ECA
European Compliance Academy


Image: Cilag

GMP-compliant Lyophilisation

With Plant Tour at Cilag and Parallel Workshops on PAT, Annex 1/Media Fill and Integrity Testing

Zürich, Switzerland, 14-15 October 2010

SPEAKERS

DR DIETER BACHMANN
Cilag AG/Johnson & Johnson, Switzerland

BORKE VAN BELLE
Cilag AG/Johnson & Johnson, Switzerland

KLAUS EICHMÜLLER
District Government of Upper Bavaria Munich, GMP Inspectorate

DR PETER GASSMANN
Cilag AG/Johnson & Johnson, Switzerland

DR THORSTEN HERKERT
Roche Diagnostics GmbH, Germany

DR WOLFRAM LINDNER
F. Hoffmann-La Roche AG, Switzerland

DR STEFAN MERKLE
Cilag AG/Johnson & Johnson, Switzerland

DR KATHRIN SCHERSCH
Novartis Pharma AG, Switzerland

ROLAND SCHUHWERK
Cilag AG/Johnson & Johnson, Switzerland

DR HARALD STAHL
GEA Pharma Systems, Germany

DANIEL STEINKELLNER
GEA Pharma Systems

DR ANDREA WEILAND-WAIBEL
Explicat Pharma GmbH, Germany

HIGHLIGHTS:

- Regulatory Requirements
- Quality Topics regarding Lyophilisation
- Equipment Qualification
- Media Fill
- Effect of collapse on pharmaceutical protein lyophilisates
- Risk Assessment and Process Development
- Process development requirements and PAT: Laser spectroscopy as a control tool for lyophilization cycles
- Implementation of new lyophilisation equipment
- Workshops

This conference is recognised for the ECA GMP Certification Programme „Certified Biotech Manager". Please find details at www.gmp-certification.eu

Objectives

How can regulatory requirements regarding lyophilisation be put into practice?
This question will be discussed with regard to

- Remodelling
- Equipment Qualification
- Risk Assessment and Process Development
- Trouble Shooting
- Media Fill

Also regulatory aspects inclusive inspection results presented by a GMP Inspector will be discussed. Additionally, a view in the future rounds off the course.

Parallel-Workshops regarding
- PAT
- Annex 1/Media Fill
- Integrity Testing

guarantee practical aspects

The target is to discuss current GMP aspects on lyophilisation and to inform about practical solutions.

Background

The individual steps of freeze-drying technology in the processing of raw materials into stabile products in the pharmaceutical and food industry are a highly complex manufacturing process. The strict requirements defined for aseptic production processes also apply to lyophilisation. Corresponding regulations by EC, FDA and PIC/S as well as more detailed guidelines (e.g. ISO 13408, PDA Technical Report 22) representing the state of the art are in place.

Target Audience

The event is directed at staff from companies who are responsible for the use of lyophilisation and who would like to inform themselves about current GMP aspects in this technology. It also targets engineers in the field of lyophilisation.

Moderator

Dr Stefan Merkle, Cilag AG/Johnson & Johnson, Schaffhausen, Switzerland

Programme

Regulatory Requirement for Lyophilisation
- Revision of Annex 1, EEC GMP Guide
- FDA Aseptic Guide
- FDA: Guide to Inspection of Lyophilization of Parenterals
- PIC/S Recommendation on Aseptic Processing
- ISO 13408-1
- PDA Technical Report 22
- Inspection findings regarding lyophilisation

Quality Topics regarding Lyophilisation
- Lyophilisation Phases in the view of QA
- Case Studies due to Trouble Shooting/Influences on the product and compliance
- Complaints and follow-ups

Equipment Qualification
- Common qualification (DQ, IQ, OQ, PQ)
- Case Study lyophilisator

Media Fill
- Regulatory Requirements
- To put regulatory requirements into practice
  - What media?
  - How many vials?
  - Simulation of the lyophilisation process
  - Incubation
  - Resulting
  - How to handle positive results

Programme (cont'd)

Effect of collapse on pharmaceutical protein lyophilisates

- Pro and Cons of lyophilisation
- Alternatives of lyophilisation
- Why is it worth drying close to the collapse temperature
- Effect of collapse on protein stability

Risk Assessment Tables as risk management tool for development and validation of lyophilisation processes

- Short introduction into risk assessment and PAT
- General information on the project
- Explanation of the risk assessment table
- Information on the project team structure, disciplines, structure of the risk assessment
- Lyoprocess analysed by RAT format
- PAT-Tools used in development and validation
- Data package – what can it be used for

Process development requirements and PAT: Laser spectroscopy as a tool to control for lyophilization cycles

- Development requirements
- Impact factors for lyophilization
- Disadvantages of classical control strategies in the Lyophilization
- Presentation of a Tunable Diode Laser Spectrometer as a tool on the lyophilization
- Strategies for controlling lyophilization cycles

Remodeling – The challenge of the implementation of a new lyophilisation line

- Project Management
- Running a multipurpose line
- Charging in an extremely limited space
- Manufacturing of clinical trials material on a production line
- Cleaning Validation aspects

Workshops

Workshop 1

- PAT-applications with lyophilisation

Moderation: Dr Harald Stahl
After a short theoretical introduction of PAT-applications the participants will discuss practical aspects how to put theory into practice.

