Incl. 2 workshops:
- Entering the clean area
- Establishing an environmental monitoring program and handling of failures in microbiology

GMP for Beginners in Sterile Manufacturing

17-18 September 2013, Copenhagen, Denmark

SPEAKERS:

Colin Booth
Thermo Fisher Microbiology

Dr Bettina Lauer
Vetter Pharma Fertigung

Wolf-Dieter Wanner

Dr Björn Wiese
Zimmer

LEARNING OBJECTIVES:

- Clean Rooms and Barrier Systems
- Training requirements
- Cleaning and Disinfection
- Hygiene
- Sterilisation Processes
- Environmental Monitoring
- Media Fills
- Handling Failures – CAPA
- Inspections – Audits - Observations

ECA
EUROPEAN COMPLIANCE ACADEMY

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

GMP for Beginners in Sterile Manufacturing

17-18 September 2013, Copenhagen, Denmark

Objectives

The course is designed for people working in sterile manufacturing to get basic knowledge of GMP.

- You get to know the most important pharmaceutical regulations for sterile manufacturing and their importance,
- You get a basic overview of general GMP requirements and specific requirements in sterile manufacturing and
- You become familiar with the most important basic processes in sterile pharmaceutical production

Background

Knowing and applying the GMP regulations is one of the key elements in the manufacture of medicinal products and medical devices. Particularly in the manufacture of sterile medicinal products, employees have to comply with extensive requirements. Against this background, employees have to know the GMP requirements and must know how to use them in practice.

The question is: how can employees implement in their daily work regulations which are usually formulated in a very general manner?

The aim of the course is to help answer this question and enable the concrete transfer of regulatory requirements into practice. Where are the main difficulties and how can they be solved pragmatically? The course will present elements and situations which employees are regularly confronted with, like for example:

- Correct cleaning / disinfection
- Behaviour in clean rooms
- Correctly passing into the clean rooms
- Environmental Monitoring
- Performance of Media Fills

Target Group

The course is directed to staff from the healthcare industry having no or little experience with the current GMP requirements for sterile manufacturing. This includes both employees who, after their vocational training, enter the pharmaceutical industry and experienced colleagues who work for the first time in sterile manufacturing areas. Suppliers who have to understand the quality requirements of their customers should also attend this course.

Moderator

Colin Booth

Programme

Introduction – What is specific for sterile manufacturing?

- What does sterile actually mean?
- Controlling raw material supply
- Sterilisation
- Sterile Manufacturing Facilities
- Process simulations
- Microbiological control

Regulations for sterile manufacturing

- Overview of regulation hierarchy
- Regulations on Aseptic Processing
- Applicable ISO standards

Clean rooms and Barrier Systems

- Differences in the technology
- Decontamination vs. disinfection
- Validation aspects
- Environmental monitoring
- Risk considerations

Specific training requirements for sterile manufacturing

- Basics of microbiology
- Contamination sources and transfer
- Clean rooms
- Hygienic behaviour

Cleaning and disinfection

- Definitions
- Requirements - results – parameters
- Types of detergents and disinfectants
- Microbiological efficacy
- Compatibility of materials
- Types of application
- Surface wetting

Hygiene

- General definitions
- Purpose and function to pharmaceutical manufacturing with reference to personnel, surfaces, equipment
- Diversity of hazard – hazard analysis
- Clean room conception
- Gowning procedures
- Decontamination procedures

Workshop: Entering the clean area

- Requirements
- How to meet the criteria - practice

Entering a clean area is a very critical step to fulfil the GMP requirements. Employees must be trained and qualified and the gowning process must be validated. Attendees will learn different procedures and discuss the advantages and disadvantages.

Sterilisation processes
- Controlling bioburden / pyroburden
- Autoclaving
- Filtration
- Dry heat
- Gamma irradiation
- Ethylene Oxide

Involvement of the microbiological lab
- Counting micro-organisms
- Identifying micro-organisms
- Process validation
- Validating the sterility test
- Raw material testing strategy
- Trouble shooting

Environmental monitoring
- Regulatory requirements
- Content and establishing of an environmental monitoring program
- Requirements concerning media and media suppliers
- Documentation and trending

Media Fill
- Regulatory requirements
- Microbiological media types
- Process simulation contamination
- Sample incubation
- Laboratory work
- Formal report

Handling failures in sterile manufacturing
- Historic background
- Regulatory requirements
- Example for a non-conformity system
- Case studies

Workshop Establishing an environmental monitoring program and handling of failures in microbiology.
Some practical examples from a pharmaceutical company will be demonstrated and discussed with the attendees.

