ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Technical Operations Manager

Speakers


Anthony Cannon
MSD, Switzerland


Richard Denk
SKAN, Switzerland


Maik Guttzeit
Bayer, Germany


Kristien Janssen
Pfizer, Belgium


Prof Alf Lamprecht
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Dr Beate Reutter
GMP Inspectorate Federal State of Schleswig-Holstein, Germany


Andrea Sardella
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Prof Evangelos Tsotsas
University of Magdeburg, Germany


Dr Andrea Weiland-Waibel
Explicat, Germany


Rita Welser
Boehringer Ingelheim, Germany

Lyophilization 2022

Opportunities and Challenges for the Pharmaceutical Industry

Live Online Conference on 17/18 May 2022


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

Programme

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 **virtual workshop** where you can get a **hands-on experience in freeze drying yourself**. 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 Live Online 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 Live Online Conference is also of interest for participants working in the areas of container development and manufacturing process/packaging.

Chair

Thomas Beutler

Programme 17 May 2022

Please note

- Provisional timetable, the actual schedule may vary depending on the situation
- In certain cases participation may not be possible due to competitive reasons

09.00 - 09.15 h Welcome/Introduction

09.15 - 10.15 h

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

10.15 - 10.30 h Break

10.30 - 11.30 h

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

11.30 - 12.00 h

Workshop: 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.

12.00 - 12.30 h Q&A Session 1

12.30 - 13.30 h Break

13.30 - 14.30 h
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.)

14.30 - 14.40 h Break

14.40 - 15.15 h
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

15.15 - 16.00 h
Atmospheric Spray Freeze Drying

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

16.00 - 16.15 h Break

16.15 - 16.45 h
Workshop Tour including visit of shelf manufacturing area, freeze dryer testing as well as simulation and system integration.

16.45 - 17.15 h Q&A Session 2

Programme 18 May 2022

09.00 - 09.30 h
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.

09.30 - 10.15 h
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

10.15 - 10.30 h Break

10.30 - 11.15 h
Lyophilizer in Aseptic Production Lines - Challenges and Chances

- Loading and unloading of freeze dryers
- Lead times and campaigning
- Equipment characterizations
- FD cycles monitoring
- Vacuum and silicone oil leak tests
- Maintenance

11.15 - 11.45 h
Live Demonstration of Automated Loading and Unloading Systems
Demonstration of fully operative fixed and moveable load/unload system. Additionally, it will be possible to look at a system with special features, including online moisture control.

11.45 - 12.15 h Q&A Session 3

12.15 - 13.15 h Break

13.15 - 14.00 h
Implications of the new Annex 1

- EU GMP Annex 1 – What´s new?
- GMP Issues in Inspections & Requirements for
  - Sterile manufacturing of Lyo products
  - Personnel (e.g. qualification, training, gowning, monitoring)
  - Sterile packaging materials

14.00 - 14.10 h Break

14.10 - 14.45 h
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

14.45 - 15.30 h
100% Inspection

- 100% quality monitoring for continuous production process improvement
- Different inspections:
  - Container closure integrity (CCIT)
  - Visual Inspection (defects / particles)
  - AQL testing

15.30 - 15.45 h Break

15.45 - 16.15 h
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.

16.15 - 16.45 h Q&A Session 4

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

Speakers

Anthony J. Cannon, MSD, Switzerland
Tony is currently Director, Global Pharm Ops, External Manufacturing, Sterile, at MSD International located in Lucerne, Switzerland. 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 AG, 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 (Commissioning and Qualification) 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.

Dr Beate Reutter, GMP Inspectorate Schleswig-Holstein, Germany
Beate Reutter studied food technology in Muenster and Kiel. After 15 years in a Laboratory for quality control, she moved to the competent authority for GMP inspections in Schleswig-Holstein. She is currently head of the inspectorate and member of the inspector´s expert group 3 for sterile manufacturing at the ZLG.

Andrea Sardella, Stevanato Group, Italy
Since 2008 Andrea has been with Stevanato Group as R&D Manager to develop new automation and inspection products for pharmaceutical customers. Before that he was R&D Manager at Brevetti CEA where he developed innovative inspection technology for the inspection machines.

Prof Evangelos Tsotsas, University of Magdeburg, Germany
Evangelos Tsotsas holds the Chair of Thermal Process Engineering at Otto von Guericke University Magdeburg, Germany, since 1994. His research concentrates on drying and on particle formulation processes related to drying (coating, granulation, agglomeration). He is the recipient of the Hosokawa Award for Innovation and the ProcessNet Award for Excellence in Drying Research, Chairman of the German Working Party on Drying, former Chairman of the European Working Party on Drying, and editor of the book series Modern Drying Technology (Wiley-VCH).

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.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Conference in detail and with which you document your training.

Lyophilization 2022 is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. The Live Online Conference „Lyophilization 2022" is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP:
  APIs (ICH Q7), Medicinal Products, Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

Why not online? GMP/GDP seminars, webinars and e-learning

Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course.

Find out more at https://www.gmp-elearning.com
and https://www.gmp-compliance.org/recordings.

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Reservation Form (Please complete in full)

Lyophilization 2022 - Opportunities and Challenges for the Pharmaceutical Industry
Live Online Conference on 17/18 May 2022

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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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 January 2012).
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 http://www.gmp-compliance.org/eca_privacy.html). 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 of the Live Online Conference
Tuesday, 17 May 2022, 9.00 – 17.15 h
Wednesday, 18 May 2022, 9.00 – 16.45 h

All times mentioned are CEST.

Technical Requirements
For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At https://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)
ECA Members € 1,990
APIC Members € 2,090
Non-ECA Members € 2,190
EU GMP Inspectorates € 1,095
The conference fee is payable in advance after receipt of invoice.

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 will be made available to you prior to the Live Online Conference as PDF files. After the event, you will automatically receive your certificate of participation.

Ordering Recordings
Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

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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