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Lyophilization 2019

Opportunities and Challenges for the
Pharmaceutical Industry

Includes Workshop at
GEA

Speakers:



Anthony Cannon
MSD, Switzerland



Richard Denk
SKAN, Switzerland



Maik Gutzzeit
Bayer, Germany



Christoph Herdlitschka
Wilco, Switzerland



Benoît Moreau
GSK, Belgium



Alexandra Stärk
*Novartis Pharma Stein,
Switzerland*



Prof Evangelos Tsotsas
*University of Magdeburg,
Germany*



Markus Wahlen
GEA, Germany



Dr Andrea Weiland-Waibel
Explicat, Germany



Image: GEA, Germany

14 – 16 May 2019, Cologne, Germany

Highlights

- Fundamentals of freeze drying
- Formulation development
- Process development
- 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 to pilot/
commercial-scale freeze dryer
 - Computer simulation
 - Automated loading and unloading systems
 - Innovations



Lyophilization 2019

14 - 16 May 2019, Cologne, Germany

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.

Modern 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, Benjamin Kammerich

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.)

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

Media Fill

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

How to organize a GMP-compliant lyophilization project

- Effective customer/supplier relation
- Definition of scope of supply (URS vs. supplier standard)
- Managing project organization and set up of controls
- Risk based life cycle approach in accordance with GAMP 5

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

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

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.

Workshops on Thursday, 16 May 2019



Image: GEA

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.

Target group of the Course

Process Engineers, Pharmaceutical Technologists, Pharmaceutical Formulation Scientists, Application Chemists, Drug Development Engineers, Particle Design Engineers.

■ 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 and controls.

■ 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 operative stationary and transfer cart system. Additionally, it will be possible to look at a multiple load/unload system with special features, including single row unloading and conveyance with clean-in-place functionality, and an isolator zone concept.

■ Workshop tour including visit of shelf manufacturing area, freeze dryer testing as well as software development and simulation.

■ New Innovations in Freeze Drying Applications

This workshop will highlight new innovations of production freeze dryer and includes processing highly potent products, vial track and trace and technologies for controlled nucleation.

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.

Social Event

In the evening of the first conference day, 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 the 2017 and 2018 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



Speakers



Anthony J. Cannon, MSD, Switzerland

Tony is currently Regional Director of Global Technical Operations, External Manufacturing for Sterile Products at MSD International located in Lucerne, Switzerland. He is responsible for all technical support of sterile drug products external manufacturing operations for the European Region. 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. He has 20 years' in the industry with experience in biologics, small molecules, medical devices, reagents, potent compounds, vaccines and cytotoxics, focused on lyophilization development and manufacturing. He has also presented on the fundamental of lyophilization, formulation, process development, thermal characterization, finished product analysis, and scale up and tech transfer at various conferences, seminars and pharmaceutical and biotech companies in North America, Europe and Asia.



Richard Denk, SKAN, Switzerland

Richard Denk is working at the company SKAN AG, headquartered in Allschwil in the position Head Sales Containment. Mr Denk founded 8 years ago the expert Containment group of the ISPE D/A/CH. The Containment Group published the Containment Manual Mr Denk was responsible for in September 2015. Mr Denk 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.



Christoph Herdlitschka, Wilco, Switzerland

Since 2016, Christoph Herdlitschka is leading the product management department at Wilco AG, Switzerland. In this role he is responsible for product strategy and road mapping as well as the innovation management. Besides inspection technologies, he is working on Pharma 4.0 and digitalization for pharmaceutical packaging processes. Christoph has more than 8 years of experience in pharmaceutical fill & finish solutions, including CCIT and inspection that he gained in his roles as a technical sales and project manager at Bausch+Ströbel and Wilco.



Benoît Moreau, GSK, Belgium

Mr Moreau is a senior specialist Manufacturing Science and Technology for filling & freeze-drying operations at GSK Vaccines. He holds a Pharm.D. and a MS in Pharmaceutical Sciences from the University of Grenoble, France and has more than fifteen years of experience in the pharmaceutical sector. He has worked for different companies and managed activities such as parenterals and solid dosage forms production, design of freeze-drying cycle, process evaluation/validation and transfer of product towards different internal and external sites. Now he's focusing on life cycle management of product and support operations in process improvements, troubleshooting, evaluation and implementation of new technology.



Alexandra Stärk, Novartis Pharma Stein AG, Switzerland

After studying Hygiene Technology at the Technical University of Albstadt-Sigmaringen, Alexandra Stärk has worked since 1995 at Novartis Pharma Stein AG and was heading the microbiological QA/QC department till October 2016. In October 2016 she moved into a new role within Novartis Pharma Stein AG and is now responsible for a team of microbiological experts in the department of Manufacturing, Science & Technology which defines the microbiological control strategies for sterile and non-sterile production on a global and local level.



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


Markus' career at GEA started in 2008 when he initiated a cooperative education at the DHBW Mannheim. After obtaining the bachelor degree in engineering in 2011 he proceeded to work 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 is a Pharmacist with a Ph.D. in Pharmaceutical Technology. She 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 Weiland held the position of Director Pharmaceutical Development. She is founder of Explicat Pharma GmbH and Managing Director since 2005. Hers and her team's experience covers the development of biopharmaceuticals, development of lyoformulations and lyocycles, analytical development and related QA as well as regulatory issues. Regarding lyocycle development, Explicat Pharma cooperates with iQ-mobil applying TEMPRIS®, the TEMPERATURE Remote Interrogation System. Explicat Pharma has been assigned several projects involving the modern process validation approach, including lyocycle robustness testings.

Easy Registration

 **Reservation Form:**
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

 **Reservation Form:**
+ 49 6221 84 44 34

 **e-mail:**
info@concept-heidelberg.de

 **Internet:**
www.gmp-compliance.org

Date

Tuesday, 14 May 2019, 12.30 to approx. 18.00 h,
(Registration and coffee/snack 12.00 – 12.30 h)
Wednesday, 15 May 2019, 08.30 to approx. 17.00 h
Thursday, 16 May 2019, 8.00¹-14.30² h, 15.15³ h

¹ transfer from H+ Hotel Hürth-Köln to GEA
(bus transfer will be provided)

² approx. end of course

³ approx. arrival at Cologne Central Station
(bus transfer will be provided)

Venue

H+ Hotel Hürth-Köln
Kreuzstr. 99 / Theresienhöhe
50354 Hürth, Germany
Phone +49 (0)2233 94400
Email koeln.huert@h-hotels.com

Fees including Workshop (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 and includes conference documentation, dinner on 14 May, lunch on 15 May and business lunch on 16 May, and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form 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.

In certain cases a participation in the workshop may not be possible due to competitive reasons.

Conference language

The official conference language will be English.

Organization and Contact

ECA has entrusted Concept Heidelberg with the organization of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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For questions regarding content please contact:

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

For questions regarding reservation, hotel, organisation, etc. please contact:

Mr Niklaus Thiel (Organisation Manager) at
+49-6221/84 44 43, or per e-mail at
thiel@concept-heidelberg.de

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Registration form (please complete in full)

Lyophilization 2019

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Mr Ms Title _____

First name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order No. (if applicable)**

Street / P.O. Box

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%
- until 1 week prior to the conference 50%
- 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 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 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.