20 YEARS ECA Academy Your GMP/GDP Information Source

Process Simulation / Media Fill

GMP Requirements on the Validation of Aseptic Processes

SPEAKERS:

Colin Booth
The Binding Site, UK

Natasha Pain
Lonza Pharma & Biotech

Alexandra Stärk
Novartis Pharma Stein

Workshops on
- Managing Interventions
- Handling a Media Fill Failure

10-11 October 2019, Berlin, Germany

PROGRAMME:

- 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

This education course is recognised for the ECA GMP Certification Programme „Sterile Production Manager".
Please find details at www.gmp-certification.eu

Process Simulation/Media Fill

10-11 October 2019, 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: 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 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
The Binding Site, 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 was Vice President Science and Technology. Since 2016 he set up his own consultancy QMS. Since 2017 Director Regulatory and Quality Assurance for "The Binding Site", a specialist IVD company making diagnostics tests for Cancer diagnosis.

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.

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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

☐ **Process Simulation / Media Fills**, 10-11 October 2019, Berlin, Germany
☐ **GMP for Beginners in Sterile Manufacturing,** 08-09 October 2019, Berlin, Germany
(Please tick)

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | Purchase Order No, if applicable

Street/P.O. Box

City | Zip Code | Country

Phone/Fax

E-Mail (please fill in)

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.

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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 %,
- until 1 weeks prior to the conference 50 %
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Date

Thursday, 10 October 2019, 09.00 h – 17.45 h
(Registration and coffee 08.30 h – 09.00 h)
Friday, 11 October 2019, 08.30 h – 15.00 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, 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 8-9 October 2019** 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 hotels. You will receive a room reservation form/POG 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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