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
Boehringer Ingelheim Pharma

NEWS

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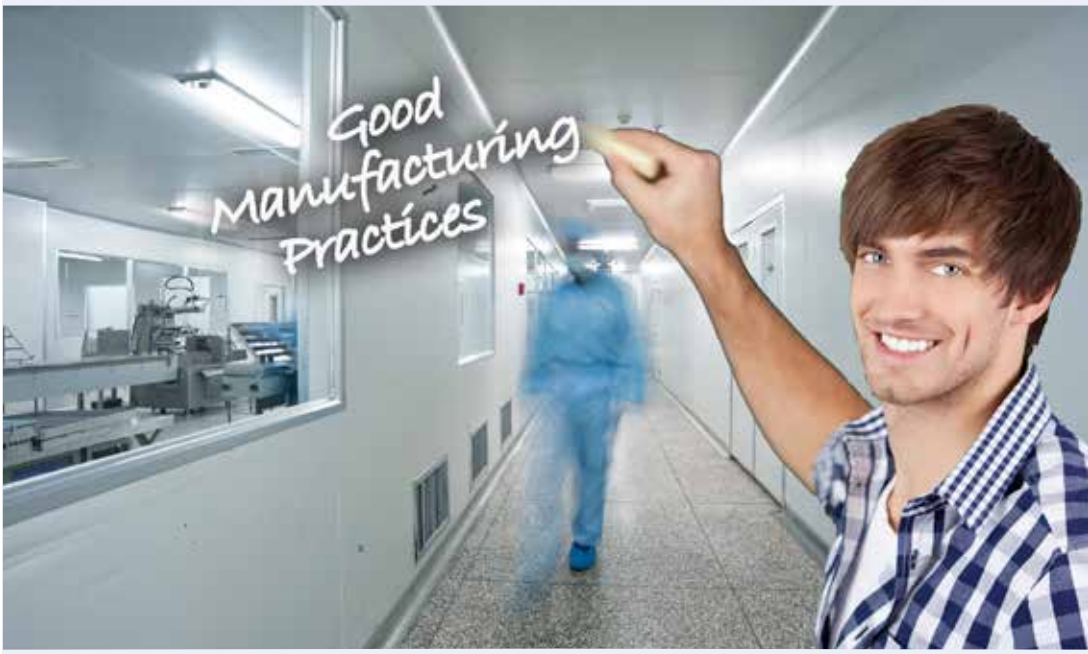
GMP for Beginners in Sterile Manufacturing

Live Online Training on 24/25 September 2024



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 Program and Handling of Failures in Microbiology“

Programme

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
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, 24/25 September 2024
☐ Live Online Training: Aseptic Process Simulation (APS) / Media Fills, 26/27 September 2024

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

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Date of the Live Online Training

Tuesday, 24 September 2024, 9.30 to 17.30 h CEST
Wednesday, 25 September 2024, 9.00 to 16.30 h CEST

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)

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APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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Would you like to save up to € 590,-?

If you register for the course GMP for Beginners in Sterile Manufacturing AND Aseptic Process Simulation (APS) /Media Fills (on 26/27 September 2024) simultaneously, the fees reduce as follows:
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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

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Dr Bettina Rietz-Wolf
GMP Inspector for EMA and local Government, Germany

Luigi Scaffidi
Boehringer Ingelheim Pharma, Germany

Dr Florian Witte
Boehringer Ingelheim Pharma, Germany

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Aseptic Process Simulation (APS) / Media Fills

GMP Requirements on Validation of Aseptic Processes

Live Online Training on 26/27 September 2024

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

Objectives

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 Aseptic 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

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

Requirements for Cleanroom Staff Qualification

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

Design of Media Fill incl. Exercise

- 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)

- 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

- 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 for EMA and local Government, Germany
Bettina is a pharmacist and GMP Inspector for the District Government of Baden-Württemberg and the EMA and performs GMP inspections worldwide. She was head of the German expert group EFG3 "Manufacturing of sterile products" at the ZLG.

Luigi Scaffidi,
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany
Luigi has been working at Boehringer Ingelheim for more than 30 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,
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Florian Witte is Chemist by education. He works in the pharmaceutical industry at Boehringer Ingelheim for 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.

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.


CERTIFICATE

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

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
- Packaging
- Medical Devices
- Technical Operations

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Date of the Live Online Training

Thursday, 26 September, 09.30 h – 17.15 h CEST
Friday, 27 September, 09.00 h – 13.30 h CEST

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