



Speakers



Natasha Pain
Lonza Pharma & Biotech



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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

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



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

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

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

D-69007 Heidelberg
GERMANY

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

Country

Phone / Fax

ZIP Code

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 week prior to the conference 50 %
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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

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
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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

ECA has entrusted Concept Heidelberg with the organisation of this event.
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