ECA Certified Sterile Production Manager Course*

Workshops on
- Managing Interventions
- Handling a Media Fill Failure

Process Simulation / Media Fill

GMP Requirements on the Validation of Aseptic Processes

7-8 October 2010, Heidelberg, Germany

SPEAKERS:

Colin Booth
Oxoid Ltd, UK

Natasha Pain
Lonza Biologics plc, UK

Alexandra Stärk
Novartis Pharma AG, Switzerland

PROGRAMME:

- The Essential Background
- How to Design a Media Fill
- Particular Technical Issues with Lyophilisation
- The Involvement of the Microbiology Lab
- Handling the Outputs
- Media Fills and Personnel
- Environmental Monitoring
- Identification of Contaminating Microorganisms
- Regulatory Problems

ECA
EUROPEAN COMPLIANCE ACADEMY

* 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

7-8 October 2010, Heidelberg, Germany

Objectives

During this event, you will learn in lectures and workshops how to

- plan a media fill in compliance with European and US GMP requirements,
- interpret the results of a media fill and
- investigate deviations and define follow-up measures.

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 EC-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.

Social Event in Heidelberg

On 7 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.

Programme

Media Fills – The Essential Background

- Regulations affecting aseptic manufacture (Annex 1 and FDA Aseptic Guide)
- PIC/S Guide 'Recommendations on the Validation of Aseptic Processes'
- What media fills consist of (in principle)
- Media Fills for validation
- Routine Media Fills
- Documentation requirements

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 Fill – Particular Technical Issues with Lyophilisation

- Different kinds of simulating lyophilisation processes
- Standing times

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

Discussion of particular issues
- Holding times
- Container / Closure integrity after Media Fills
- Holding Tanks
- Sterile APIs
- Powder Fill
- Blow-Fill-Seal

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 483s

Speakers

Colin Booth
Oxoid Ltd., Basingstoke, 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.

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.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme for the module "Sterile production manager". By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:
- API (Production) Manager
- Biotech Manager
- Computer Validation Manager
- Microbiological Laboratory Manager
- Pharmaceutical Development Manager
- Pharmaceutical Engineering/Production Manager
- Quality Assurance Manager
- Quality Control Manager
- Regulatory Affairs Manager
- Sterile Production Manager
- Validation Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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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 Fill**, 7-8 October 2010, Heidelberg, Germany
☐ **Handling Failures in Sterile Manufacturing**, 5-6 October 2010, Heidelberg, 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

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

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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 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Date

Thursday, 7 October 2010, 10.00 h – 18.00 h
(Registration and coffee 09.30 h – 10.00 h)
Friday 8 October 2010, 09.00 h – 16.00 h

Venue

NH Hotel Heidelberg
Bergheimer Str. 91, 69115 Heidelberg, Germany
Phone +49(0)6221/1327-0, Fax +49(0)6221/1327-100

Fees

Non-ECA Members € 1.690,- per delegate plus VAT
ECA Members € 1.521,- per delegate plus VAT
EU GMP Inspectorates € 845,- per delegate plus VAT
APIC Members (does not include ECA Memberhip) € 1,605,-
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 take part both in the course "Process Simulation" AND "Handling Failures in Sterile Manufacturing" (5-6 October 2010, Heidelberg) the fee reduces as follows:
Non-ECA Members € 2,980.- per delegate plus VAT
ECA Members € 2,682- per delegate plus VAT
EU GMP Inspectorates € 1,490.- per delegate plus VAT
APIC Members € 2,831.- per delegate plus VAT
(does not include ECA membership)

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention "VA 6418 ECA Course" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 9 September 2010. 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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