



Speakers



Michael Grosser
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GMP for Beginners in Sterile Manufacturing



Live Online Training on 12/13 October 2021



Highlights

- 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

Incl. Case Studies: “Entering the Clean Area” and
“Establishing an Environmental Monitoring Pro-
gram and Handling of Failures in Microbiology”

Objectives

The Online Training 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 Online Training 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 Online Training 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 Audience

The Online Training 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.

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



Case Study: 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



Case Studies „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

Speakers



Michael Grosser
Novartis Pharma Stein AG, Schweiz

Mr Grosser studied Microbiology at the Albert Ludwig University in Freiburg im Breisgau. 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

Mr Wanner 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 Biomet 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 now as Director Sterilization Technology and Analytical Testing Testing.



Dr Florian Witte
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany

Florian Witte is Chemist by education. He works in the pharmaceutical industry at Boehringer Ingelheim since 20 years in different positions. Since 2017 he is responsible for aseptic quality assurance of a factory filling aseptic inhalation solutions.

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)



- Live Online Training: GMP for Beginners in Sterile Manufacturing, 12/13 October 2021
- Live Online Training: Process Simulation / Media Fills, 14/15 October 2021

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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 2. If you have to cancel entirely we must charge the following processing fees:
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 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).
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Date of the Live Online Training

Tuesday, 12 October 2021, 9.30 to 17.30 h CEST
 Wednesday, 13 October 2021, 9.00 to 16.15 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At <http://www.webex.com/test-meeting.html> you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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.



Would you like to save money?

If you register for the course GMP for Beginners in Sterile Manufacturing AND Process Simulation/Media Fills (on 14/15 October 2021) simultaneously, the fees reduce as follows:
 ECA Members € 2,590
 APIC Members € 2,690
 Non-ECA Members € 2,790
 EU GMP Inspectorates € 1,590

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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

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