Inspections / Audits / Observations
- Preparing for a formal inspection
- Managing an FDA audit of sterile manufacturing
- Internal audit program
- Real world observations
- Your OOS and OOT process

Social Event

On Tuesday evening 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

Colin Booth
Thermo Fisher Microbiology, Basingstoke, United Kingdom
Colin Booth was the manager of Pharmaceutical Microbiology for Glaxo Wellcome Research and Development based in the UK where he was responsible for all the microbiology associated with the development of all Glaxo Wellcome new products. In 2002 he joined Oxoid Limited where he is now Vice President Science and Technology. He is a member of PDA, a group dedicated to building interfaces with regulatory colleagues across Europe.

Dr. Bettina Lauer
Vetter Pharma Fertigung GmbH & Co. KG, Ravensburg, Germany
During her time at Vetter Pharma-Fertigung GmbH & Co. KG she worked as lab manager of different laboratories focusing on environmental monitoring, testing of utilities and product testing. At present Dr. Bettina Lauer is deputy head of Microbiology and works as a senior expert in Microbiology responsible for customer audits and authority's inspections As Black Belt she is involved in process optimization projects using the tools of Six Sigma.

Wolf-Dieter Wanner
Augsburg, Germany
Studied pharmacy at the University of Munich. He started working in a free pharmacy and later joined Henkel KGaA in Düsseldorf to establish a German decontamination business relating to the industry. At Ecolab Deutschland GmbH as a sales manager he integrated the German clean room business with Adams Healthcare and Shield Medicare into an international contamination control team focused upon pharmaceutical aseptic manufacturing. Since 2011 he works as a freelancer consultant.

Dr Björn Wiese
Zimmer GmbH, Winterthur, Switzerland
From 1996 to 2000 Björn Wiese worked as project manager in R&D of Danisco Ingredients, Niebüll, Germany, and developed start up cultures. Since November 2000, he had been head of the microbiology department of Hameln Pharmaceuticals, Hameln, Germany. From 2005 - 2010 Björn worked at the pharmaceutical production site of Cilag in Schaffhausen, Switzerland. 2011 he joined Zimmer GmbH as Associate Director Sterilisation Technology and Analytical Testing.

Easy Registration

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17-18 September 2013, Copenhagen, Denmark
☐ Risk Management in Sterile Manufacturing, 19-20 September 2013, Copenhagen, Denmark

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (if applicable)**

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General terms and conditions
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Date

Tuesday, 17 September 2013, 09.30 h – 17.30 h
(Registration and coffee 09.00 h – 09.30 h)
Wednesday, 18 September 2013, 09.00 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 € 1,390.- per delegate plus VAT
APIC Members € 1,490.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,590.- per delegate plus VAT
EU GMP Inspectorates € 795.- 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.

Save up to € 290 and book the course "Risk Management in Sterile Manufacturing" on 19-20 September 2013 simultaneously:
ECA Members € 2,790.- per delegate plus VAT
APIC Members € 2,890.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 2,990.- per delegate plus VAT
EU GMP Inspectorates € 1,495.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 17th and 19th September day, lunch all days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotels. 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.

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

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Dr Andreas Mangel (Operations Director)
at ++49-(0)62 21 / 84 44 41 or at
mangel@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Jessica Stürmer (Organisation Manager)
at ++49-(0)62 21 / 84 44 43 or per e-mail at
stuermer@concept-heidelberg.de.

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Photo: LSMW Zander

With interactive workshops

Risk Management in Sterile Manufacturing

19-20 September 2013, 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

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Risk Management in Sterile Manufacturing

19-20 September 2013, 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
- End to End approach
- Continuous improvement triggered by risk management

Risk Management Tools - Overview

- Fault tree analysis
- Fishbone diagram
- FMEA
- HACCP

Route Cause Analysis (in Sterile Manufacturing)

- Methods of Root Cause Analyses
- Fields of application

Quality by Design (QbD) – Short Overview

- Relation between quality attributes and the finished product
- Definition of a process
- Risk analysis during qualification and validation

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.

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

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 19 September 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.

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Date

Thursday, 19 September 2013, 09.00 h – 17.00 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 20 September 2013, 08.30 h – 15.00 h

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