



Academy
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Information Source

Process Simulation / Media Fill

GMP Requirements on the Validation of Aseptic Processes

SPEAKERS:



Colin Booth
Thermo Fisher Scientific



Natasha Pain
Lonza Biologics



Alexandra Stärk
Novartis Pharma



Workshops on

- Managing Interventions
- Handling a Media Fill Failure

27-28 October 2016, Berlin, Germany

PROGRAMME:

- Design of a Media Fill
- QA Overview
- Qualification of Personnel
- The Involvement of the Microbiology Lab
- Mycoplasma Contamination in Process Simulation
- Handling the Outputs
- Identification of Contaminating Microorganisms



Process Simulation/Media Fill

27-28 October 2016, Berlin, Germany

Objectives

During this course you will learn in lectures and workshops

- 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 Group

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.

Moderator

Colin Booth

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 – 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
- Lyophilized products

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 microorganisms

- 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



Colin Booth, Thermo Fisher Scientific, UK

Colin Booth was the manager of Pharmaceutical Microbiology for Glaxo Wellcome Research and Development based in the UK where he was responsible for all the microbiology associated with the development of all Glaxo Wellcome new products. In 2002 he joined Oxoid Limited, now Thermo Fisher Scientific, where he is Vice President Science and Technology. He is a member of PDA, a group dedicated to building interfaces with regulatory colleagues across Europe.



Natasha Pain

Lonza Biologics plc, Slough, UK

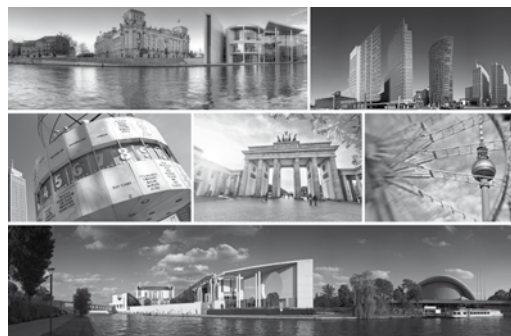
Natasha Pain is currently the QC Biochemistry Manager at Lonza Biologics. Prior to working at Lonza Natasha was the QC Microbiology Group Head for the Biopharmaceutical Centre of Excellence in Drug Discovery, UK, where her role involved environmental monitoring, product testing expertise and the evaluation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



Alexandra Stärk

Novartis Pharma AG, Basle, Switzerland

After studying Hygiene Technology at the Technical University of Albstadt-Sigmaringen, Alexandra Stärk has worked since 1995 at Novartis Pharma AG in Basel/Stein. She is currently responsible for the microbiological QA and QC. She plays a key role in rapid microbiology and in microbiology for sterile production



Social Event

On 27 October 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, 27-28 October 2016, Berlin, Germany**
- ☐ **GMP for Beginners in Sterile Manufacturing, 25-26 October 2016, Berlin, Germany**
(Please tick)

☐ Mr.

☐ Ms.

Title, first name, surname

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Date

Thursday, 27 October 2016, 09.00 h – 17.45 h
(Registration and coffee 08.30 h – 09.00 h)
Friday 28 October 2016, 08.30 h – 15.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49(0)30 2127 0
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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, social event 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 (on 25-26 October)** simultaneously, the fees reduce as follows:

ECA Members € 2,790
APIC Members € 2,890
Non-ECA Members € 2,990
EU GMP Inspectorates € 1,445

Accommodation

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

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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