Contamination Control

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

SPEAKERS:

Werner Hofstetter  
Octapharma, Austria

Arjan Langen  
GE Healthcare, The Netherlands

Carsten Moschner  
Dastex, Germany

Dr Inga Marie Schlägl  
Bayer, Germany

Axel Schroeder  
Concept Heidelberg, Germany

Robert Schwarz  
FH Campus Vienna, Austria

20-22 November 2019, Barcelona, Spain

PROGRAMME:

- Regulatory Requirements
- 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.

Please find details at www.gmp-certification.eu
Objectives

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 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.

Increasing number of FDA warning letter to sterile manufacturers/microbiological deviations:
- Total Number 2013 – 16 WL
- Total Number 2014 – 30 WL
- Until August 2015 – 28 WL

This actual state clearly demonstrates the importance to concern oneself with this topic in detail.
Microbiological Control of Water Systems
- Water as raw material
- Contamination sources within the water system
- Technical aspects
- Control methods
- Microbiological testing of water

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?

Cleaning and Disinfection of Surfaces
- Criteria of selection of disinfectants
- Rotation of antimicrobial substances
- Considering their chemical interaction
- Cleaning potential of disinfectants
- Users acceptance

Module 2: Implementation and Issues in Real Life

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

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: Disinfection Issues
Practical examples of microbial deviations after cleaning and disinfection activities. Reasons, faults and corrective actions.

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

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

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

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?

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.

Arjan Langen, GE Healthcare, The Netherlands
Arjan Langen was manager of Microbiological Quality Control and Quality Assurance officer at Intervet International in The Netherlands before he joined Nobilon International. At Nobilon he was appointed Quality Assurance Manager, responsible for the cGMP-approval of the new multi-purpose vaccine production facility in Boxmeer, The Netherlands. In 2008 Arjan became Director Compliance at DSM Pharmaceutical products and in 2009 he founded his own company for training and consulting in the field of pharmaceutical microbiology. In 2011 he became Pharmaceutical Specialist at MSD in The Netherlands, being responsible for sterile manufacturing of new products in Oss. Since 2018 he is working as Sterility Assurance Expert / QC Microbiology Lead Life Sciences | GE Healthcare. 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
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 operation director for microbiology and biotechnology at Concept Heidelberg.

Robert Schwarz, 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.

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.
Date

Wednesday, 20 November 2019, 09.30 h – 18.00 h  
(Registration and coffee 09.00 h – 09.30 h )
Thursday, 21 November 2019, 08.30 h – 18.00 h
Friday, 22 November 2019, 08.30 h – 13.30 h

Venue

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Fax +34 93 4906045
e-mail sants@barcelo.com

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectors € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on first and second day 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 event. Reservation should be made directly with the hotel. Early reservation is recommended.

Conference language

The official conference language will be English.

Organisation and Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Axel H. Schroeder (Operations Director) at
+49 (0)6221 / 84 44 10 or per e-mail at
schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Isabell Neureuther (Organisation Manager) at
+49 (0)6221/84 44 49, or per e-mail at
neureuther@concept-heidelberg.de

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

GMP/GDP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity Manager

On the Internet at www.gmp-certification.eu you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.
If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Contamination Control
20-22 November 2019, Barcelona, Spain

☐ Mr  ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company’s VAT ID Number

P.O. Number (if applicable)

Street/P.O. Box

City

Zip Code

Country

Phone/fax

E-Mail (please fill in)

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.