

Speakers



Anthony Cannon
MSD, Switzerland



Richard Denk
SKAN, Switzerland



Maik Guttzeit
Bayer, Germany



Dr-Ing. Abdolreza
Kharaghani
University of Magdeburg,
Germany



Kristien Janssen
Pfizer, Belgium



Prof Alf Lamprecht
University of Bonn,
Germany



Carlo Marconi
Antares Vision, Italy



Dr Andrea
Weiland-Waibel
Explicat, Germany



Rita Welser
Boehringer Ingelheim,
Germany

Lyophilization 2023

Opportunities and Challenges for the Pharmaceutical Industry

23 -25 May 2023 | Cologne, Germany



Image: GEA, Germany

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

- Includes Workshop at GEA
 - With a view on the implications of
 the New EU GMP Annex 1!

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.

Backgrounds

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.

Chair

Thomas Beutler, GEA

Programme

Fundamentals of Freeze Drying

Basic concepts and processes

- General advantages of freeze drying, product quality issues
- Classification and comparison of freeze drying processes
- Freeze drying in vials: Fundamentals of mass and heat transfer
- Role and importance of freezing
- Influence of process parameters, material properties, dryer design
- Process optimization, monitoring and control
- Freeze drying of frozen particles: Fundamentals of heat transfer, influence of mixing

Lyo-cycle Development and PAT-based Optimization

- Critical quality attributes and critical process parameters:
 - assessment of critical process parameters through robustness testing to establish the process boundaries as the basis for the transfer from lab to commercial scale
- Freeze drying scale-up and validation:
 - process qualification/validation in lyophilization strategies in relation to FDA/EMA modern process validation guidelines
- Process control strategies:
 - hot and cold spot determination to allow for process control by using a product temperature PAT device

Containment: Lyophilization of Highly Potent Compounds

Freeze dryer equipped with isolator

- An introduction to highly potent products
- Which are the critical limits and how are they evaluated?
- Correlation between critical limits and cleaning validation
- Determination of critical process steps
- Hardware solutions
- Examples

Lyophilization Technology - Design Requirements and Technical Solutions

- 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.)

Freeze Dryers in Aseptic Production Lines – Challenges and Chances

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

Aseptic Process Simulation (Media Fills)

- Media Fill Design
- Worst-case parameters for Media Fills
- Validation of lyophilization processes with Media Fills
- Requirements for Media Fills
- Trends with regards to Media Fills

Atmospheric Spray Freeze Drying

- Process understanding, monitoring & control
- Design of continuous lyophilization

Implications of the new Annex 1

- EU GMP Annex 1 – What’s new?
- GMP Issues in Inspections & Requirements for:
 - Sterile manufacturing of Lyo products
 - Sterile packaging materials

Qualification/Validation - to get the System tested

- Risk assessment in the context of qualification and validation
- QbD aspects for successful lyophilization projects
- Tests during qualification and validation
- IQ/OQ/PQ
- Concepts for reduced testing approach
- Definition of scope of supply (URS vs. supplier standard)
- Risk based life cycle approach in accordance with GAMP 5

LYO-CHECK: Next Level Automatic Visual Inspection & CCIT for Lyophilized Products

- Dedicated illumination patterns, wavelengths and advanced imaging techniques
- Particles detection dedicated optical setup
- LYO Handling & Inspection: how to avoid product dirt and damages
- How AQL sampling was integrated into the LYO and powder inspection process of a primary pharma manufacturer
- Applicable CCIT and Process Analytical Technologies via non-destructive methodologies
- AI Empowerment

Workshops

Thursday, 25 May 2023

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.

Workshops

- **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 highlight new developments of production freeze dryer and includes technologies for controlled nucleation and continuous freeze drying.

A shuttle bus will bring you to Cologne Central Station at approximately 15.15 h. From Cologne Central Station, frequent airport connections are available.

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

Speakers



Anthony J. Cannon, MSD, Switzerland

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.



Richard Denk, SKAN, Switzerland

Richard is working at the company SKAN AG, headquartered in Allschwil in the position Senior Consultant Aseptic Processing & Containment. He founded some years ago the expert Containment group of the ISPE D / A / CH. The Containment Group published the Containment Manual Richard was responsible for in September 2015. He has spent about 20 years with the subject production of highly active / highly hazardous substances and has developed the containment pyramid.



Maik Guttzeit, Bayer, Germany

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, Belgium

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.



Prof Alf Lamprecht, University of Bonn, Germany

Alf Lamprecht has been Professor for Pharmaceutical Technology and Biopharmacy at the University of Bonn since October 2007. His current work includes the development of continuous atmospheric freeze-drying processes.



Carlo Marconi, Antares Vision, Italy

Carlo Marconi is currently head of Visual Inspection and CCIT technical and product Departments. After studying electrical engineering at the University of Padua (Italy), he began his professional career in a pharmaceutical company for automated visual inspection in R&D and electronic design, where he was also responsible for the electronic design of HVLD for CCIT. Since 2017 Mr. Marconi has been Managing Director of the Inspection Machines Business Unit at Antares Vision, now he is Inspection Machines Business Owner for Life Science & Cosmetics Industries.



Dr-Ing. Abdolreza Kharaghani,
University of Magdeburg, Germany

Abdolreza Kharaghani has received his PhD (2010) from the Otto von Guericke University Magdeburg in the field of drying technology and since then has been leading a research team on pore network modeling and drying. He is serving as a board member of the EFCE Working Party and the German Working Party on Drying and of the Steering Committee of the German Chapter of International Society for Porous Media.



Dr Andrea Weiland-Waibel, ExplicatPharma GmbH, Hohenbrunn, 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.



Rita Welser, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany

Rita Welser works since 1992 at Boehringer Ingelheim. She is currently responsible for process- and cleaning validation for the sterile production of biopharmaceuticals including aseptic processes (Media fills). In her role she takes actively part in customer audits and GMP inspections performed by the authorities.

Social Event



In the evening of the first day of the course you are cordially invited to a social event. 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:

Reservation Form (Please complete in full)

Lyophilization 2023 - with workshop at GEA, 23 - 25 May 2023, 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

CONCEPT HEIDELBERG
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D-69007 Heidelberg
GERMANY

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 HEIDELBERG will 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 can-

cellation 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, 23 May 2023, 12.30 to approx. 18.00 h
(Registration and coffee/snack 12.00 – 12.30 h)

Wednesday, 24 May 2023, 09.00 to approx. 17.15 h

Thursday, 25 May 2023, 8.00¹ -14.30² h, 15.15³ h)

¹ transfer from Park Inn Hotel 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

Park Inn by Radisson Köln City West

Innere Kanalstraße 15 | 50823 Köln, Germany

Phone +49 (0)221 5701 0 | Email info.colognecitywest@parkinn.com

On site, we will implement the necessary and required hygiene measures in close co-operation with the hotel. If infection rates and/or travel restrictions generally do not permit an on-site event, it will be conducted live online. In this case, you will be informed in due time.

Fees (per delegate, plus VAT)

ECA Members € 2,090

APIC Members € 2,190

Non-ECA Members € 2,290

EU GMP Inspectorates € 1,145

The conference fee is payable in advance after receipt of invoice and includes conference documentation, 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 message. Or you register online at www.gmp-compliance.org.

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.

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