ECA Academy
Your GMP/GDP Information Source

Speakers


Dr Gunther Bechmann
Pfizer


Dr Andreas Flückiger
Formerly
F. Hoffmann-La Roche


Dr Filipe Gaspar
Hovione


Dr Nadine Gerlach
Lonza


Sebastian Hillbrand
Skan


Dr Morcos Loka
Minapharm


Dr Rainer Nicolai
F. Hoffmann-La Roche


Julian Petersen
groninger


Vimal Sachdeva
WHO


Prof Christa Schröder
University Albstadt
Sigmaringen


Robert G. Schwarz
FH Campus, Vienna


Dr Harald Stahl
GEA


Fred Wulfgramm
Merz Pharma

Handling of Highly Active Products

Part of PharmaCongress 2023

28/29 March 2023 | Wiesbaden, Germany


State-of-the-art Continuous Tableting equipment, Hovione Sete Casas, Portugal

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Highlights

- Case Study Pfizer: Construction of an OEB 4 Manufacturing Site
- Case Study Lonza: SU Equipment in the Commercial Manufacture of ADCs
- Case Study Minapharm: Design of a HPAPI Biomanufacturing Facility
- Case Study F. Hoffmann-La Roche: Handling of Solids with Single-Use Systems
- Case Study Merz: Production of sterile & highly potent Products
- Managing Occupational Health Risks in Potent Compound Handling
- New Approach for assessing the Performance of High-Containment Systems
- Technical Possibilities for contained Product Handling
- GMP Inspection Experience of Products containing Hazardous Substances
- New EU GMP Annex I: Cross Contamination Control Strategy

GMP–PHARMA CONGRESS

This conference is part of PharmaCongress 2023

Objectives

Main focus of this conference is on the connection of cGMPs with safety aspects, especially on avoiding cross contamination and minimizing exposure. Recently completed projects and facilities for the production of highly potent products demonstrate the state of the art.
It will also deal with exposure & cleaning validation limits and the possibilities offered by containment technology, shown by real life examples from pharmaceutical industry including oral solid dosage forms and sterile medicinal products.

Background

Exposure to active pharmaceutical ingredients must be kept within acceptable limits. The protection of employees must be achieved primarily by technical measures and not through personal protective equipment. Several containment solutions like glove boxes, isolators, special valves and transfer ports are available. This equipment has to fit to the surrounding, the product requirements and the organisational circumstances. Therefore detailed planning is necessary.
But GMP also has requirements for contamination or the avoidance of contamination / cross contamination as far as possible (see chapters 3 (Premises & Equipment) and 5 (Production) of the EU GMP Guidelines. By introducing the PDE concept (Permitted Daily Exposure) by the European Medicines Agency, occupational medicine and GMP requirements are now based on the same scientific basis, namely on the question: how much exposure is uncritical for a person (whether patient or employee)? This important question has to be answered for both, dedicated and multipurpose equipment.
And since the new Annex 1 also requires measures against cross contamination, this is also becoming increasingly relevant for sterile products. And all the more so, the more potent the starting materials or products are. How can a cross contamination control strategy look like and how is it documented?
Learn from recently finished projects and see how the state-of the-art looks like. This applies to oral solid forms as well as to liquid, sterile medicinal products.

Target Audience

This conference aims at persons from production, engineering and quality, responsible for

- Design of new manufacturing areas
- Operation of processes containing highly potent material
- Occupational safety
- Cleaning concepts and contamination prevention

as well as engineering and plant-construction companies working in containment projects.

Moderator

Dr Harald Stahl, GEA

Programme 28 March 2023

Principles of Assessing and Managing Occupational Health Risks in Potent Compound Handling

Dr Andreas Flückiger, formerly F. Hoffmann-La Roche

- Legal requirements regarding worker safety
- Assessing the hazard: potency and toxicity of the compounds. Occupational exposure limits and exposure bands
- Ensuring the right level of process containment: Design exposure limits as drivers for equipment selection. The illusion of "closed processes".
- Setting of health-based exposure limits and process containment: great benefits for GMP

Exposures to pharmaceuticals at the workplace must be controlled to below acceptable limits. For most APIs, the manufacturer himself needs to develop these limits, and compliance with them must be documented. Protection of the workers from overexposure must be achieved primarily by technical means and not by means of personal protective equipment. Equipment must have adequate containment so that the required exposure control is ensured at least in all routine situations. Existing facilities must be upgraded accordingly. The toxicological and pharmacological basis of assessing APIs with the objective of worker protection is the same as the one justifying GMP cleaning criteria and acceptance of multi-product use of a facility. Primary process containment is the key tool for the prevention of airborne cross-contamination and via the one by mechanical transfer.

