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


Dr Matthias Kahl
Wilco, Switzerland


Prof Alf Lamprecht
University of Bonn, Germany


Prof Evangelos Tsotsas
University of Magdeburg, Germany


Markus Wahlen
GEA, Germany


Dr Andrea Weiland-Waibel
Explicat, Germany


Rita Welser
Boehringer Ingelheim, Germany

Lyophilization 2021

Includes Virtual Workshop at GEA

Live Online Conference 5/6 May 2021


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

Opportunities and Challenges for the Pharmaceutical Industry

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 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 Day 1

Please note

- Provisional timetable, the actual schedule may vary depending on the situation
- In certain cases a participation in the workshop 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 Media Fill

- 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 - 15.45 h Lyophilization Cycle Improvement and Control by using Mass Spectroscopy

Application of GEA LYOPLUS® for verification of freeze drying batches

- Online data acquisition for monitoring the solution concentration in the freeze drying chamber
- Verification of freeze drying end points for primary and secondary drying
- Investigation of opportunity to use LYOPLUS® as PAT tool during freeze drying cycles

15.45 - 16.00 h Break

16.00 - 16.30 h
Workshop Tour including visit of shelf manufacturing area, freeze dryer testing as well as simulation and system integration.

16.30 - 17.00 h Q&A Session 2

Programme Day 2

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 Atmospheric Freeze Drying

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

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 illustrated with a lyo process application.
- Different inspections:
  - Container closure integrity before and after the crimping process,
  - Cake residual moisture evaluated by means of NIR spectroscopy, combined with product identification and cake defect detection,
  - Downstream inline laser coding is clearly identifying the vial as a container which fully complies to all quality requirements.

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

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 2021 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 2021" 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

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 Head Sales Containment. He founded 8 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 nearly 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 and also member of ASME BPE Subcommittee on System Design. Since September 2018 he is working for Bayer as Global Technology Manager Aseptic and Sterile.

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.

Dr Matthias Kahl, Wilco, Switzerland
Matthias Kahl is a physicist and was Project Development Leader and Vice-Head of Development at Boegli-Graavures SA, Switzerland. Currently he is Head of Development and Lab Services at Wilco AG, Switzerland.

Prof. Alf Lamprecht
Alf Lamprecht is 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.

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).

Markus Wahlen, GEA, Germany

After obtaining the bachelor degree in engineering in 2011 Markus proceeded to work at GEA in the department of electrical engineering as a SCADA programmer. His position involved developing and realizing visualization concepts both for freeze dryers and automatic loading and unloading systems (ALUS®). He particularly specialized in the field of LYOPLUS® systems, GEA's solution for the application of mass spectroscopy in pharmaceutical freeze drying. At the end of 2016 Markus took up a new position in GEA's department of product and innovation as product manager for LYOPLUS®.

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.

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 2021 - with Virtual Workshop at GEA
Live Online Conference on 5./6. May 2021

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 %.

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 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

Wednesday, 5 May 2021, 9.00 – 17.00 h
Thursday, 6 May 2021, 9.00 – 16.45 h

All times mentioned are CEST.

Technical Requirements

For our Live Online Conferences, 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.

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:
Dr Andrea Kühn-Hebecker (Director Operations) at
+49(0)62 21/84 44 35 or per e-mail at
kuehn@concept-heidelberg.de

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