



Workshops on

- Managing Interventions
- Handling a Media Fill Failure

Process Simulation / Media Fill

GMP Requirements on the Validation of
Aseptic Processes

7 – 8 May 2015, Berlin, Germany

SPEAKERS:

Colin Booth
Oxoid

Natasha Pain
Lonza Biologics

Alexandra Stärk
Novartis Pharma

PROGRAMME:

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



Process Simulation/Media Fill

7 – 8 May 2015, 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 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

Oxoid Ltd., 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 where he is now 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 7 May 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, 7 - 8 May 2015, Berlin, Germany**
 Environmental Monitoring, 5 - 6 May 2015, 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)

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

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 %

- until 1 week prior to the conference 50 %

- within 1 week prior to the conference 100 %

CONCEPT HEIDELBERG reserves the right to change the materials, in-

structors, 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 HEIDELBERG will not

be responsible for discount airfare penalties or other costs incurred

due to a cancellation.

Terms of payment: Payable without deduc-

tions 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)

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 pri-

vacv 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, 7 May 2015, 09.00 h - 17.15 h
(Registration and coffee 08.30 h - 09.00 h)
Friday, 8 May 2015, 08.30 h - 15.00 h

Venue

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
10557 Berlin
Phone +49 (0)30 288 755 0
Fax +49 (0)30 288 755 900

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.

Save up to € 400,-

If you register for course **Process Simulation/Media Fills AND Environmental Monitoring on 5-6 May 2015** simultaneously, the fees reduce as follows:

ECA Members € 2,780

APIC Members € 2,880

Non-ECA Members € 2,980

EU GMP Inspectorates € 1,490

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.

CONCEPT HEIDELBERG

P.O. Box 10 17 64

D-69007 Heidelberg, Germany

Phone +49 (0) 62 21/84 44-0

Fax +49 (0) 62 21/84 44 34

E-mail: info@concept-heidelberg.de

www.concept-heidelberg.de

For questions regarding content:

Dr Andreas Mangel (Operations Director) at
+49-62 21 / 84 44 41, or per e-mail at
mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Ms Marion Weidemaier (Organisation Manager)
at +49-62 21 / 84 44 46, or per e-mail at
weidemaier@concept-heidelberg.de.