



## Speakers



Michael Grosser  
Novartis Pharma Stein



Wolf-Dieter Wanner



Dr Björn Wiese  
Zimmer Biomet



Dr Florian Witte  
Boehringer Ingelheim Pharma

# 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

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

## Involvement of the Microbiological Lab

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- Counting micro-organisms
- Identifying micro-organisms
- Process validation
- Validating the sterility test
- Raw material testing strategy
- Trouble Shooting

## Environmental Monitoring

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

## Media Fill


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

## Handling Failures in Sterile Manufacturing

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- 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“**

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Some practical examples from a pharmaceutical company will be demonstrated and discussed with the attendees.

## Inspections / Audits / Observations

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- 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.

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### 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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## 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

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## 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:

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## Organisation and Contact

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

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+49(0)62 21/84 44 41, or per e-mail at  
[mangel@concept-heidelberg.de](mailto:mangel@concept-heidelberg.de)

For questions regarding organisation please contact:

Mr Niklaus Thiel (Organisation Manager) at  
+49(0)62 21/84 44 43, or at  
[thiel@concept-heidelberg.de](mailto:thiel@concept-heidelberg.de)



## Speakers



Dr Bettina Rietz-Wolf  
Inspector




Luigi Scaffidi  
Boehringer Ingelheim Pharma



Dr Florian Witte  
Boehringer Ingelheim Pharma

# Process Simulation / Media Fills

GMP Requirements on Validation of Aseptic Processes

 Live Online Training on 14/15 October 2021



## Highlights

- Details from the Revised EU GMP Annex 1
- Expectations from an Inspector
- Design of a Media Fill
- Risk Management During Media Fills
- QA-Overview
- Qualification of Personnel
- The Involvement of the Microbiology Lab
- Managing Deviations – Root Cause Analysis

Exercises / Case Studies on: Design of a Media  
Fill – Risk-Based Determination of Interventions  
– Managing Deviations



## Objective

During this course you will learn in lectures and workshops

- The new requirements of the revised EU Annex 1
- How to plan a media fill in compliance with European and US GMP requirements,
- How to interpret the results of a media fill,
- How to investigate deviations and define follow-up measures and
- How QA should be involved

## Background

In the aseptic processing of medicinal products, the product quality usually cannot be ensured by means of lab controls of the final product. Process validation by means of media fills is the only way to furnish proof of product safety, which is why it justly is the focus of regulatory requirements and official inspections.

A number of revised and harmonised international regulations, especially the FDA Guidance for Industry „Sterile Drug Products Produced by Aseptic Processing“, the EU-GMP-Guide Annex 1, ISO 13408 and the PIC/S Guide „Recommendation on the Validation of Aseptic Processes“, define highly detailed requirements, the implementation of which is critically examined within the framework of official inspections.

In general, the required media fills should be able to simulate both routine operation and worst-case conditions.

In practice, the question of practicability often arises. How should the requirements be interpreted and how can they be implemented even for special production processes or dosage forms?

## Target Audience

This Education course is directed at staff from

- Production
- Quality Assurance
- Microbiological Quality Control

who are responsible for the planning and evaluation of Process Simulation (Media fill) programmes.

It is also valuable for decision makers who have to deal with Process Simulation data within the framework of production release and Aseptic Process validation.

## Programme

### Current Regulatory Requirements and Expectations of an Inspector

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- EU-GMP Guide Annex 1
- Regulatory changes through the new EU GMP Guide Annex 1 Draft
- Contamination control
- Inspection practice, questions
  - Design
  - Interventions
  - Visual inspection
  - Target, Assessment
- Media Fill Observations

### Requirements for Cleanroom Staff Qualification

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- Staff qualification
- Staff disqualification
- Training
- Gowning qualification
- Qualification with APS (success control)
- Personnel Monitoring

### Design of Media Fill incl. Exercise

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- Overview PDA TR22
- Parameter, which have to be consider in MF design
- Different MF design alternatives
- Consideration of long filling times
- Consideration of holding times
- The role of the MF in aseptic personnel qualification

### Risk Management During Media Fill (Bracketing / Definition of Simulations / Interventions)

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- Approaches and parameters for bracketing concepts
- Classification and grouping of interventions
- Examples of simulations
- Influence of the barrier system
- Examples of risk management tools

### QA-Oversight

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- Regulatory requirements
- Different approaches to QA Oversight
- Oversight during Media Fill execution
- Link between Media Fill Interventions and Smoke Studies



## Exercise Risk-based Determination of Interventions

### Microbiological Investigations and Environmental Monitoring as Part of the Media Fill

- EM and personnel monitoring during Media Fill
- Responsibility for execution
- Fertility testing of the growth medium

### Incubation, Assessment and Evaluation

- Important conditions for visual inspection
- Personnel qualification
- Evaluation methods for the Media Fill

### Managing Deviations - Root Cause Analysis

- Consequences of deviations in Media Fill
- Retrospective and prospective evaluation
- Relevant parameters in root cause analysis



### Case Study: Managing Interventions

## Speakers



**Dr. Bettina Rietz-Wolf**  
GMP Inspector, Local Authority of Baden  
Württemberg, Tübingen

Since 1995 responsible for inspections of pharmaceutical companies at the local authority Tübingen, Baden-Württemberg. She was the head of the expert group "Sterile and Aseptically Manufactured Medicines".



**Luigi Scaffidi**  
Boehringer Ingelheim Pharma GmbH & Co.  
KG, Ingelheim, Germany

Luigi has been working at Boehringer Ingelheim for 34 years. From 1989 – 2012 in different areas and functions in research and development. Since 2012 in quality assurance of a factory filling aseptic inhalation solutions with special focus on qualification, validation, aseptic and hygiene.



**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.

## Your Benefits

### Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.



### This Training Course is recognized for the GMP/ GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at [www.gmp-certification.org](http://www.gmp-certification.org)

### This could be of interest for you as well

### Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
- APIs (ICH Q7)
- Medicinal Products
- Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
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You will find a time schedule for each training course at <https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings>.

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## Date of the Live Online Training

Thursday, 14 October 2021; 09.30 h – 17.00 h  
Friday 15 October 2021, 09.00 h – 13.00 h  
Times mentioned are CEST.

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[mangel@concept-heidelberg.de](mailto:mangel@concept-heidelberg.de)

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