ECA Academy
Your GMP/GDP Information Source

Handling of Highly Potent Compounds

Usage of Single-Use Systems

Image: Lugaia

Flexibility for Operators & Product Safety

Speakers:


DR STEFAN BENKEL
Lonza


DR ANDREAS FLÜCKIGER
F. Hoffmann-La Roche


RAINER GLÖCKLER
Swissfillon


JORGE GUERREIRO
Hovione


DR RAINER NICOLAI
F. Hoffmann-La Roche


DR ANDREAS NIXDORF
SGS Institut Fresenius


DR PETER PÖSCHL
Holopack


VIKTOR SCHNYDER
Lugaia


DR HARALD STAHL
GEA

5-6 October 2016, Vienna, Austria

Highlights

- Toxicological evaluation of potent APIs
- GMP requirements on films used for SU equipment
- Available SU equipment for API production (small and large molecules)
- Evaluation of Leachables & Extractables
- Operational aspects of using SU equipment in the pharmaceutical environment
- Qualification of disposable equipment
- Case Study Holopack: Usage of a single-use isolator
- Case Study Lonza: Manufacture of ADCs with SU equipment
- Case Study Hovione: From installation to qualification
- Case Study Swissfillon: Final Filling of HPAPIs

This course is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager“.
Please find details at www.gmp-certification.eu

Handling of Highly Potent Compounds

5-6 October 2016, Vienna, Austria

Objectives

The main focus of this conference is on the connection of handling highly potent APIs and the usage of disposable equipment. GMP and safety aspects will be covered and examples from real life will be shown. Amongst others, the following topics will be discussed:

- Definition of the appropriate containment level
- Available single-use components and solutions
- GMP and ATEX requirements for single-use equipment
- Implementation of disposables in pharmaceutical processes
- Qualification of disposable equipment
- Risk handling strategies

Background

The usage of disposable and single-use equipment in the biopharmaceutical production has been growing for years. Well-known examples are disposable bags, hoses and bioreactors. But also in the manufacture of small molecule APIs, the usage of single-use equipment is increasing.

The pharmaceutical industry is now facing a new challenge after a long-time experience had been won with product contact interaction of stainless steel, ceramics or other alloys. Whereas the compatibility of traditional materials is (almost) no topic, plastic material raises discussions. Leachables and Extractables are the big topic here. Many studies have been done already, focusing on effects in aqueous buffer solutions. But coming to the production of small molecule APIs much fiercer conditions have to be considered with respect to organic solvents.
Another issue is caused by the advantages of single-use equipment. It is ready to use and does not have to be cleaned before use. So GMP-relevant steps are shifted towards the supplier of the plastic equipment who has to take care of the GMP-compliant production of his equipment, an appropriate packaging and the necessary documentation. The responsibility remains with the pharmaceutical manufacturer though. Also the handling of disposable equipment is much more demanding compared to robust stainless steel equipment. The training of the production staff gets thus even more important.
Furthermore, the SU equipment does not have to be cleaned after use which is - of course - one of the biggest advantages.

The containment aspect when manufacturing or handling potent APIs is independent from the material of the equipment. The production equipment has to be tight, not only from the GMP aspect to protect the product from the environment, but also from the occupational health point of view to protect the worker from the product. Both have to be proven by measurements.
Yet, with the flexible plastic equipment being much more sensitive to injuries compared to stainless steel equipment, optimised accident scenarios have to be in place.

Besides, there is another advantage of disposable systems. The shift to more single-use systems also brings a higher flexibility to production. More and more single-use isolators are used instead of fixed and immobile isolators - not only to avoid cleaning effort but also to minimize change-over times.

Target Audience

Managers and technical experts from production, development and occupational health & safety, responsible for:

- Production
- Design and installation of equipment
- Selection and testing of components

are the target group of this conference.

Moderator

Dr Harald Stahl

Programme

Toxicological fundamentals in the evaluation of highly potent APIs

- Legal requirements regarding worker safety and GMP requirements to control cross contamination
- Assessing the hazard: potency and toxicity of APIs and intermediates
- Usage of default values, category- and TTC-based approaches
- Usage of occupational hygiene data in the context of cross contamination control

Overview: available SU Systems for small and large scale API manufacture

In this presentation manufacturing steps of small and large scale API manufacturing are compared and available disposable equipment for each step is shown and discussed

- Processing
- Separation
- Transfer
- Sampling
- Filling

Films and Film Handling according to Pharma Requirements

- Film Manufacturing, processing, transportation and packaging
- Clean room conditions for film manufacturing and processing
- Available films and film materials
- ATEX vs GMP certification – how to combine both requirements
- How to seal SU equipment: Crimping vs Welding
- Proof of tightness: SMEPAC measurements

A pragmatic approach to Leachable/Extractable evaluation

- API and disposable material interactions, biocompatibility
- GMP and ISO certificates
- Designing a L&E study
- Usage of risk analysis tools
- Industrial practice and examples

Single Use Equipment - Operational Aspects and Qualification of Material

Using "Single Use Equipment" within the chemical production of API has tremendous advantages, but there are also plenty obstacles to overcome. Typical areas of conflicts are the needs of the production environment such as fulfilling ATEX rules and having a wide range of operational parameters like pressure and temperature versus the unquestionable need of qualifying the material of such systems. As these materials are in many cases different types of plastic there are wide-spread uncertainties how to handle e.g. material certificates.

