Contamination Control Strategies
Requirements, Measures and Strategies
26 - 28 September 2023 | Barcelona, Spain

with an optional Post-Conference Workshop “Risk Assessment in Contamination Control” on 29 September 2023, Barcelona, Spain

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.

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
STERIS Corporation, Belgium
Walid El Azab is a Technical Services Manager for the Life Sciences Division of STERIS Corporation. He currently provides technical support related to cleaning chemistries, disinfectants and sterility assurance products and their application and validation. Walid has held various positions including Project Manager, Inspection Readiness Manager, Quality and Regulatory Manager, and Qualified Person (QP).

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
CEO Dastex GmbH & Co. KG, Germany
Carsten Moschner studied engineering economics at the University for applied Sciences in Karlsruhe. Currently he is 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.

Dr Inga Marie Schlägl
Bayer - GP Grenzach Produktions GmbH, Germany
Inga Marie studied Biology at the Universities Konstanz and Freiburg. After her degree, she worked at the clinical research Center in Freiburg until 2013. In 2014 she joined Bayer as GMP Compliance Manager. In her current position, she is leading the department for monitoring and media.

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
University of Applied Sciences, FH Campus Vienna, Austria
Robert Schwarz studied biotechnology and quality management. He joined Baxter in 2001 as coordinator of environmental monitoring. From 2005 he was validation specialist responsible for equipment qualification, sterilisation validation and cleaning validation. Since 2010 he is university lecturer in the field of biotech at the University of Applied Sciences in Vienna.

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.
Reservation Form (Please complete in full)

- Contamination Control Strategies, 26 - 28 September 2023, Barcelona, Spain
- Post-Conference Workshop „Risk Assessment in Contamination Control“, 29 September 2023, Barcelona, Spain

Title, first name, surname

Department                                           Company

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

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Organisation and Contact

For questions regarding organisation etc., please contact:

Ms Isabell Helm (Organisation Manager) at +49(0)62 21/84 44 49, or at helm@concept-heidelberg.de

For questions regarding content please contact:

Mr Axel H. Schroeder (Director) at +49(0)62 21/84 44 40, or at schroeder@concept-heidelberg.de

For questions regarding content please contact:

Ms Isabell Helm (Organisation Manager) at +49(0)62 21/84 44 49, or at helm@concept-heidelberg.de

The official conference language will be English.

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 there will not be any opportunity to print the course materials before and after the event. The fee is payable in advance. The certificate of participation will automatically be sent as part of the final invoice.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG on-line via the reservation form by email or by fax message. The fee is payable in advance. The certificate of participation will automatically be sent as part of the final invoice. Additional fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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Venue

Barcelo Sants Hotel 
Pl Pius Catalans s/n, 08041 Barcelona, Spain
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Fees (per delegate, plus VAT*)

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