ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Walid El Azab
QP Pro Servives, Belgium

Werner Hofstetter
Octapharma, Austria

Arjan Langen
GE Healthcare, The Netherlands

Carsten Moschner
CMC3, Germany

Inga Marie Schlägl
Bayer, Germany

Axel Schroeder
Concept Heidelberg, Germany

Robert G. Schwarz
GxP TrainCon, Austria

Wolf-Dieter Wanner
Germany

Contamination Control Strategies

Requirements, Measures and Strategies

05 - 07 November 2024, Berlin, Germany

with an optional Post-Conference Workshop „**Risk Assessment in Contamination Control**“ on 08 November 2024, Berlin, Germany

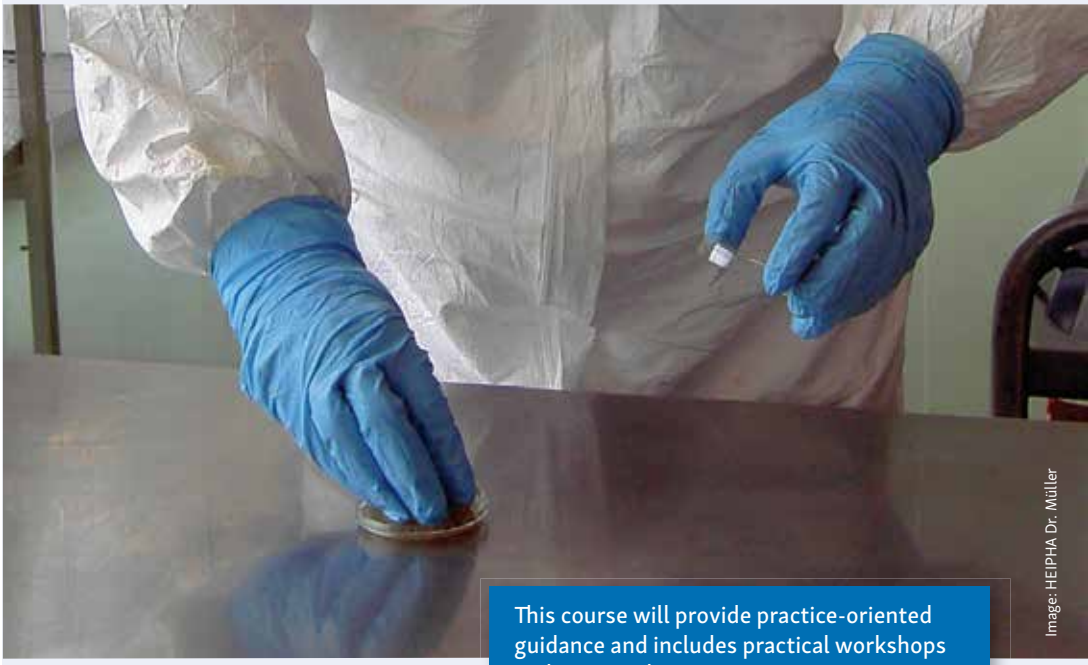

Image: HEIPHA Dr. Müller

This course will provide practice-oriented guidance and includes practical workshops and case studies

Highlights

- Regulatory Requirements, incl. Annex 1
- Principles of Hygiene and Microbiology
- Disinfectants: Characteristics, Selection and Qualification
- Sources of Contamination and Preventive Measures
- Microbiological Monitoring and Trending
- Risk Management
- Handling of OOS Results
- Cleanroom Garment and Single-Use Consumables
- Hygiene of Personnel and Training of Operators
- Contamination Control Strategy – a Dynamic System

Highlights Post-Conference Workshop

- ICH Q8, Q9 and Q10 Principles
- How to apply Risk Assessment in Contamination Control
- Example of a Contamination Control Strategy
- Short Interactive Session (Participants do an FMEA on a Certain Topic)

Objective

In most cases the implementation of appropriate hygiene programmes and measures have been implemented as an essential part for the manufacturing of pharmaceutical products. A series of regulations address the subject of microbiological facility control but GMP requirements are mostly described in more general terms. But how can they be introduced in pharmaceutical companies in a practice-oriented way? What is state-of–the-art? How should detergents and disinfectants be used?

The overall goal of such a system is to prevent microbiological contamination of the pharmaceutical product. But even if such a system has been established, it is of utmost importance that these programmes and measures are understood and followed by all operators who carry out quality-relevant work. Therefore, regulations demand intensive training in hygiene issues.

