ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Walid El Azab
Steris Corporation, Belgium

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

Contamination Control Strategies

Live Online Training from 18 - 20 November 2020

From the microbiological basics via contamination sources, hygiene measures and monitoring to life cycle management

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
- CCS – a Dynamic System

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

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.

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.

Background

The lack of control of microbiological contamination is an outstanding 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 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.

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

This actual state clearly demonstrates the importance to concern oneself with this topic in detail.

In pharmaceutical manufacture, cleaning and disinfection 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.

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

Provisional timetable, the actual schedule may vary depending on the situation

Day 1 - Module 1: Regulatrory Requirements and Background

09.00 – 09.15 h Welcome/Introduction

09.15 – 10.15 h
Basic Principles of Microbiology, Hygiene and Contamination Control

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

10.15 -11.15 h
Regulatory Requirements

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

11.15 -11.30 h Break

11.30- 12.30 h
Sources of Contamination and Preventive Measures

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

12.30 – 13.00 h
Questions and Answers

13.00 – 14.00 h Break

14.00 - 15.00 h
Effective Training of Operators

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

Day 1 - Module 2: Monitoring and Control Strategies

15.00 – 15.45 h
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

15.45 - 16.00 h Break

16.00 – 16.45 h
Microbiological Control of Water Systems

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

16.45 – 17.30 h
Trending of Environmental Monitoring Data

- How do you do it?
- What do the results really tell you?
- How should you react on the results?

17.30 – 18.00 h
Questions and Answers

Day 2 - Module 3: Personnel Hygiene and Implementation of a Cleaning/Disinfection Strategy

08.30 – 09.30 h
Cleaning and Disinfection of Surfaces

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

09.30 - 10.30 h
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?

10.30 - 10.45 h Break

10.45 – 11.45 h
Hygiene of Personnel – Cleanroom Behaviour

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

11.45 -12.15 h
Questions and Answers

12.15 – 13.15 h Break

13.15 – 14.15
Case Study: Managing Disinfection Programmes

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

14.15 – 15.00 h
Case Studies: Disinfections Issues

- Practical examples of microbial deviations after cleaning and disinfection activities.
- Root causes and pitfalls
- Measures for troubleshooting in practice
- Preventive measures to avoid errors

15.00 – 15.15 h Break

15.15 – 16.15 h
Handling of Microbiological OOS/OOL Results

- Failure investigation,
- Following corrective actions and preventive actions

16.15 – 17.15 h
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

17.15 – 18.00 h
Questions and Answers

Day 3

08.30 – 09.30
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

09.30 – 10.30 h
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?

10.30 – 10.45 h Break

10.45 – 11.45 h
Quality Risk Management

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

11.45 – 12.45 h
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.

12.45 – 13.30 h
Questions and Answers

Moderator

Axel H. Schroeder, Concept Heidelberg

Date of the Live Online Training

Wednesday, 18 November 2020 09.00 h – 18.00 h CET
Thursday, 19 November 2020, 08.30 h – 18.00 h CET
Friday, 20 November 2020 , 08.30 h – 13.30 h CET

Technical Requirements

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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.

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 will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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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Speakers

Walid El Azab, STERIS Corperation, 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.

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 until 2013 at the clinical research Center in Freiburg. 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. He worked in different positions with responsibilities in contamination control for Henkel, Ecolab and Basan. Since 2008 he is operation 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 and later Ecolab. There 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 freelancer consultant.

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Reservation Form (Please complete in full)

Contamination Control Strategies, Live Online Training from 18-20 November 2020

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