Risk Management in Sterile Manufacturing

29-30 March 2012, Heidelberg, Germany

SPEAKERS:

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

Mats Johansson
MJ Micro Compliance, Sweden

Dr. Daniel Kockelkorn
F. Hoffmann-La Roche, Switzerland

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

You can participate in two interactive workshops:
- Risk evaluation using examples of aseptic processing
- Environmental monitoring

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

Interactive Workshop
Risk evaluation using examples of aseptic processing

Based on 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 29 March 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

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.

Dr Daniel Kockelkorn
F. Hoffmann-La Roche AG, Basel, Switzerland
Daniel Kockelkorn studied biology at the university Freiburg and Madrid. He did his doctorate in microbiology and biochemistry and worked as a postdoctoral fellow in Freiburg. From 4/2010 to 9/2011 he worked as a deputy line Manager for liquid vials at F. Hoffmann-La Roche AG in Basel. Since 10/2011 he is working as laboratory head for environmental monitoring of the new Roche parenteralia production site in Kaiseraugst.
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P.O. Box 101764
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GERMANY

Reservation Form (Please complete in full)

Risk Management in Sterile Manufacturing
29-30 March 2012, Heidelberg, Germany

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)

Date

Thursday, 29 March 2012, 09.00 h – 17.00 h

Venue

NH Hotel Heidelberg
Bergheimer Str. 91
69115 Heidelberg, Germany

Phone +49(0)6221/1327-0
Fax +49(0)6221/1327-100

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT (does not include ECA membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectors € 845.- per delegate plus VAT

The fees are payable in advance after receipt of invoice. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. Please use this form for your room reservation. Late or no-shows will be calculated according to the point of time at which we receive your message. In case you do not appear at the hotel without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Early reservation is recommended.

Schedule

29 March 2012, 09.00 h – 17.00 h

Thursday – Registration and coffee 08.30 h – 09.00 h

Friday, 30 March 2012, 08.30 h – 17.00 h

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., Mr. Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

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 week prior to the conference: 50 %
   - Cancellation within 1 week prior to the conference: 100 %

Important: This is a binding registration, and fees are due in case of cancellation or non-appearance. If you cannot cancel, you must 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).

Terms of payment

Payable without deductions within 10 days after receipt of invoice.

Important

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