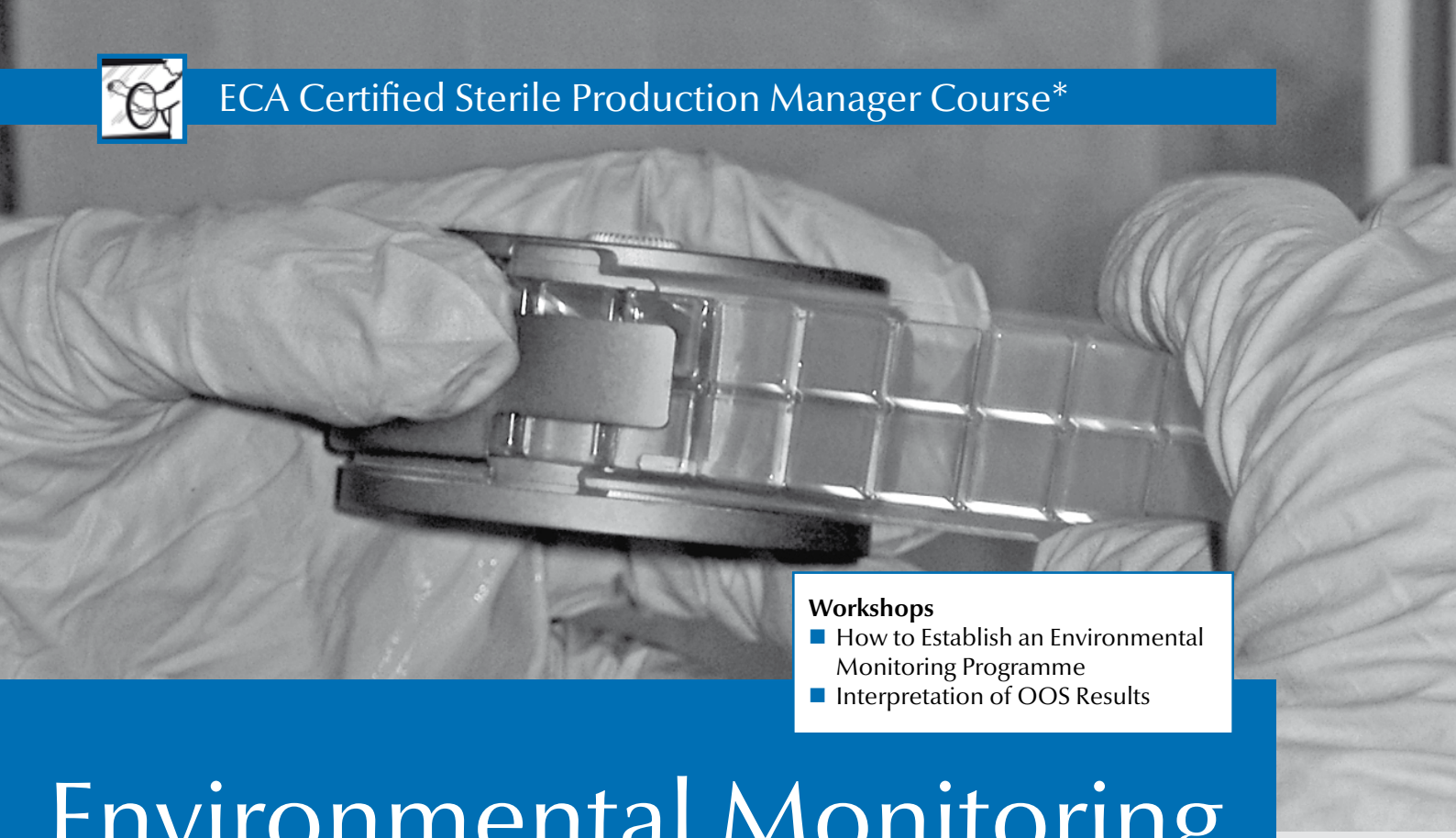
ECA Certified Sterile Production Manager Course*



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

Environmental Monitoring

Compliant and Reasonable

15-16 May 2012, Copenhagen, Denmark

SPEAKERS:

Colin Booth
Oxoid, UK

Christopher Randell
Microsulis Medical, 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: The Trending Tool for Environmental Monitoring Data at Cilag
- Surface / Personnel / Air Monitoring
- Deviation Management for Environmental Monitoring
- Microbiological Methods
- Investigations / Documentation / Trending

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

Environmental Monitoring

15-16 May 2012, Copenhagen, Denmark

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 Tuesday 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 Data

- 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, *Microsulis Medical Ltd., 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 Quality & Regulatory Manager for a medical device manufacturer, Microsulis Medical Ltd.

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.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide 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.

What Are the Benefits of ECA?
First benefit:
During the membership, you enjoy a 200 EUR discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG.
More information about ECA can be obtained on the Website **http://www.gmp-compliance.org**

About CONCEPT HEIDELBERG

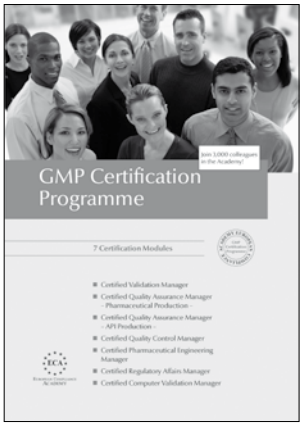
Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG.
ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

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.



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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Environmental Monitoring, 15-16 May 2012, Copenhagen, Denmark

☐ 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)

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 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, 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 deductions 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)!

Date

Tuesday, 15 May 2012, 09.30 – 17.45 h
(Registration and coffee, 09.00 – 09.30 h)
Wednesday, 16 May 2012, 08.30 – 16.30 h

Venue

Radisson BLU Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark
Phone +45 33 96 50 00
Fax +45 33 96 55 00

Fees

ECA Members EUR 1,490.- per delegate plus VAT
APIC Members EUR 1,590.- per delegate plus VAT
Non-ECA Members EUR 1,690.- per delegate plus VAT EU GMP Inspectorates EUR 845.- per delegate plus VAT
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.

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 "ECA Environmenal Monitoring" to receive the specially negotiated rate (DKK 1,445,- per night, excl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 13 April 2012. 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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