ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

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

27/28 October 2020 | Berlin, Germany

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. workshop: “Entering the clean area” and Case studies “Establishing an environmental monitoring program and handling of failures in microbiology“

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Natasha Pain
Lonza Pharma & Biotech

Alexandra Stärk
Novartis Pharma Stein

Dr Florian Witte
Boehringer Ingelheim Pharma

Process Simulation / Media Fills

GMP requirements on validation of aseptic processes

29/30 October 2020 | Berlin, Germany

Highlights

- Design of a Media Fill
- Specific Requirements for Isolators and Lyophilised Products
- QA-Overview
- Qualification of personnel
- The involvement of the Microbiology Lab
- Mycoplasma Contamination in Process Simulation
- Handling the outputs
- Identification of contaminating microorganisms

Workshops on Managing Interventions / Handling a Media Fill failure

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

Media Fills – The Essential Background

- Regulations affecting aseptic manufacture
  - EU GMP Guide Annex 1
  - FDA Aseptic Guide
- PIC/S Guide 'Recommendations on the Validation of Aseptic Processes'
- What media fills consist of (in principle)

Media Fills – How to Design a Media Fill

- What medium?
- How many units?
- How long?
- Interventions?
- Personnel?

Workshop Managing Interventions

- Different kinds of interventions
- Selection of interventions for media fills
- Selection of interventions for personal qualification
- Tracking of interventions between media fills
- Assessment of interventions

This workshop involves participants in the issues to be resolved in the identification and management of interventions during media fills in order to answer the demand from the regulatory inspector – "what's the name of the person making that intervention, please show me the evidence from media fills that she has been qualified to perform it".

Media Fills: Specific requirements for isolators and freeze dryers

- Media fill design for isolators and freeze dryers
- Special interventions into isolators and freeze dryers
- Validation of standing times for isolators and freeze dryers
- Isolator gloves

Media Fills – The Involvement of the Microbiology Lab

- Why we use TSB
  - Limitations
  - BSE/TSE-free?
- Problems with TSB
  - Contamination of the dehydrated medium (Bacillus)
  - Issue with Mycoplasma
  - Irradiated dehydrate (effects of irradiation on growth)
- Growth Support Checks
  - Pharmacopoeial organisms
  - Local isolates
  - Preparation of Cultures
- Incubation temperatures
- Inverting units during incubation
- Aerobic vs. anaerobic media fills
- Incubation and inspection

QA-Oversight

- Regulatory background
- QA-Oversight during Media Fill versus QA-Oversight during routine production
- How to perform QA-Oversight?
- Interpretation of QA-Oversight results

Discussion of particular issues

- Holding times
- Container / Closure integrity after Media Fills
- Holding Tanks

Media Fills and Personnel

- Training and qualifying personnel for aseptic manufacture through media fill
- Maintaining qualification
- Regulatory requirements

Media Fills and Environmental Monitoring

- Environmental monitoring activities during Media Fills
- Handling deviations

Media as a Source of Mycoplasma Contamination in Process Simulation

- Mycoplasma myths
- Plant vs animal media
- Process simulations
- Media production
- A new breed of media

Media Fills – Handling the outputs

- Limits (practicalities and impracticalities)
- Handling failures

Workshop Handling a Media Fill Failure

- Types of failures
- Evaluation of failures
- Documentation requirements

The current regulations on media fills include strict acceptance criteria. But how do out-of-specification results and failures during media fills have to be handled? Which consequences does a media fill failure have? In this workshop, the participants learn how failures have to be evaluated and which consequences they have.

Media Fill - Identification of contaminating micro-organisms

- What the regulators expect
- Likely contaminants, unlikely contaminants !!
- Isolating contaminating micro-organisms
- Identification methods, including genetic
- Mycoplasma contamination
- What the identification tells you about the process

Regulatory Problems with Media Fills

- What the regulators expect
- Examples from Warning Letters
- Examples from 483's

Speakers

Natasha Pain
Lonza Pharma & Biotech, Tokyo, Japan

Natasha Pain is currently Senior Manager QC at Lonza Pharma & Biotech. Prior to working at Lonza Natasha was the QC Microbiology Group Head for the Biopharmaceutical Centre of Excellence in Drug Discovery, UK, where her role involved environmental monitoring, product testing expertise and the evaluation of rapid microbiological test methods.

Alexandra Stärk
Novartis Pharma Stein AG, Basle, Switzerland

After studying Hygiene Technology at the Technical University of Albstadt-Sigmaringen, Alexandra Stärk has worked since 1995 at Novartis Pharma Stein AG and was heading the microbiological QA/QC department till October 2016. In October 2016 she moved into a new role within Novartis Pharma Stein AG and is now responsible for a team of microbiological experts in the department of Manufacturing, Science & Technology which defines the microbiological control strategies for sterile and non-sterile production on a global and local level.

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.

Social Event

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P.O. Box 101764
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D-69007 Heidelberg
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Reservation Form (Please complete in full)

☐ Process Simulation / Media Fills, 29/30 October 2020, Berlin, Germany
☐ GMP for Beginners in Sterile Manufacturing, 27/28 October 2020, Berlin, Germany

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
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Thursday, 29 October 2020; 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Friday 30 October 2020, 08.30 h – 15.15 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Email berlin@steigenberger.de

Fees (per delegate, plus VAT)
ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Would you like to save money?
If you register for the course Process Simulation/Media Fills AND GMP for Beginners in Sterile Manufacturing AND (on 27/28 October 2020) simultaneously, the fees reduce as follows:
ECA Members € 2,790
APIC Members € 2,890
Non-ECA Members € 2,990
EU GMP Inspectorates € 1,690

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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

Conference language
The official conference language will be English.

Organisation and Contact
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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
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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 reservation, hotel, organisation etc. please contact:
Mr Niklaus Thiel (Organisation Manager) at
+49(0)62 21/84 44 43, or at
thiel@concept-heidelberg.de

Programme

Objective

The course 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 course 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 course 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 course 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

Workshop: 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
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

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Tuesday, 27 October 2020, 09.30 h – 17.30 h
(Registration and coffee 09.00 h – 09.30 h)
Wednesday, 28 October 2020, 09.00 h – 16.15 h

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