And in the **new Annex 1**, the overarching interlinking of the individual measures is now also clearly required with the **Contamination Control Strategy.**

Against the background of these requirements, this ECA education course is designed to cover all important aspects of controlling microbiological contamination. It ranges from sources of contamination to validation of cleaning and disinfection processes and training of operators. A focus will be on those problems that occur frequently in pharmaceutical production; possible solutions to these challenges will be discussed.

The course ranges from regulatory requirements and microbiological basics, sources of contamination, hygiene measures and monitoring to life cycle management of the overall strategy.

Background

In pharmaceutical manufacture, cleaning and disinfection and other hygienic measures are important and decisive process steps for fulfilling the quality requirements on the medicinal product. To carry them out properly, personnel needs to be both qualified and motivated.

All national and international pharmaceutical GMP regulations — especially those on sterile manufacturing — call for cleaning and hygiene programmes in the pharmaceutical companies.

The lack of control of microbiological (and other) contamination is an outstanding integral part of inspection findings.

Not all authorities regularly publish overviews or inspection results, but if one looks at the available data of the last 20 years from various inspection authorities, the following picture emerges:

Between 1995 and 2005, the potential risk of microbiological contamination was the No 2 critical GMP deficiency and the No 1 major GMP deficiency observed during inspections requested by the CHMP/CVMP of EMEA.

MHRA's review of the deficiencies 2011/2012 issued 57 deficiencies related to personnel as well as 75 contaminations by chemical/physical and microbial causes.

In 2018 and 2019, Annex 1 was the second most frequently mentioned annex of the GMP Guide when it came to deviations in MHRA inspections.

A permanent high number of FDA warning letters with microbiological deviations or issues in cleaning and contamination control:

Fiscal Year 2016 - 23 WL
Fiscal Year 2017 - 24 WL
Fiscal Year 2018 - 16 WL
Fiscal Year 2019 - 32 WL
Fiscal Year 2020 - 25 WL
Fiscal Year 2021 - 36 WL

This current situation clearly shows how important it is to deal with this issue in depth and also why an overall strategy for linking the various measures plays such an important role.

Target Audience

People who are involved in

- Microbial Monitoring
- Implementation of Hygiene Programmes
- Selection and Qualification of Disinfectants
- Handling of microbial Deviations
- Training of Operators for Monitoring

Moderator

Axel H. Schroeder, Concept Heidelberg

Social Event

In the evening of the first course 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.

Programme

Module 1: Regulatory Requirements and Background

Basic Principles of Microbiology, Hygiene and Contamination Control

- Microorganisms
  - Microbial growth
  - Characteristics
  - Sources
- Basic hygienic actions
- Cleaning/disinfecting/sterilization
- Way of contamination

Regulatory Requirements

- General regulatory requirements and guidelines
- Prevention of contamination and cross contamination
- Requirements for validation
- ISO standards
- Quality Risk Management

Sources of Contamination and Preventive Measures

- Sources of contamination throughout the facility
- HVAC
- Water
- Raw materials and packaging components
- Personnel and clothing

Effective Training of Operators

- Regulatory requirements (EU-GMP, FDA Guidelines, experiences from inspections)
- Methods and tools
- Measurement and documentation of training success
- Practical approaches

Module 2: Monitoring and Control Strategies

Microbiological Monitoring

- Monitoring of non-sterile processes
- Aseptic manufacture:
  - developing a programme
  - interpreting data
  - regulatory requirements
- Monitoring methods, air, surface, people
- A complete programme for a sterile product

Cleanroom Garment - Requirements, Selection and Laundering

- Different fabrics and their characteristics like filtration capacity and wearing comfort
- Garment systems oriented by the cleanroom class
- Requirements on decontamination and laundering
- Outsourcing

Microbiological Control of Water Systems

- Water as raw material
- Contamination sources within the water system
- Technical aspects
- Control methods
- Microbiological testing of water

Trending of Environmental Monitoring Data

- How do you do it?
- What do the results really tell you?
- How should you react on the results?
- Criteria of selection of disinfectants
- Rotation of antimicrobial substances considering their chemical interaction
- Cleaning potential of disinfectants
- Users acceptance

Module 3: Cleaning/Disinfection – Measures, Pit Falls, Deviation Handling

Cleaning and Disinfection of Surfaces

- Criteria of selection of disinfectants
- Rotation of antimicrobial substances considering their chemical interaction
- Cleaning potential of disinfectants
- Users acceptance

Qualification of Disinfectants

- Guidance documents, standards and regulatory requirements
- Basis for qualification
- Case study for qualification of disinfectants
- Efficacy – how to control?

