ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

Speakers

Michael Grosser
Lonza Biologics

Wolf-Dieter Wanner
GMP Consultant

Dr Björn Wiese
Janssen Cilag

Dr Florian Witte
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NEWS

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GMP for Beginners in Sterile Manufacturing

Live Online Training on 18/19 November 2025

Highlights

- Clean Rooms and Barrier Systems
- Contamination Control Strategy
- Microbiological Basics
- Training Requirements
- Cleaning and Disinfection
- Hygiene
- Sterilisation Processes
- Environmental Monitoring
- Aseptic Process Simulation / Media Fill
- Handling Failures – CAPA
- Inspections – Audits - Observations

Incl. Case Studies: “Entering the Clean Area” and “Establishing an Environmental Monitoring Program 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

Contamination Control Strategy (CCS)

- Something new?
- Requirements from EU GMP Guide Annex 1
- What does CCS include?

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
Lonza Biologics, Switzerland

Michael Grosser is a microbiologist and has been working in contract laboratories and the pharmaceutical industry in Germany and Switzerland for more than 25 years. As Senior QA Expert Manufacturing, he is responsible for aseptic working and behaviour in cleanrooms and isolators.

Wolf-Dieter Wanner
GMP Consultant, 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
Janssen Cilag, Schaffhausen, Switzerland

Since November 2000, Björn had been head of the microbiology department of Hameln Pharmaceuticals, Hameln, Germany. From 2005 - 2010 he worked at the pharmaceutical production site of Cilag in Schaffhausen, Switzerland. From 2011 to 2022 he was Director Sterilization Technology and Analytical Testing at Zimmer Biomet. Since September 2022 he leads the Community of Practice for Sterilization Technologies at Janssen Cilag, Schaffhausen.

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 22 years in different positions: Analytical, formulation and device development of inhalative medicines; process development and quality assurance for aseptic filling of inhalation solutions. Since 2021 he is heading the quality assurance unit for device development.

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Reservation Form (Please complete in full)

☐ Live Online Training: GMP for Beginners in Sterile Manufacturing, 18/19 November 2025
☐ Live Online Training: Aseptic Process Simulation (APS) / Media Fills, 20/21 November 2025

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

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- Cancellation until 4 weeks prior to the conference 10 %,
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German law shall apply. Court of jurisdiction is Heidelberg.

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 https://www.gmp-compliance.org/privacy-policy). 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.

Date of the Live Online Training

Tuesday, 18 November 2025, 09.00 h – 17.30 h CET
Wednesday, 19 November 2025, 09.00 h – 17.30 h CET

Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice.

Would you like to save € 500,-?

If you register for the course GMP for Beginners in Sterile Manufacturing AND Aseptic Process Simulation (APS) /Media Fills (on 20/21 November 2025) we will offer you a discount of € 500.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21908.

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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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