ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

Speakers

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

NEWS

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Aseptic Process Simulation (APS) / Media Fills

GMP Requirements on Validation of Aseptic Processes

Live Online Training on 20/21 November 2025

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
- Manual Processes
- 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 Monitroing

Design of Media Fill incl. Exercise

- Overview PDA TR22
- Parameter, which have to be considered 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

Requirements for Manual Processes

- Differences compared to conventional drugs
- Annex 1 9.39
- Challenges for the APS design

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, Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany

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


CERTIFICATE

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

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

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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GERMANY

Reservation Form (Please complete in full)

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

E-Mail (Please fill in)

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 until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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 July 2022).
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

Thursday, 20 November 2025, 09.00 h – 17.30 h (CET)
Friday, 21 November 2025, 09.00 h – 15.30 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 trainings 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The fee is payable in advance after receipt of invoice.

Would you like to save up to € 590,-?

If you register for the course Aseptic Process Simulation (APS) / Media Fills AND GMP for Beginners in Sterile Manufacturing (on 18/19 November 2025) simultaneously, the fees reduce as follows:
ECA Members € 2,990
APIC Members € 3,090
Non-ECA Members € 3,190
EU GMP Inspectorates € 1,890

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 21910.

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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