Hygiene of Personnel – Cleanroom Behaviour

- Contamination from personnel
- Classic employee deviance
- Gowning procedure
- Hand disinfection

Case Study: Managing Disinfection Programmes

- Hygiene programme
- Cleanroom concept
- Demands on environment, equipment and personnel
- Cleaning and disinfection concept

Validation of a Decontamination System for Production Equipment, Process Devices and Cleanrooms

- Technical requirements & background
- Qualification of a fogging system
- Validation of a fogging process

Parallel Workshops

During the second day, parallel workshops will be conducted in order to reinforce the content of the lectures and to discuss practical aspects in detail.

Workshops will be offered on the following topics:

1. Case Studies: Disinfections Issues
Practical examples of microbial deviations after cleaning and disinfection activities. Causes, faults and correcting actions.

2. Handling of OOS Results
Failure investigation, following corrective actions and preventive actions.

Module 4: Additional Challenges and Annex 1-compliant Overarching Strategies

Cleanroom Consumables - a so called „Cent Product", but with Consequences

- Definition of cleanroom consumable products
- The impact during the daily application
- How is that reflected in guidelines?

Quality Risk Management

- Risk assessment:
  - Risk identification
  - Risk analysis
  - Risk evaluation
- Risk management

Contamination Control Strategy - An interdisciplinary and Dynamic System

- Formulate a CCS
- Implement a CCS and develop a strategic plan to make the strategy work as intended by mapping/designing the organizational structure, procedures, control processes, distributing resources, developing the decision-making processes, etc.
- Evaluate the CCS efficiency to ensure process performance and product quality while improving the CCS level over time.

Risk Assessment in Contamination Control

From ICH to Annex 1 –
Risk Evaluation as a Part of Contamination Control Strategies

Background and Objectives

Risk-based approaches have gained considerably in importance in all branches in recent years. Pharmaceutical production, quality assurance and quality control would be unthinkable without them. Starting with the FDA initiative "cGMPs for the 21st Century" for the introduction of the risk-based approach, through the subsequent ICHQ9 guideline on risk management, which can now be found as Part III of the EU GMP guidelines, to the revised Annex 15 with a wealth of risk analyses, these principles are anchored everywhere. With the revision of Annex 1, risk management is also increasingly becoming part of the main guideline for the manufacture of sterile pharmaceutical products.

In this workshop on the principles, regulations and application of risk assessment in the context of contamination control, you will gain insight into the relevant underlying guidelines and guides as well as valuable pointers for practical implementation using practical examples. The following areas are covered:

- General introduction on risk assessments
- ICH Q8, Q9 and Q10 principles
- How to apply risk assessments in contamination control
- Example of a Contamination Control Strategy
- Interactive session: FMEA

Target Group

The workshop is designed for personnel of pharmaceutical companies, their suppliers and representatives of authorities with responsibilities in Contamination Control, Aseptic Manufacturing, Quality Assurance, Quality Control, Internal Quality Audits, External Inspections.

Programme

General Introduction on Risk Assessments

- Principles of ICH Q9
- Patient safety and product quality
- Dos and don'ts
- Tools and methods

ICH Q8, Q9 and Q10 Principles

- Quality by Design (QbD)
- Criticality of quality attributes and process parameters
- Control strategy life cycle
- Knowledge management

Post-Conference Workshop

How to apply Risk Assessments in Contamination Control

- Pro-active vs. reactive
- FMEA for equipment and processes
- Risk assessments for impact assessments
- HACCP for contamination control

Example of a Contamination Control Strategy

- Contamination control master file
- Reference document
- Annual report

Short Interactive Session (Participants do an FMEA on a Certain Topic)

- Executing an FMEA (on a sterilizer or isolator)
- Evaluation – what went well and what were the challenges?

Speakers

Walid El Azab
Co-founder and Managing Director, QP Pro Services, Belgium

Walid, is a senior consultant, specializes in GMP and GDP activities, with a focus on contamination control, sterility assurance, and inspection readiness. Acting as a Qualified Person and Responsible Person, he possesses expertise in non-sterile and sterile processes, including drug substance and product manufacturing. Walid's auditing proficiency covers CMOs, API manufacturers, and suppliers. Engaged in professional organizations, he contributes to conferences, and industry guidelines. Committed to education, He is a professor at Brussels and Liège University and co-founded the QP Academy. He provides consultancy support through QPM Consulting and QP Pro Services, acting as a strategic partner for pharmaceutical industry business continuity.

Werner Hofstetter
Octapharma GmbH, Austria

After his studies of food- and biotechnology, he was engaged as head of laboratory of waste processing and as department manager at the pharmaceutical industry. Since 2002 he is working at the pharmaceutical production of Octapharma Pharmazeutika GmbH, Vienna and is, among other things, responsible for validation of disinfectants and the cleanroom monitoring. Since 2006 he is head of aseptic production at Octapharma.

