



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

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



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

Programme

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.



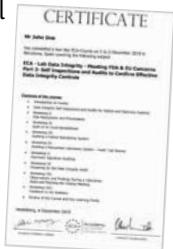
**Dr Florian Witte,
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany**

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

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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Reservation Form (Please complete in full)



Live Online Training: Aseptic Process Simulation (APS) / Media Fills, 26/27 September 2024
 Live Online Training: GMP for Beginners in Sterile Manufacturing, 24/25 September 2024

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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Thursday, 26 September 2024, 09.30 h – 17.15 h CEST
Friday, 27 September 2024, 09.00 h – 13.30 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 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 24/25 September 2024) 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](https://www.gmp-compliance.org) under the number 21331.

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.

CONCEPT HEIDELBERG

P.O.Box 10 17 64, 69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0 | Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de | www.concept-heidelberg.de

For questions regarding content please contact:

Dr Andreas Mangel (Operations Director) at
+49(0)62 21/84 44 41, or per e-mail at
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