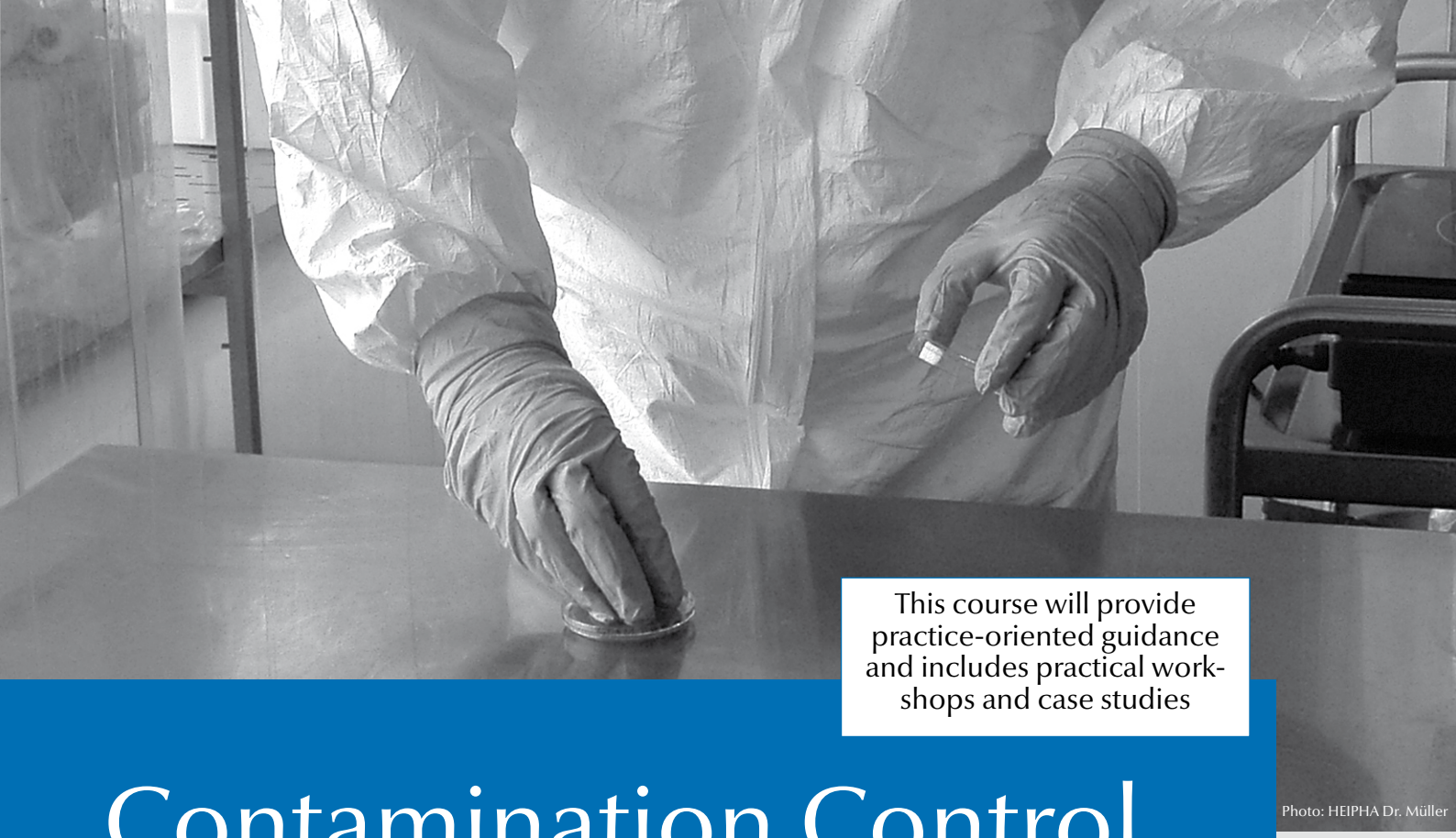


This course will provide practice-oriented guidance and includes practical workshops and case studies

