Photo: LSMW Zander

With interactive workshops

Risk Management in Sterile Manufacturing

13-14 May 2014, Copenhagen, Denmark

SPEAKERS:

Dr Daniel Kockelkorn
F. Hoffmann-La Roche

Dr Sandra Schinzel
F. Hoffmann-La Roche

Dr Ingrid Walther
Pharma Consulting Walther

LEARNING OBJECTIVES:

- Principles of risk management in sterile manufacturing
- Risk management tools and how to use them
- Microbiological and non-microbiological risks
- Risk management during qualification and validation

ECA 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

13-14 May 2014, Copenhagen, Denmark

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

- ICH Q 9
  - Risk analysis
  - Risk control
  - Risk communication
- End to End approach
- Continuous improvement triggered by risk management

Risk management tools - Overview

- Fault tree analysis
- Fishbone diagram
- FMEA
- HACCP

Interactive Workshop:
Exercises FMEA (Sterile Filling Process)

Attendees will execute a process related FMEA on the base of a sterile filling process.

Interactive Workshop:
Exercise HACCP (Cleanroom Qualification)

Attendees will execute a HACCP risk assessment as a starting point for the cleanroom qualification. They will apply an easy to use documentation approach with office tools.

Root Cause Analysis (in sterile manufacturing)

- The RCA process
- Methods of Root Cause Analyses
  - Five times "Why"
  - Barrier analysis
- Fields of application
- Specific challenges in sterile manufacturing

Example:
Microbiological Risk Management (equipment)
The sample devices for active air samplers in Isolators are solid installed and cannot be exchanged during operations. This example deals with a risk based approach how to increase the reliability of this devices.

Interactive Workshop:
Microbiological risk management

End to end Approach in Sterile Filling
- Description of a process using process maps
- Applying risk analysis systematically end to end
- Case studies

Interactive Workshop:
End to End Approach in Sterile Filling

Non-microbiological Risks in Sterile Manufacturing
- Packaging Material Quality
- Product mix-ups
- Particles
- Degradation products
- Cross-contamination

Trending / Microbiological Deviations / Failure Investigations and CAPA
- Why is trending important?
- What are the possibilities?
- How to handle deviations and how to invest them
- The pain of finding a useful CAPA

Social Event

On 13 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

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.

Dr Sandra Schinzel
F. Hoffmann-La Roche AG, Basel, Switzerland
Sandra Schinzel obtained a chemistry diploma from the University of Würzburg and a chemical engineer diploma from CPE Lyon in France. She joined F. Hoffmann-La Roche in 2010 as an operational excellence project manager in Parenterals Production Kaiseraugst, Switzerland. In this brand-new and strategically important production facility of Roche, she is responsible for executing risk assessment and deploying various optimization projects. Sandra Schinzel is a LeanSixSigma green belt.

Dr Ingrid Walther
Pharma Consulting Walther, Friedrichsdorf, Germany
Dr Walther joined Fresenius AG in 1986. She was employed in various positions and has long years of experience in the fields of research and development, quality assurance/quality control and the management of strategic projects. In 1997 she assumed a position as head of the Business Unit Validation and GMP Compliance at Pharmaplan GmbH, a daughter company of Fresenius. In a subsequent position at Pharmaplan, she became responsible for consulting projects and became COO. In 2007, she re-joined Fresenius, heading the business unit iv Drugs & Oncology. Since July 2009 she runs her own business as consultant.

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
13-14 May 2014, 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

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 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)

Date

Tuesday, 13 May 2014, 09.00 h – 17.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday, 14 May 2014, 08.30 h – 16.00 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
APIC Members € 1,590.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
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 conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. 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
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.