Workshop 2

- Annex I/Media Fill

Moderation: Klaus Eichmüller
After a short introduction to Annex 1 the participants will discuss problems regarding this Annex – also in comparison to the FDA Aseptic Guide.

Workshop 3

- Integrity Testing

Borke van Belle, Cilag AG/Johnson & Johnson
After a short introduction in integrity testing the participants will discuss problems regarding integrity testing

Plant tour at Cilag

During the plant tour you will be informed about the application of current GMP requirements in the field of Lyophilisation.

Due to organisational reasons the plant tour is limited.
The participation is registered at a first come, first serve basis.

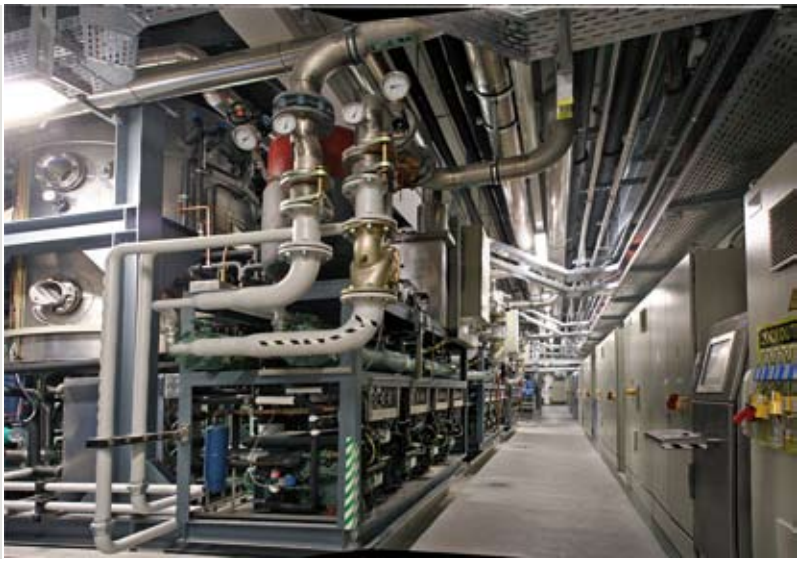


Image: Cilag

Speakers

DR DIETER BACHMANN, *Cilag AG/Johnson & Johnson, Switzerland*
Dieter Bachmann has worked for more then 10 years with Johnson & Johnson (Cilag AG) in R&D and operations. Since 2005 he is associate Director of the Qualification & Validation department.

BORKE VAN BELLE, *Cilag AG/Johnson & Johnson, Switzerland*
Borke Van Belle started his career at Johnson & Johnson in 1998 with Janssen Pharmaceutica, Beerse (Belgium) as Quality Assurance Expert. In his last position he was Senior Manager Quality Assurance for some Pharmaceutical Production Units. In December 2005, he transferred to Cilag AG, Schaffhausen (Switzerland) to take the role of Associate Director Lyophilisation Production Facility.

KLAUS EICHMÜLLER, *District Government of Upper Bavaria, GMP Inspectorate, Germany*
After working in the pharmaceutical Industry Klaus Eichmüller joined the District Government of Upper Bavaria in Munich. Since 1996 he is working in the field of GMP Inspections of manufacturer of medicinal products and importers. He is Deputy Head of the Central Surveillance of Medicinal Products in Bavaria.

DR THORSTEN HERKERT, *Roche Diagnostics GmbH, Germany*
In 2001, Thorsten Herkert joined AstraZeneca at the Plankstadt Site in Germany. In 2007 the AZ approch to Real-Time Release of tablet products was approved by the authorities and implemented in Plankstadt. In his role as AZ site Qualified Person for tablets produced at the Plankstadt site he released the first RTR batch produced. In 2008 Thorsten joined Roche Diagnostics Mannheim, Germany as a Plant Manager for Sterile Production of Biotech Products. In this plant commercial product as well as clinical trial materials are produced.

DR PETER GASSMANN, *Cilag AG/Johnson & Johnson, Switzerland*
After getting the Doctorate in Pharmaceutical Technology, Peter Gaßmann worked 6 years in developing protein solutions or lyophilisates at Novartis. Following this, he was Production Director of Pharmaceutical Production at Vetter Pharma in Germany for 12 years, with a focus on dual-chamber freeze drying. Since 2005, Peter Gaßmann joined the QA/QC department of Cilag/Johnson & Johnson, with his latest role being Director of Quality Operations and Tech Support.

DR WOLFRAM LINDNER, *F. Hoffmann-La Roche AG, Basle, Switzerland*
Wolfram Lindner, Pharmacist worked for more than 15 years in the pharmaceutical industry at Boehinger Mannheim and F. Hoffmann-La Roche, Basel. After several positions in the production (packing) and process development (solids, semisolid, liquids, parenterals), he heads the process development parenterals since 2007.

