ECA Academy
Your GMP/GDP Information Source

GMP for Beginners in Sterile Manufacturing

SPEAKERS:

Colin Booth
Thermo Fisher Scientific

Michael Grosser
Novartis Pharma Stein

Wolf-Dieter Wanner

Dr Björn Wiese
Zimmer, Switzerland

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

25-26 October 2016, Berlin, Germany

LEARNING OBJECTIVES:

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

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

25-26 October 2016, Berlin, Germany

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

Microbiological basics

- Characteristics of microorganisms
- Microbial growth
- Microbial identification techniques
- Detection methods and their limitations

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 Scientific, 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, now Thermo Fisher Scientific, where he is Vice President Science and Technology. He is a member of PDA, a group dedicated to building interfaces with regulatory colleagues across Europe.

Michael Grosser
Novartis Pharma Stein AG, Schweiz
Michael Grosser studied Microbiology at the Albert Ludwig University in Freiburg/ Breisgau. He then worked for 14 years as Head of Microbiology at UFAG Laboratorien AG, Eurofins Scientific AG and GP Grenzach Produktions GmbH (Bayer Health Care). Since 2009 he is working for Novartis Pharma Stein AG as Senior QA-Specialist, responsible for environmental monitoring in the sterile plant, QA oversight, validation of new cleanrooms or isolators, deviation management and microbiological product release.

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

Reservation Form:
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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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **GMP for Beginners in Sterile Manufacturing,** 25-26 October 2016, Berlin, Germany
☐ **Process Simulation / Media Fills,** 27-28 October 2016, Berlin, 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)

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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
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- until 1 weeks prior to the conference 50 %
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Date

Tuesday, 25 October 2016, 09.30 h – 17.30 h
(Registration and coffee 09.00 h – 09.30 h)
Wednesday, 26 October 2016, 09.00 h – 16.15 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49(0)30 2127 0
Fax +49(0)30 2127 117

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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.

Would you like to save money?

If you register for the course **GMP for Beginners in Sterile Manufacturing** AND **Process Simulation/ Media Fills (on 27-28 October)** simultaneously, the fees reduce as follows:
ECA Members € 2,790
APIC Members € 2,890
Non-ECA Members € 2,990
EU GMP Inspectorates € 1,445

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.

Conference Language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
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