Photo: HEIPHA Dr. Müller

Contamination Control

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

21 – 23 May 2014, Prague, Czech Republic

SPEAKERS:

Werner Hofstetter
Octapharma, Austria

Arjan Langen
MSD, The Netherlands

Markus Schad
decontam, Germany

Axel Schroeder
Concept Heidelberg, Germany

Robert Schwarz
Baxter, Austria

Hans Peter Volkland
gmp-experts, Germany

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, Requirements, Laundering and Outsourcing
- Hygiene of Personnel and Training of Operators

ECA
EUROPEAN COMPLIANCE ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager". Please find details at www.gmp-certification.eu

Contamination Control

21 – 23 May 2014, Prague, Czech Republic

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 – 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 EMA.

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

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 Group

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

Programme

Module 1 Requirements and Background

Basic Principles of Hygiene and Microbiology
- 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

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

Trending of Environmental Monitoring Data
- How do you do it?
- What do the results really tell you?
- How should you react on the results?

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

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. Reasons, faults and corrective actions.

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

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

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

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

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, *MSD, 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. He is a member of the PDA and a member of the Dutch Society of Pharmaceutical Microbiology.

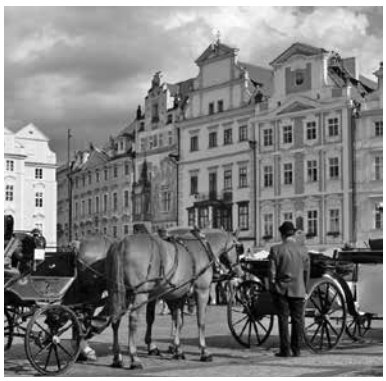
Robert Schwarz, *Baxter AG, Austria*
After his apprenticeship as medical/technical analyst Robert Schwarz joined at IMCL / Labor Hernals, Vienna. From 2001 to 2005 he stays as coordinator of environmental monitoring at Baxter, Vienna. Since 2005 he is validation specialist for equipment qualification. He is responsible for the validation of decontamination systems.

Markus Schad, *decontam GmbH, Germany*
After working for several years in risk control in the bank sector, Markus Schad started in 2004 in laundry business at the Schlee GmbH (Germany) with focus on cleanroom services. Since 2006 he is managing director of decontam - specialised on full-service concepts for cleanroom garments and training.

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 HenkelEcolab 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 at Concept Heidelberg for microbiology and biotechnology.

Dr Hans-Peter Volkland, *gmp-experts GmbH, Germany*
Dr Volkland studied Chemistry at the University of Constance and graduated in microbiology (ETH Zürich). He worked for several years in R&D and in various quality positions (QA, QC, Validation, Qualification). In 2001 he joined PCS (Pharmaceutical Consultancy Services) as Senior Consultant and Senior Auditor. In 2006 he set up his own consultancy company, Pharma and API Consulting (PAAC). In 2009 he founded GMP Experts which provides GMP consulting, auditing and training for the pharma and API business.

Social Event



On 21 May, 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@gmp-compliance.org

Internet:
www.gmp-compliance.org

Date

Wednesday, 21 May 2014 09.30 h – 17.30 h
(Registration and coffee 9.00 h – 09.30 h)
Thursday, 22 May 2014, 08.30 h – 18.00 h
Friday 23 May 2014, 08.30 h – 13.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague, Czech Republic
Phone +(0) 420 261 191 111
Fax +(0) 420 261 225 011

Fees

ECA Members € 1,790.- per delegate plus VAT
APIC Members € 1,890.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,990.- per delegate plus VAT
EU GMP Inspectorates € 995.- per delegate plus VAT
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 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:
Axel H. Schroeder (Operations Director) at
+49 (0)62 21 / 84 44 10 or per e-mail at
schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager)
at +49 (0)62 21/84 44 22 or per e-mail at
bach@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 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

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:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Contamination Control,
21 – 23 May 2014, Prague, Czech Republic

☐ 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)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

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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 %,
- until 1 weeks prior to the conference 50 %
- 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 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)