DR STEFAN MERKLE, *Cilag AG/Johnson & Johnson, Switzerland*
Stefan Merkle is currently Director of the Parenteral Business Unit of J&J's Global Pharmaceutical Supply Group at Cilag AG, responsible for fill and finish of all J&J parenteral biotech compounds manufactured in Europe and sold in all major markets. He's been with Johnson & Johnson for 18 years, in Pharmaceutical Development, Clinical Supplies Manufacturing, Technology Transfer and Operations

DR KATHRIN SCHERSCH, *Novartis Pharma AG, Switzerland*
Kathrin Schersch is working as a Senior Scientist at Novartis Pharma AG, Basel, Switzerland where she works in the field of formulation and process development of biopharmaceutical products. Before joining Novartis she completed a PhD at the University of Munich under the supervision of Prof. Gerhard Winter.

ROLAND SCHUHWERK, *Cilag AG/Johnson & Johnson, Switzerland*
Roland Schuhwerk joined CILAG, J&J in 2003. Currently he is Director Project Engineering Group of „Global Parenterals Technology Platform Europe".

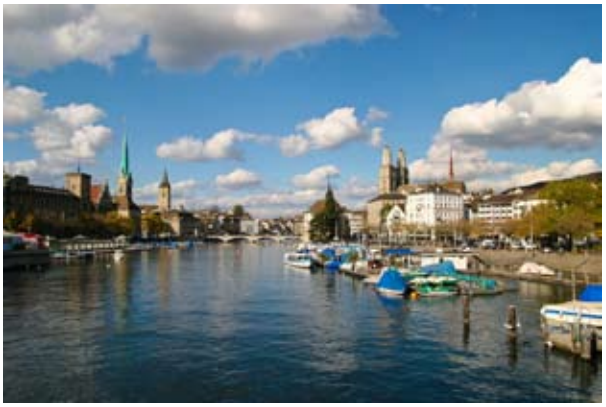
DR HARALD STAHL, *GEA Pharma Systems, Germany*
Dr Harald Stahl worked for 3 years in the Pharmaceutical Development of Schering AG in Germany, where he worked on the the aseptic production of pellets. Since 1995 he served within GEA Process Technology in various positions. Presently he owns the position of a Senior Pharmaceutical Technologist of GEA Pharma Systems. He has published more than 20 papers on various aspects of pharmaceutical production.

DANIEL STEINKELLNER, *GEA Pharma Systems*
Daniel Steinkellner studied process engineering at the Fachhochschule Cologne. After his studies he joined GEA Lyophil working in the construction of refrigeration technology and process engineering. Since two years he works in the department System Engineering as process engineer with the responsibility for R&D projects.

DR ANDREA WEILAND-WAIBEL, *Explicat Pharma GmbH, Germany*
After several leadership positions within Pfizer in production and development, she worked as Director Pharmaceutical Development at IDEA AG, a biotechnology company in Munich. She is managing director of Explicat Pharma GmbH specialised in CMC (Chemistry-Manufacturing-Controls) - technical project management for pharmaceutical development projects.

Social Event

On 14 October 2010, 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.



GMP Certification Programme

This conference is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

ECA Certified Validation Manager
ECA Certified QA Manager
ECA Certified API Production Manager
ECA Certified Quality Control Manager
ECA Certified Technical Operations Manager
ECA Certified Computer Validation Manager
ECA Certified Regulatory Affairs Manager
ECA Certified Microbiological Laboratory Manager
ECA Certified Sterile Production Manager
ECA Certified Biotech Manager
ECA Certified Pharmaceutical Development Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

What Are the Benefits of ECA?

First benefit:
During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years - free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website http://www.gmp-compliance.org

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
Thursday, 14 October 2010, 9.00 -18.00
(Registration and coffee 08.30 – 9.00)
Friday, 15 October 2010, 08.30 – 17.30
Transfer to the hotel 16.30 – 17.30 h via Zurich airport and train station Oerlikon.

Venue
Renaissance Zürich Hotel
Thurgauerstr. 101
8152 Zürich-Glattpark, Switzerland
Tel. +41 44 874 5000
Fax +41 44 874 5001

Fees
Non-ECA Members € 1,790.- per delegate plus VAT
ECA Members € 1,611.- per delegate plus VAT
APIC Members € 1700.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates € 895.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days 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 when you have registered for the event. Please use this form for your room reservation or be sure to mention "VA 6470 ECA Event" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 13 September 2010. 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.

Conference language
The official conference language will be English.

Organisation and Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Sven Pommeranz (Operations Director) at +49-62 21/84 44 47 or per e-mail at pommeranz@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Jessica Stürmer (Organisation Manager) at +49-62 21/84 44 43, or per e-mail at stuermer@concept-heidelberg.de.

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

69007 Heidelberg
Germany

Reservation Form (Please complete in full) +49 6221 84 44 34

GMP-compliant Lyophilisation
14-15 October 2010, Zürich, Switzerland
Please choose ONE workshop:
☐ Workshop 1 PAT-applications with lyophilisation
☐ Workshop 2 Annex I/Media Fill
☐ Workshop 3 Integrity Testing

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

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

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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 weeks 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 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)!