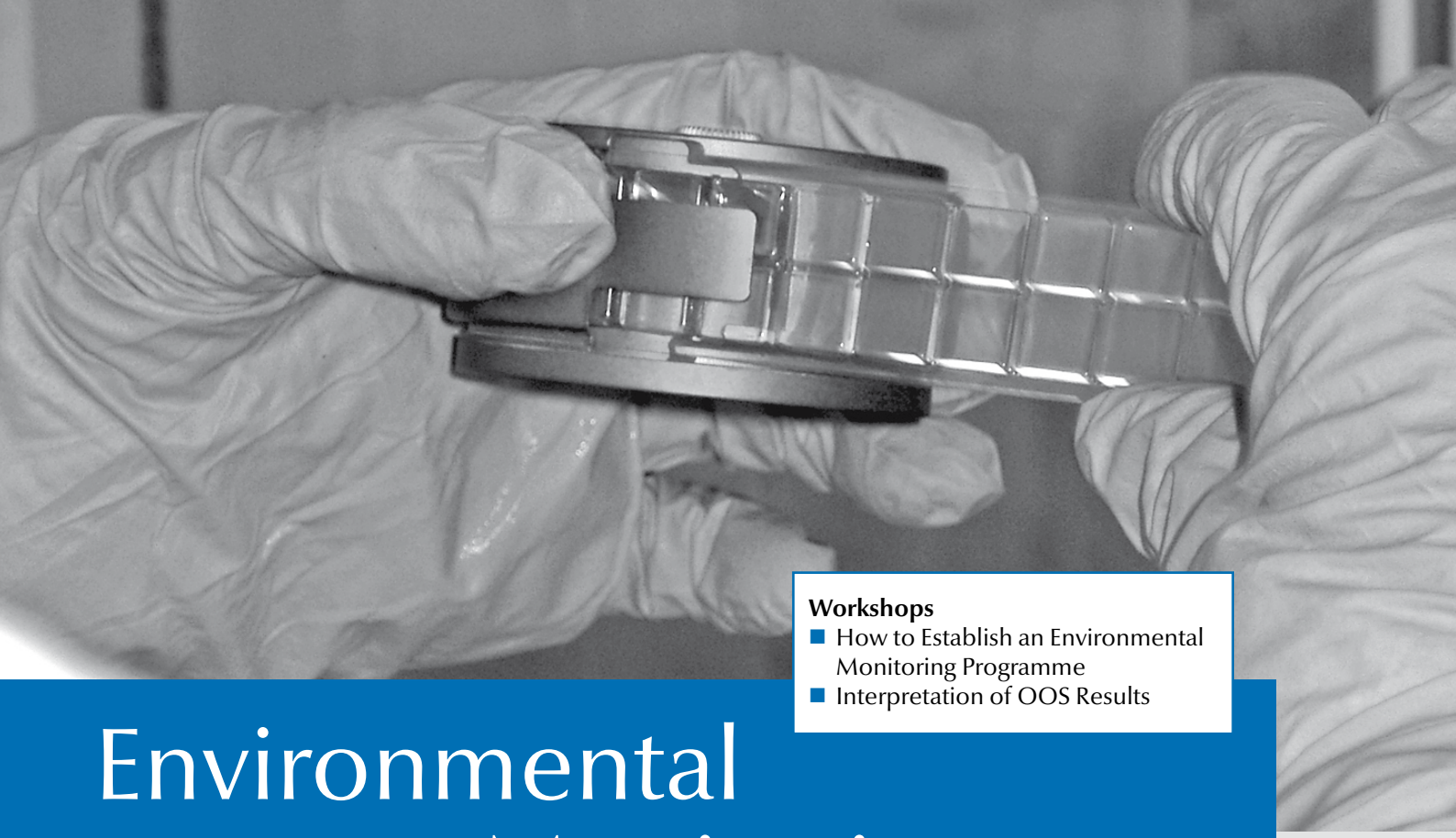

Workshops
- How to Establish an Environmental Monitoring Programme
- Interpretation of OOS Results

