ECA Certified Sterile Production Manager Course*

You can participate in two interactive workshops:

- Risk evaluation using examples of aseptic processing
- Environmental monitoring

Photo: LSMW Zander

Risk Management in Sterile Manufacturing

17-18 May 2011, Copenhagen, Denmark

SPEAKERS:

Irmhild Bernhard
F. Hoffmann-La Roche AG, Switzerland

Dr Klaus Haberer
Compliance Advice and Services in Microbiology GmbH, Germany

Mats Johansson
MJ Micro Compliance, Sweden

PROGRAMME:

- Introduction: Risk Management in Sterile Manufacturing
- Risk Management Tools
- Use of Risk management tools
- System Approach for Sterile Pharmaceuticals
- Risk Management and Personnel
- Risk Management in Sterilisation Processes
- Media Fill Simulation and Risk Management
- Environmental Monitoring and Risk Recognition
- Failure Investigations and CAPA

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Risk Management in Sterile Manufacturing

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Learning Goals

Why you should attend this course:

- You get to know the methods of risk analysis and learn how to apply them to the specific questions of sterile manufacturing,
- You can distinguish between critical and uncritical risks and accordingly define measures for controlling these risks,
- In workshops, you analyse sterile processes, assess possible risks and suggest suitable countermeasures.

Background

The manufacture of sterile medicinal products is a risk-prone process. Whereas the product safety of terminally sterilised products can usually be ensured by validating the sterilisation process, aseptic manufacture makes great demands on process safety. As early as 2001, the FDA had defined the „Risk-based Approach" for future inspections; involving high risk in the sense of the authority's definition and therefore being automatically in the focus of inspections is „aseptic processing".

Even in advance, one has to study the question whether each process step poses a contamination risk, and if so, which one. Good risk management consists in identifying and assessing risks in time and taking measures in the production process in order to control or – if possible – eliminate these risks.

Everyday routine confronts us with a multitude of potential risks. Which of them are critical, which ones rather uncritical? How can risk assessment be done and which rationales play a role in this decision?

The speakers provide you with practice-oriented approaches to assessing, controlling and reducing risks in „sterile processes" and to get safely through inspections.

Target Group

The event is directed at all those working in the field of sterile manufacturing who have to implement risk-based approaches in planning and assessing their company's production.

Programme

Introduction: Risk managment in sterile manufacturing

- Sterility concept
- Sterilization and Aseptic Processing
- Strategies and risks
- Use of risk evaluation in sterile manufacturing

Risk management tools

- FMEA and HACCP
- Case study with HACCP analysis

Use of Risk management tools

- Case studies

System approach for sterile pharmaceuticals

- Process flow-charts
- Unit operations
- Suitability of products for sterile manufacturing
- Contamination sources
- Bioburden and the risks for product and process
- Risks during processing
- Risks in terminal sterilization and aseptic processing

Risk management and personnel

Interactive Workshop
Risk evaluation using examples of aseptic processing

Based on of process-flowcharts of a fictive process, risks for product sterility will be evaluated. Ad hoc groups formed from the participants will discuss potential risks and group proposals for mitigation measures will be elaborated and justified. Group proposals will be presented in a plenary session of all participants.

Risk management in sterilisation processes

- What are critical risks in sterilisation processes?
- Steam sterilisation
  - Bioburden
  - Steam quality
  - Sterilisation process
- Membrane filtration of solutions
  - Filter integrity
  - Products properties
  - Properties of microorganisms
  - Risk reduction by sterilisation process development
- Risk reduction in processing after sterilisation

Media Fill simulation and risk management

- Media fill simulation concept
- Contamination sources
- Worst case approaches
- Interventions
- Use of risk evaluation

Environmental Monitoring and risk recognition

- Monitoring methods and their limits
- Microbiological clean room qualification
- Evaluation of sample points
- Definition of sample frequency
- Monitoring results and their significance

Interactive Workshop
Risk Management and Environmental Monitoring

Based on environmental monitoring data of a fictive aseptic processing facility, risks to the process will be presented. Ad hoc groups formed from the participants will discuss environmental results and their significance and propose action plans and corrective or preventive measures. Group proposals will be presented in a plenary session of all participants.

Failure Investigations and CAPA

- Case study of a positive Sterility test
- OOS investigation
- Designing the CAPA actions
- Implementation and Verification

Social Event

On 17 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.

Speakers

Irmhild Bernhard,
F. Hoffmann-La Roche AG, Basel, Switzerland
Irmhild Bernhard obtained a degree in hygiene technology and a Master degree in biomedical engineering at the University of Sigmaringen. Since 2007 she works at Hoffmann La Roche for the start up of the Microbiology in the New Parenteral Facility in Kaiseraugst/Switzerland. She is responsible for the clean room qualification, the implementation of the environmental monitoring soft ware and the process definition of the lab. As Head of EMT / Microbiology in this new Facility she is now responsible for the microbiological lab, the environment monitoring, water/gas monitoring and the media fill control

Dr Klaus Haberer, *Compliance Advice and Services in Microbiology GmbH, Cologne, Germany*
Klaus Haberer studied Biology and Biochemistry at the Universities of Tübingen and Cologne. From 1983 to 1986, Head of Microbiological Quality Control at Hoffmann-La Roche AG, Grenzach, Germany. From 1986 to 1999 Head of Microbiological Quality Control and later Director Microbiology Global Quality Operations at Hoechst Marion Roussel AG in Frankfurt, Germany. Beginning from 1999: Managing Director of Compliance Advice and Services in Microbiology GmbH at Cologne, Germany, his own consulting company with microbiological laboratory service. Dr. Haberer is working as an expert in a number of international committees, e.g. of European Pharmacopoeia, ISO, and PDA.

Mats Johansson, *MJ Micro Compliance, Sundbyberg, Sweden*
Started in Vitrum 1975 as microbiology laboratory manager, later corresponding positions in Kabi and KabiPharmacia. Between 1997 and 2000 he was corporate microbiological auditor within Pharmacia & Upjohn. Until June 2006 he was responsible for microbiological support for Pharmacia / Pfizer sterile manufacturing sites in Europe. Today he is a consultant within pharmaceutical microbiology. Mats is also active in ISO and CEN standards on sterilization processes and aseptic processing.

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@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

Risk Management in Sterile Manufacturing
17-18 May 2011, Copenhagen, Denmark

☐ 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 %.

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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)!

Date

Tuesday, 17 May 2011, 09.00 h – 17.00 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday, 18 May 2011, 08.30 h – 17.00 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark
Phone +45 33 96 50 00
Fax +45 33 96 55 00

Fees

ECA Members € 1,490.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT (does not include ECA membership)
EU GMP Inspectorates € 845.- 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 both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the Radisson Blu Scandinavia Hotel. Reservation should be made directly with the hotel not later than 16 April 2011. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention ECA/CONCEPT and the password A170511CON to receive the specially negotiated rate for the duration of your stay. 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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-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:
Dr Andreas Mangel (Operations Director) at
+49-62 21 / 84 44 41,
or per e-mail at mangel@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager) at
+49-62 21 / 84 44 22, or per e-mail at
bach@concept-heidelberg.de.