Case Study Holopack: Implementation of a flexible and single-use Isolator

- Usage of a single-use isolator for open API weighing processes
- Contamination-free transfer
- Safety vs GMP aspects
- Qualification
- Necessary supplier documents (certificates, etc.)
- Containment performance (measurements/results)

Case Studies

Case study Hovione: Manufacturing and Release of Potent APIs made easy

- Installations design to manufacture/release potent compounds
- Containment strategies used (practical examples)
- Qualification of the installation / surrogate testing
- Procedures and training

Case study Lonza: Manufacturing of Antibody Drug Conjugates using Single Use Equipment

- High Potent classification at Lonza
- Facility Layout
  - Safety vs. Quality
  - ISO/GMP Classification
  - Pressure Cascade
- Single-Use Equipment
  - Advantages/Disadvantages
  - Equipment used
  - Single-Use Experiences
- Operational Hygiene: results

Case Studies

Case Study Swissfillon: Single Use <-> „Final Fill of HPAPIs" - A Contradictory Situation?

- Single Use in its established environment
- Environment – Health – Safety Policy of Swissfillon
- Implementing "Single Use" into compounding and Final Fill of HPAPIs
- Design Criteria to be met
- Layouts
- Pros and Cons
- Conclusion

Speakers

DR STEFAN BENKEL, LONZA AG
Stefan Benkel is chemist by training. He has been working for BASF PharmaChemikalien GmbH, where he was accountable for the manufacturing of several pharmaceutical APIs at large scale. In 2007 he moved to Lonza, where he was responsible for various API and investment projects, focusing on new technologies and technology transfer. In 2011 he took over the responsibility for the manufacturing of highly potent small molecule APIs. Since 2012 he has been heading the manufacturing for Antibody Drug Conjugates at Lonza AG.

DR ANDREAS FLÜCKIGER, F. HOFFMANN-LA ROCHE AG
An occupational physician by training, Andreas Flückiger has been the head of the occupational health services of the Roche Group for almost 30 years. He is active in leading roles in numerous national and international associations such as the International Association for Occupational and Environmental Health in the Chemical Industry (Medichem), in the Scientific Committee of the European Council for Ecotoxicology and Toxicology of Chemicals (ECETOC).

RAINER GLÖCKLER, SWISSFILLON AG
Rainer Glöckler is microbiologist by training. Since 1990 he has been employed by Lonza, starting in R&D, moving over into the role of a project leader followed by the responsibility as plant manager first. Since 2010 he was, as Senior Process Expert, part of the MSAT group in Lonza focused on Tech Transfer and new technologies. From March 2016 on he is moving over into the responsibility as Plant and Production Manager for final fill at Swissfillon.

JORGE GUERREIRO, HOVIONE FARMACIENCIA SA
Jorge Guerreiro holds a degree in Chemical Engineering. He joined Hovione as a process engineer and worked in the generic production in Lisbon as well as at the US Hovione site. After coming back to Portugal he moved into R&D – Pilot Plant where he was the lead engineer responsible for the manufacture and scale up of multiple API campaigns. In Pilot Plant he also gathered extensive experience in spray drying technique, working with several scales of spray dryers, from lab to industrial scale.

DR RAINER NICOLAI, F. HOFFMANN-LA ROCHE
Dr Nicolai is a process engineer and joined Roche in 1998 as an engineering project manager. Between 2000 and 2007 he worked for Evonik Industries (formerly Degussa) as process manager for the production of ultra high pure raw materials and later as head of production and technology for this business unit. Since 2007 he has worked for Roche again as project manager with the focus on handling highly active substances.

DR ANDREAS NIXDORF, SGS INSTITUT FRESENIUS GMBH
Andreas Nixdorf has sixteen years of experience with analytical questions. Since 2007, he has been responsible for project management at the customer service pharma at SGS Insitute Fresenius with focus on development of methods, validation and analysis of leachables and extractables.

DR PETER PÖSCHL, HOLOPACK® VERPACKUNGSTECHNIK GMBH
Dr Pöschl studied Process Engineering with focus on fluids. He has gained many years experience in various leadership positions. In 2013 he was appointed as Managing Director at Holopack® Packaging Technology, the largest contract manufacturer of BFS Technology in Europe. Dr Pöschl is also responsible for implementing the HP² efficiency programme.

VIKTOR SCHNYDER, LUGAIA AG
Viktor Schnyder studied engineering and worked in the development of gearboxes for robots as well as in the development of welding processes for the pharmaceutical industry. In 2006 he founded the company Lugaia. In 2009 he started a cooperation with Optima Packaging. He holds four patents in the field of containment and transfer of sterile products.

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

Social Event

On 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.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme (ECA Certified Technical Operations Manager). 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
ECA Certified GMP Auditor
ECA Certified GDP Compliance Manager
ECA Certified Packaging 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 are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to 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. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

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
Wednesday, 5 October 2016, 10.00 to approx. 17.30 h
(Registration and coffee 09.30 – 10.00 h)
Thursday, 6 October 2016, 08.30 to approx. 15.45 h

Venue
Austria Trend Hotel
Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
Fax +43/1/891 109 050

Accomodation
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.

Conference fees (per delegate plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-Members € 1,790
EU GMP Inspectorates € 895

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

Registration
Via 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
ECA has entrusted Concept Heidelberg with the organisation of this event.

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For questions regarding content:
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For questions regarding reservation, hotel, organisation etc.:
Ms Katja Kramer (Organisation Manager) at
+49-62 21/84 44 16 or per e-mail at
kramer@concept-heidelberg.de.

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Registration form (please complete in full)

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5-6 October 2016, Vienna, Austria

☐ Mr ☐ Ms Title _____

First name, surname

Company

Department

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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 %
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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).

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