Environmental Monitoring

Compliant and Reasonable

5 - 6 May 2015, Berlin, Germany

SPEAKERS:

Colin Booth
Oxoid, UK

Christopher Randell
De La Rue plc, UK

Dr Björn Wiese
Zimmer GmbH, Switzerland

PROGRAMME:

- Environmental Monitoring. Why do we do it – what does it tell us?
- Relevant Guidelines
- Non-viable (particulate) Air Monitoring
- Environmental Monitoring for Non-Steriles
- Clean Rooms - RABS - Isolator: Points to consider
- Case Study: Trending of Environmental Monitoring Results
- Surface / Personnel / Air Monitoring
- Deviation Management for Environmental Monitoring
- Microbiological Methods
- Investigations / Documentation / Trending

ECA ACADEMY

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

Environmental Monitoring

5 - 6 May 2015, Berlin, Germany

Objectives

Environmental monitoring is one of the systems that decide about the product quality in the manufacture of sterile medicinal products. Both European and American GMP regulations place special focus on this topic.

The USP 1116 and especially the FDA's "Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice" deal in detail with environmental monitoring.

However, many of the requirements laid down in these documents seem to be excessive for everyday practice on the one hand and leave great scope for interpretation on the other hand.

In practice, environmental monitoring programmes sometimes develop into time-consuming, cost- and personnel-intensive measures. Therefore, it is the aim of this course to provide the participants with pragmatic recommendations for the creation and implementation of environmental monitoring programmes.
Within the framework of this course, the participants are confronted with current hot topics, like:

- Alert / action levels
- Relationship to batch release
- Locations and frequency
- Identification of isolates
- Sampling procedures

and get to know solutions for their own company practice.

Target Group

This Education Course is directed at staff from Production, Quality Assurance and Quality Control who is responsible for the planning and implementation of environmental monitoring programmes.

Moderator

Colin Booth

Social Event

On Wednesday evening 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

Environmental Monitoring.
Why do we do it – what does it tell us
Colin Booth

Relevant Guidelines
- EU-GMP Guide Annex 1
- USP <1116>
- FDA Aseptic Processing Guide
- ISO 14644 and ISO13824
- An overview about the most important guidances

We are confronted with a wealth of environmental monitoring guidelines, which means that we are sometimes faced with conflicting specifications and classifications. Which one(s) should I follow? The objective of this session is to review the key points of the guidelines and to apply a common sense approach to their application to your facility and processes.
Dr Björn Wiese

Non-viable (particulate) Air Monitoring
- The grading of areas for manufacture of sterile medicinal products in the EU
- How to claim classification of areas to current standards
- How to ensure continuing compliance with the classification
- Selection of sampling locations for qualification and routine
- Particle monitoring, how and how often
- Handling the data

This session addresses non-viable (particulate) monitoring in the context of the manufacture of sterile medicinal products. It highlights the current regulations and standards in Europe and the USA, explains why these requirements have been put in place, and describes how to comply with them.
Dr Björn Wiese

Viable Air Monitoring
- Regulatory Standards
- Settle Plates
  - Validation
  - Drying Issues
  - Where to place them?
- Active Air Sampling
  - Equipment options / comparison
  - Validation
  - Where to place them?

Viable air monitoring gives a snapshot in time of the microbiological status of a clean room. Current debates centre on the value of settle plates vs. active air monitoring. In this presentation we will evaluate both types in detail and establish when best and how to use them as part of your environmental monitoring programme.
Colin Booth

Workshop

How to Establish an Environmental Monitoring Programme

- Identifying weaknesses in contamination control systems
- Identifying locations which will provide "early warning" signals of loss of control
- Preparing useful environmental monitoring SOPs
- Keeping manageable records

Most personnel in the pharmaceutical industry inherit environmental monitoring programmes from the past and rarely get the opportunity to establish a programme for the regulatory requirements and first principles. This session gives participants hands-on experience of working with the regulations and standards versus simplified but "real-life" situations. It is intended to encourage participants to leave with a new outlook on what is being done in their own facilities with a view to improving compliance and adding value.

