ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

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

- 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

- 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 Inpector, 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


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.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Live Online Training: Process Simulation / Media Fills, 14/15 October 2021
☐ Live Online Training: GMP for Beginners in Sterile Manufacturing, 12/13 October 2021

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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 January 2012).
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 http://www.gmp-compliance.org/eca_privacy.html). 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, 14 October 2021; 09.30 h – 17.00 h
Friday 15 October 2021, 09.00 h – 13.00 h
Times mentioned are CEST.

Technical Requirements

For our 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 email 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 € 1,290
APIC Members € 1,390
Non-ECA Members € 1,490
EU GMP Inspectorates € 745
The conference fee is payable in advance after receipt of invoice.

Would you like to save money?

If you register for the course Process Simulation/Media Fills AND GMP for Beginners in Sterile Manufacturing (on 12/13 October 2021) simultaneously, the fees reduce as follows:
ECA Members € 2,590
APIC Members € 2,690
Non-ECA Members € 2,790
EU GMP Inspectorates € 1,590

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

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.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at any time at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

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