Review of technical Requirements for contained Product Handling

Dr Harald Stahl, GEA

- Product transfer- review of current possibilities
- Sampling 1 - Review of possibilities for contained sampling
- Sampling 2 - Examples for in-line measurements allowing to drop sampling
- Cleaning: Examples of automatic cleaning

Case Study Pfizer: Constructional and regulatory Challenges of an OEB 4 Manufacturing Site

Dr Gunther Bechmann, Pfizer
Prof. Christa Schröder, University Albstadt Sigmaringen

Special requirements have to be considered for planning and construction of buildings intended for manufacture of highly potent medicinal products

- Implementation of special GMP Requirements
- Special staff training
- Environmental aspects

GMP Inspection Experience of Products containing hazardous Substances & Introduction to WHO's Prequalification Program

Vimal Sachdeva, WHO

- WHO Prequalification (PQ) history and process
- WHO PQ of pharmaceutical products containing hazardous substances
- GMP-compliant handling of hazardous substances
- Challenges during GMP inspections

Case Study Hovione: Spray Drying and Continuous Tableting of highly active Materials

Dr Filipe Gaspar, Hovione

- Relevance of Spray Drying and Continuous Tableting in the Pharmaceutical Industry
- From risk assessment to lab development and to commercial manufacturing
- Specific requirements for Spray Drying and Continuous Tableting
- Examples of lab to commercial units capable of handling potent APIs

Programme 29 March 2023

Cross Contamination Control Strategy in Light of the new Annex I

Robert G. Schwarz, FH Campus, Vienna

- OHS-requirements and CCS according new Annex 1
- Cross Contamination Control - the unseen stepchild of them with maybe a high potent habit
- How to implement a compliant CCS with Containment requirements properly
- "Close, closer, isolator - but what about RABS?" - Question from the desperate pharmacies

Case Study Lonza: Use of Single-Use Equipment for the commercial Production of highly potent ADCs

Dr Nadine Gerlach, Lonza

- Challenges in the production of ADCs (Antibody drug conjugates)
  - GMP aspects
  - Personal safety
- Current challenges in the use of single use components in the pharmaceutical industry
  - Multisourcing
  - Qualification of single-use materials
- A look into the future: Single-use equipment in ADC production

Case Study Minapharm: Design of a HPAPI Biomanufacturing Facility

Dr Morcos Loka, Minapharm

- How to apply risk management in the design of a facility for biopharmaceutical HPAPIs
- How to achieve compliance with US & EU GMP and EHS requirements
- What controls can be applied regarding equipment closure, flow of materials and personnel, waste management, cleanroom, HVAC
- How to set a suitable containment strategy
- What are the possible challenges and how to overcome
- How to quantitatively evaluate the effectiveness of these controls

Case Study Merz: Production of sterile & highly potent Products

Fred Wulfgramm, Merz
Julian Petersen, groninger
Sebastian Hillbrand, Skan

Handling of Solids with Single-Use Systems in the chemical Synthesis of highly active Substances

Dr Rainer Nicolai, F. Hoffmann-La Roche

- Available Equipment & Technology
- Pros and Cons of Single-Use Systems
- Case Studies: Experience with SUT in chemical synthesis of highly active substances

New Approach for assessing Dust-Retention Performance of high-containment Systems

Dr Andreas Flückiger, formerly F. Hoffmann-La Roche

- Continuous or periodic dust emission monitoring. Results in µg/m³.
- Early detection of otherwise unnoticed leakage
- Intervention before worker exposures become too high

High containment systems have generally been tested for their containment performance, for example based on ISPE's "SMEPAC" guide. This reflects the design and performance of the equipment as it leaves the factory of its manufacturer. Over time, these systems may lose some of their containment capability, and this is often not visible to the naked eye. The Digital Canary is a system to continuously or periodically monitor dust emissions with the objective to detect leakage before it becomes critical for worker safety. Contrary to a particle counter, it delivers the results in µg/m3. The results can serve as a trigger for preventive maintenance and can replace costly substance-specific industrial hygiene sampling. The system is compatible with a range of solid dosage applications. The Digital Canary is being developed for additional uses.

Speakers

Dr Gunther Bechmann, Pfizer

Gunter Bechmann is a Pharmacist and since 2005 employee of Pfizer in different leading positions.

Dr Andreas Flückiger
Formerly F. Hoffmann-La Roche

An occupational physician by training, Andreas Flückiger has been the head of the occupational health services of the Roche Group for 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).

Dr Filipe Gaspar, Hovione

Vice President, Technology Intensification.

Dr Nadine Gerlach
Lonza

Senior Teamlead Operations, PCP.

Sebastian Hillbrand
Skan

Strategic Product Manager.