Colin Booth

Surface / Personnel Monitoring

- Surface:
  - How?
  - Surface sampling techniques
  - Limitations
  - Validation?
- Personnel:
  - When and how?
  - Results and specifications
  - How to deal with shedders/pathogen carriers.

Surface sampling techniques give a qualitative indication of surface cleanliness, their limitations should be understood before the results can be meaningfully interpreted. The question of validating recovery has often been raised but it is a question of trying to validate the impossible. Personnel are without doubt the major source of contamination in a clean room environment and are therefore the major hazard to aseptic process. Personnel monitoring is obviously of value in assessing contamination risks. The questions in personnel monitoring are basically when and how? There is the potential that the monitoring interventions do more harm than good and the results generated are valueless for risk assessment purposes but are very useful for pressurising QA personnel. The intention in this session is how to achieve results of real value from your surface and personnel monitoring programme.

Christopher Randell

Case Study: Trending of Environmental Monitoring Results

- What is a trend?
- How can I use electronic systems to track and trend EM data?
- How to get meaningful information from trending
- Alert and action level setting
- Using trending as tool for pro-active environmental control measures

This case study will focus on the benefits you can achieve by effective trending of EM data. It will demonstrate the importance of getting the complete picture. Actual examples will show how you can succeed in identifying the root cause of microbiological contaminations.

Dr Björn Wiese

Microbiological Methods

- Microbiological media, growth requirements
- Identification of isolates
- Validating your methods
- Using rapid identification techniques
- Recovery problems
- Identification to the level of DNA, what value does it bring

Taking microbiological environmental samples is just the first step in your monitoring programme, you now have to grow, isolate and identify the microorganisms that your have collected. This session deals with all the aspects of this process and how to get reliable, consistent results.

Colin Booth

Clean Rooms – RABS – Isolator: Points to consider in Environmental Monitoring

- Comparison of the technical concepts
- Validation of microbiological media for the isolator
- Selection of sampling points
- Transfer of microbiological media
- Interpretation of the results and handling of excursions

The requirements on the manufacture of sterile products increase. RABS (Restricted Access Barrier Systems) and isolators represent the state of the art. Which consequences arise for environmental monitoring?

Björn Wiese

Environmental Monitoring for Non-Steriles

- Why monitor non-sterile areas
- Risk vs impact
- Overview of regulatory position
- Case study

In this session we will discuss the reasons behind environmental monitoring in a non-sterile area. Is it worth doing? Should you do this? Cover potential benefits against the cost, discuss regulatory view-point, and provide a case study.
Christopher Randell

Deviation Management for Environmental Monitoring

- Steps to be taken in case of excursions
- When is an excursion a deviation?
- Comprehensive root cause analysis
- The nasty "re-occurrence"
- Finding of appropriate actions

FDA and other inspectorates frequently observe deficiencies in deviation handling of Environmental and Utility Monitoring. It is crucial to have a well documented, comprehensive process. Finding a clear root cause for microbiological excursions is often not easy and effective measures against re-occurrence are also difficult to define. This session will discuss tools, concepts and examples for compliant deviation management.
Dr Björn Wiese

Workshop

Interpretation of OOS Results

- What is an OOS in environmental monitoring?
- OOS in relation to trends
- How to investigate
- Follow-up and corrective actions
- Consequences for batch release

Real life case studies are used to get an insight in how to investigate and handle OOS results in environmental monitoring. After an introduction on the principles, participants have to develop an investigation plan, define corrective actions on the presented cases, and assess the product impact. The workshop is very practical and requires the active participation of the participants.
Christopher Randell

Investigations / Documentation

- The information content of "variables" data versus quantitative limits
- Published and practical limits
- The information content of qualitative data
- Communicating with technical management and higher management

The final session of the programme addresses the translation of data from environmental monitoring into information which may be of practical use, add value to the company's operations and ensure compliance.
Colin Booth

Speakers

Colin Booth, *Oxoid, UK*
Colin 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.

