



You can participate in two interactive workshops:

- Risk evaluation using examples of aseptic processing
- Environmental monitoring

# 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



# Risk Management in Sterile Manufacturing

29-30 March 2012, Heidelberg, Germany

## 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

### 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 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.

## 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

+ 49 6221 84 44 34

Reservation Form (Please complete in full)

### Risk Management in Sterile Manufacturing

29-30 March 2012, Heidelberg, Germany

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)

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

#### 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 %
  - until 1 week 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!).

#### Date

Thursday, 29 March 2012, 09.00 h – 17.00 h  
(Registration and coffee 08.30 h – 09.00 h)  
Friday, 30 March 2012, 08.30 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 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 conference hotel. Reservation should be made directly with the hotel not later than 1 March 2012. 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" to receive the specially negotiated rate (single room € 124,- per night incl. breakfast) 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](http://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](mailto:info@concept-heidelberg.de)  
[www.concept-heidelberg.de](http://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](mailto: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](mailto:strohwald@concept-heidelberg.de).