Dr Morcos Loka, Minapharm

Dr Morcos Loka is Training Manager & GMP Advisor at Minapharm, Cairo, Egypt. He has over 20 years of experience in the pharmaceutical & biopharmaceutical industry including manufacture of sterile and non-sterile products, handling and conduction of of audits, GMP training, QRM studies including manufacturing of HPAPIs in shared facilities and design of pharmaceutical and biopharmaceutical manufacturing facilities. He also has a Master in Business Administration (MBA), B.Sc. (Hons) in Pharmaceutical Sciences.

Dr Rainer Nicolai
F. Hoffmann-La Roche

Dr Nicolai has been involved in the handling of high purity and high activity substances since 1998. With a total of 15 years of experience as a project manager and containment expert at Roche, he is involved in a wide range of issues with high practical relevance.

Julian Petersen,
groninger

Director of Business Development and Product Management.

Vimal Sachdeva, WHO

Vimal Sachdeva, based in Geneva, Switzerland, has been working with the WHO PQ program as a Senior GMP inspector since October 2020. Prior to joining WHO, he worked as a Senior GMP Auditor with Singapore's Health Sciences Authority.

Prof Christa Schröder
University Albstadt Sigmaringen

Christa Schröder is a Pharmacist, has been QP at Janssen-Cilag. Since 2009 she is Professor at the University of applied sciences Albstadt-Sigmaringen.

Robert G. Schwarz, FH Campus, Vienna

Robert Schwarz, graduate in "Bioprocess Engineering" and "Biotechnological Quality Management", was responsible for environmental monitoring as well as validation of decontamination systems at Baxter (now Shire). Since 2010 he is working as a lecturer in the field of biotechnology with a focus on validation/qualification, aseptic process methods and cleanroom technology at the University of Applied Sciences Vienna.

Dr Harald Stahl, GEA

Dr Harald Stahl worked in the Pharmaceutical Development of Schering AG in Germany. At that time his main interest was the aseptic production of pellets. Since 1995 he served within GEA Process Technology in various positions. Presently he owns the position of a Group Director Application & Strategy Management of GEA. He has published more than 20 papers on various aspects of pharmaceutical production.

Fred Wulfgramm, Merz Pharma

Fred Wulfgramm has a wealth of experience in Engineering in clean room industries. He has worked in this capacity for different Companies in the Pharma, Cosmetics and Food Industries in a lot of roles. Today he is Head of Engineering at the Merz Pharma Site in Dessau.

PharmaCongress 2023

GMP–PHARMA CONGRESS

The guiding theme of the PharmaCongress 2023 on 28/29 March will be „users sharing challenges and solutions in practice". Therefore, benefit from your colleagues' experience and from the direct information exchange at PharmaCongress & PharmaTechnica 2023.

The Tracks

As a participant you can switch between any of the tracks any time and also visit the PharmaTechnica Expo with more than 100 international exhibitors.

Conference Tracks	28 Mar	29 Mar
European Aseptic Conference	✓	✓
New Developments in Barrier Systems & Robotics	✓	✓
PUPSIT: Complying with the Main Annex 1 Changes	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Pharma 4.0 & Digitalisation	✓	✓
Handling of Highly Active Products	✓	✓
ATMP – Manufacturing, Quality & Safety	✓	✓
PharmaTechnica Expo	✓	✓

Find out more about the other conference tracks on our website www.pharma-congress.com.

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GERMANY

Reservation Form (Please complete in full)

Handling of Highly Active Products - Part of PharmaCongress 2023, 28/29 March 2023, Wiesbaden, Germany

☐ **Day 1 & 2 (28/29 March 2023)**
☐ **Day 1 (28 March 2023)**
☐ **Day 2 (29 March 2023)**

☐ **Yes, I would also like to take part in the Social Event on the evening of 28 March 2023.**

Title, first name, surname

Department | Company

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

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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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Conference
Tuesday, 28 March 2023, 09.00 - 18.00 h
Wednesday, 29 March 2023, 09.00 - 17.00 h
Registration: 28/29 March 2023, 08.00 - 09.00 h

Venue
RheinMain CongressCenter (rmcc)
Friedrich-Ebert-Allee 1
65189 Wiesbaden
Phone: +49 (0) 611 / 1729-444
veranstaltungsservice-rmcc@wicm.de

Fees (per delegate, plus VAT)
The one day ticket is available for € 690,- plus VAT (until 31 January 2023 only € 590,- plus VAT), both days for € 1,380 plus VAT (until 31 January 2023 only € 1,180 plus VAT). It includes participation in any conference track of PharmaCongress 2023 on that day(s) and the visit of the PharmaTechnica Expo. In addition, lunch and beverages during the tracks and in breaks as well as the social event on the evening of the first congress day, 28 March is included; please mark if you would like to attend the Social Event.

The fee is payable in advance after receipt of invoice.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms close to the CongressCenter. You will receive a room reservation form when you have registered for the conference. 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.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. 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.
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