Dr Björn Wiese, *Zimmer GmbH, Winterthur, Switzerland*
From 1996 to 2000 Björn Wiese worked as project manager in R&D of Danisco Ingredients, Niebüll, Germany, and developed start up cultures. Since November 2000, he had been head of the microbiology department of Hameln Pharmaceuticals, Hameln, Germany. From 2005 - 2010 Björn worked at the pharmaceutical production site of Cilag in Schaffhausen, Switzerland. 2011 he joined Zimmer GmbH as Associate Director Sterilisation Technology and Analytical Testing.

Christopher Randell, *De La Rue plc, UK*
Chris has been working in the pharmaceutical and medical device industry for over 24 years, he has vast experience in both sterile and non-sterile pharmaceutical manufacturing environments as a microbiologist and as a quality assurance manager at Wyeth/Pfizer. Currently he is QC Laboratory Manager for De La Rue plc.

Conference Exhibition

The European Compliance Academy offers you the opportunity to present your company, your products and services to your target group almost without any scattering losses. The costs for an exhibition space at this event are € 1,490,-.
You will find details and a registration form on our website www.gmp-compliance.org. Just follow the link „Conferences" on the homepage.

Organisation and Contact

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mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager) at
+49 (0)62 21 / 84 44 46, or by e-mail at
weidemaier@concept-heidelberg.de

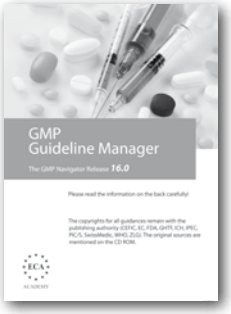
What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?



During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG.
ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- ECA Validation Manager
- ECA QA Manager
- ECA API Production Manager
- ECA Quality Control Manager
- ECA Technical Operations Manager
- ECA Computer Validation Manager
- ECA Regulatory Affairs Manager
- ECA Microbiological Laboratory Manager
- ECA Sterile Production Manager
- ECA Biotech Manager
- ECA Pharmaceutical Development 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.

Lufthansa
Mobility Partner

Lufthansa is Mobility Partner for all ECA Events
As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

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Easy Registration

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69007 Heidelberg
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Reservation Form:
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e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Reservation Form (Please complete in full)

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☐ **Environmental Monitoring**, 5 - 6 May 2015, Berlin, Germany
☐ **Process Simulation/Media Fills**, 7 - 8 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**

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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

Tuesday, 5 May 2015, 09.00 – 17.45 h
(Registration and coffee 09.00 – 09.30 h)
Wednesday, 6 May 2015, 08.30 – 16.00 h

Venue

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
10557 Berlin, Gemany
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 **Environmental Monitoring** AND **Process Simulation/Media Fills on 7-8 May 2015** simultaneously, the fees reduce as follows:
ECA Members € 2,780
Non-ECA Members € 2,980
APIC Members € 2,880
EU GMP Inspectorates € 1,490

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. 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.

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

ECA 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 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.

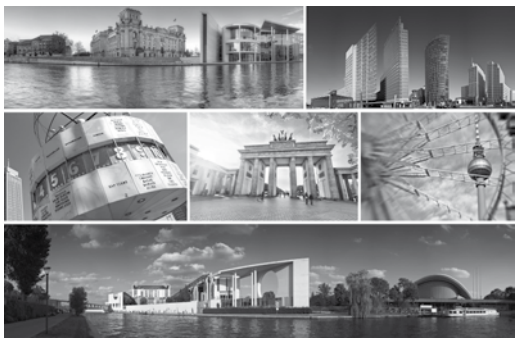
Regulatory Problems with Media Fills
- What the regulators expect
- Examples from Warning Letters
- Examples from 483's

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

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(Please tick)

☐ Mr. ☐ Ms.

Title, first name, surname

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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, 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)

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Organisation and Contact

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Ms Marion Weidemaier (Organisation Manager)
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