Arjan Langen
Director Sterility Assurance, GE Healthcare, The Netherlands

Arjan Langen has over 20 years of experience within the field of pharmaceutical microbiology. He worked for several pharmaceutical and biotech companies (Nobilon, DSM, MSD) and had various local and global roles within QC, QA, manufacturing and auditing. Currently he is a Director Sterility Assurance at GE Healthcare, responsible for the global Sterility Assurance program. Besides, he is a member of the ECA Annex 1 Task Force and of the Dutch Society of Pharmaceutical Microbiology. He is microbiologist by training, qualified IRCA/QCI auditor and Green Belt certified.

Carsten Moschner
CMC3, Germany

Carsten Moschner studied engineering economics at the University for applied Sciences in Karlsruhe. Until 2023, he was owner and CEO of Dastex with a focus on research and development as well as optimising of textile cleanroom garment. Carsten is a member of several expert committees, e.g. deeply involved in the new VDI 2083 chapter about the suitability of cleanroom equipment. In 2024 he founds his new consulting service CMC3.

Dr Inga Marie Schlägl
Bayer - GP Grenzach Produktions GmbH, Germany

Inga Marie studied Biology at the Universities Konstanz and Freiburg. Since 2014 she is working for Bayer holding different roles in quality control, project management and production. Currently, she is part of the Site Leadership team of the Supply Center Grenzach as Head of Bulk manufacturing and Steriles.

Axel H. Schroeder
Concept Heidelberg, Germany

Axel Schroeder got his degree in Biology at Ruprecht-Karls University Heidelberg. From 1994 to 2000 he was Territory Manager for Hygiene and Medical Devices at Henkel Ecolab GmbH. From 2000 to 2005 he was Key Account Manager for Industrial Hygiene and Contamination Control at Ecolab GmbH, Düsseldorf, and from 2003 to 2005 Member of the International Cleanroom-Team of Ecolab. Between 2005 and 2008 he was engaged at Basan GmbH as Key Account Manager for Pharmaceuticals and Biotechnology. Since 2008 he is operations director at Concept Heidelberg for microbiology and biotechnology.

Robert G. Schwarz
GxP TrainCon, Austria

Robert Schwarz has a degree in bioprocess engineering and biotechnological quality management. From 2001, he led the environmental monitoring team at Baxter, and from 2005 to 2018 he was a validation specialist for device qualification, sterilisation validation and cleaning validation. Since 2010, he has also been passing on his experience as a university lecturer. In 2019, he began working as a freelance trainer and founded his consulting company GxP-TrainCon in 2022.

Wolf-Dieter Wanner
Germany

Wolf-Dieter Wanner studied pharmacy at the University of Munich. He started working in a free pharmacy and later joined Henkel KGaA in Düsseldorf to establish a German decontamination business relating to the industry. At Ecolab Deutschland GmbH as a sales manager he integrated the German clean room business with Adams Healthcare and Shield Medicare into an international contamination control team focused upon pharmaceutical aseptic manufacturing. Since 2011 he works as a freelance consultant.

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P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Contamination Control Strategies, 05 - 07 November 2024, Berlin, Germany
☐ Post-Conference Workshop „Risk Assessment in Contamination Control“, 08 November 2024, Berlin, Germany

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 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 %.

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

Contamination Control Strategies:
Tuesday, 05 November 2024, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 06 November 2024, 08.30 – 18.00 h
Thursday, 07 November 2024, 08.30 – 13.30 h

Post-Conference Workshop:
Friday, 08 November 2024, 09.00 – 15.00 h
(Registration and coffee 08.30 09.00 h

Venue

HYPERION Hotel Berlin
Prager Straße 12 | 10779 Berlin, Germany
Phone +49(0)30 236250 0
Email hyperion.berlin@h-hotels.com

Fees (per delegate, plus VAT*)

Contamination Control Strategies:
ECA Members € 2,190 | APIC Members € 2,290
Non-ECA Members € 2,390 | EU GMP Inspectorates € 1,145
The fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on two days and all refreshments.

Post-Conference Workshop:
ECA Members € 990 | APIC Members € 1,040
Non-ECA Members € 1,090 | EU GMP Inspectorates € 545
The fee is payable in advance after receipt of invoice and includes lunch and all refreshments.

Save up to 400 € by booking both the conference and the post-conference workshop!
ECA Members € 2,780 | APIC Members € 2,880
Non-ECA Members € 2,980 | EU GMP Inspectorates € 1,490
The fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on three 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/POG 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.

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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