Contamination Control Strategies

18-20 November 2020 | Barcelona, Spain

Microbial Contamination Sources / Preventive Measures / Disinfection Management and Staff Hygiene Requirements

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

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

Speakers

Werner Hofstetter
Octapharma, Austria

Arjan Langen
GE Healthcare, The Netherlands

Carsten Moschner
Dastex, Germany

Inga Marie Schlägl
Bayer, Germany

Axel Schroeder
Concept, Germany

Robert Schwarz
FH Campus Vienna, Austria

Wolf-Dieter Wanner
Germany
Programme

Objective

In most cases the implementation of appropriate hygiene pro-
grammes 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 con-
trol but GMP requirements are mostly described in more general
terms. But how can they be introduced in pharmaceutical com-
panies 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.

Against the background of these requirements, this ECA educa-
tion course is designed to cover all important aspects of control-
ing microbiological contamination. It ranges from sources of
contamination to validation of cleaning and disinfection pro-
cesses and training of operators. A focus will be on those prob-
lems that occur frequently in pharmaceutical production; possi-
ble solutions to these challenges will be discussed.

Background

The lack of control of microbiological contamination is an out-
standing integral part of inspection findings.

Between 1995 – 2005, the potential risk of microbiological
contamination was the No 2 Critical GMP Deficiency and the
No 1 Major GMP Deficiency observed during inspections re-
quested by the CHMP/CVMP of EMEA.
MHRA’s review of the deficiencies 2011/2012 issued 57 defi-
ciencies related to personnel as well as 75 contaminations by
chemical/physical and microbial causes.

A Permanent high number of FDA warning letters with micro-
biological 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

This actual state clearly demonstrates the importance to con-
cern oneself with this topic in detail.

In pharmaceutical manufacture, cleaning and disinfection meas-
ures 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 motivat-
ed.

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

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

Programme

Module 1: Requirements and Background

Basic Principles of Microbiology, Hygiene and Con-
tamination 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
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?

Module 3: Basics and Implementation of a Cleaning/Disinfection Strategy

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

Case Study: Managing Disinfection Programmes
- Hygiene programme
- Cleanroom concept
- Demands on environment, equipment and personnel
- Cleaning and disinfection concept

Hygiene of Personnel – Cleanroom Behaviour
- Contamination from Personnel
  - Classic Employee Deviance
  - Gowning procedure
  - Hand disinfection

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

Module 4: Additional Challenges

Quality Risk Management
- Risk Assessment:
  - Risk Identification
  - Risk Analysis
  - Risk Evaluation
- Risk Management

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

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?

Moderator
Axel H. Schroeder, Concept Heidelberg

Speakers
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.
Speakers

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 that works on the detailed review of the draft revision text of Annex 1. He is microbiologist by training, qualified IRCA/QCI auditor and Green Belt certified. He is a member of the PDA and a member of the Dutch Society of Pharmaceutical Microbiology.

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 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.
Date
Wednesday, 18 November 2020 09.30 h – 18.00 h
(Registration and coffee 09.00 h – 09.30 h)
Thursday, 19 November 2020, 08.30 h – 18.00 h
Friday, 20 November 2020, 08.30 h – 13.30 h

Venue
Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 (0)93 503 53 00
Email sants@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on two 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.

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 please contact:
Mr Axel H. Schroeder (Operations Director) at
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schroeder@concept-heidelberg.de

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Isabell Neureuther (Organisation Manager) at
+49(0)62 21/84 44 49, or at
neureuther@concept-heidelberg.de

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.

GMP/GDP Certification Scheme
Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.
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 %,
   - Cancellation until 1 weeks prior to the conference 50 %
   - Cancellation 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 HEIDELBERG will 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 in 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.

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GERMANY

Reservation Form (Please complete in full)

Contamination Control Strategies, 18-20 November 2020, Barcelona, Spain

Title, first name, surname

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Important: Please indicate your company’s VAT ID Number

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