 m² commercial freeze dryers. Following this, Kristien worked as a production support engineer supporting freeze drying and preparation. In 2010 Kristien joined the project engineering group again and currently she is involved in a new project to install an ALUS in an existing facility.

Dr Benjamin Ledermann
GEA

Dr Benjamin Ledermann has been working at GEA Lyophil GmbH as an expert in freeze-drying technology since 2018. At GEA, he is involved in the development and evaluation of innovative technologies such as microwave-assisted freeze drying and controlled nucleation.

Dr Bernhard Luy
Meridion Technologies GmbH

Bernhard spent >20 years in the area of Solid Dosage form technologies in Glatt with various positions in the development area and senior manage-ment functions in Glatt Germany's headquarters and Switzerland. He founded Meridion in 2010, aiming at developing the spray freeze drying technology for applications in pharma, diagnostics and specialty chemicals.

Heide Nagel
Novartis Pharma Stein AG

Heide Nagel has been with Novartis Pharma AG since 2012 and currently as Senior Process Expert Microbiology, Sterility Assurance responsible for the microbiological concepts for sterile production (e.g. APS, Microbial Contamination Control Strategy).

Speakers

Prof Dr Luis Padrela
University of Limerick

Luis Padrela is an Associate Professor and Principal Investigator in the Bernal Institute, at the University of Limerick in Ireland. He is a biochemist and chemical engineer by training, having developed expertise in supercritical fluid technology, drug particle engineering and bioprocessing in the academia and in the pharmaceutical industry.

Dr Frank Sielaff
Hessian State Office Of Health and Care, Darmstadt, Germany

GMP Inspector at the competent authority of Hessen with the focus on inspection of drug manufacturers and laboratories in Germany and countries outside of the EU. Before joining the GMP inspectorate Dr Sielaff was several years employed in the pharmaceutical industry as Head of Quality Control and as Qualified Person.

Dr Andrea Weiland-Waibel
ExplicatPharma GmbH, Germany

Andrea held several leadership positions within Pfizer, working as Project Manager in process technology and being responsible for technology transfer & process development. After joining IDEA AG, a biotechnology company based in Munich, Andrea held the position of Director Pharmaceutical Development. She is founder of Explicat Pharma GmbH and Managing Director since 2005.

Social Event

On Tuesday evening, you are cordially invited to a social event in the city of cologne.
This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Participants' comments from past Lyophilization courses:

„Conference was top class, highly recommend."
Prof. Michelle Donohoe, Endo Ventures, Ireland

„Very good conference with useful information."
Dr Onyesom Ichioma, hameln pharmaceuticals, Germany

„Perfect!" - Dr Marzieh Aryan Pour, AryoGen Pharmed, Iran

„The course was perfect and informative for me."
Mohamad Hosein Ghavanini, AryoGen Biopharma Co., Iran

„Very good lectures. Will definitely recommend to colleagues"
Andrius Arelis, Thermo Fisher Scientific Baltics, Lithuania

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Lyophilization 2025 - with workshop at GEA, 21 - 23 October 2025, Cologne, Germany

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

City ZIP Code Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Tuesday, 21 October 2025, 12.30 h - 17.45 h,
(Registration and coffee/snack 12.00 h – 12.30 h)
Wednesday, 22 October 2025, 09.00 h - 17.00 h
Thursday, 23 October 2025, 08.00[1] -14.30[2] h, 15.15[3] h)

[1] transfer from Mercure Hotel Köln West to GEA (bus transfer will be provided)
[2] approx. end of course
[3] approx. arrival at Cologne Central Station (bus transfer will be provided)

In certain cases, participation may not be possible due to competitive reasons.

Venue

Mercure Hotel Köln West
Horbeller Strasse 1
50858 Cologne, Germany
Phone +49 2234 514-0
Email H0705@accor.com

Fees, including workshop (per delegate, plus VAT)

ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245
The conference fee is payable in advance after receipt of invoice and includes dinner on first day, lunch on second day and business lunch on third day, and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel.
Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21954.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site.
After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O.Box 10 17 64, 69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0, Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de, www.concept-heidelberg.de

For questions regarding content please contact:
Mr ClemensMundo (Director Operations) at
+49(0)62 21/84 44 42 or per e-mail at
mundo@concept-heidelberg.de

For questions regarding organisation etc. please contact:
Mr Niklaus Thiel (Organisation Manager) at
+49(0)62 21/84 44 43, or per e-mail at
thiel@concept-heidelberg.de.