

# Environmental Monitoring

Compliant and Reasonable

## Workshops

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

## SPEAKERS:



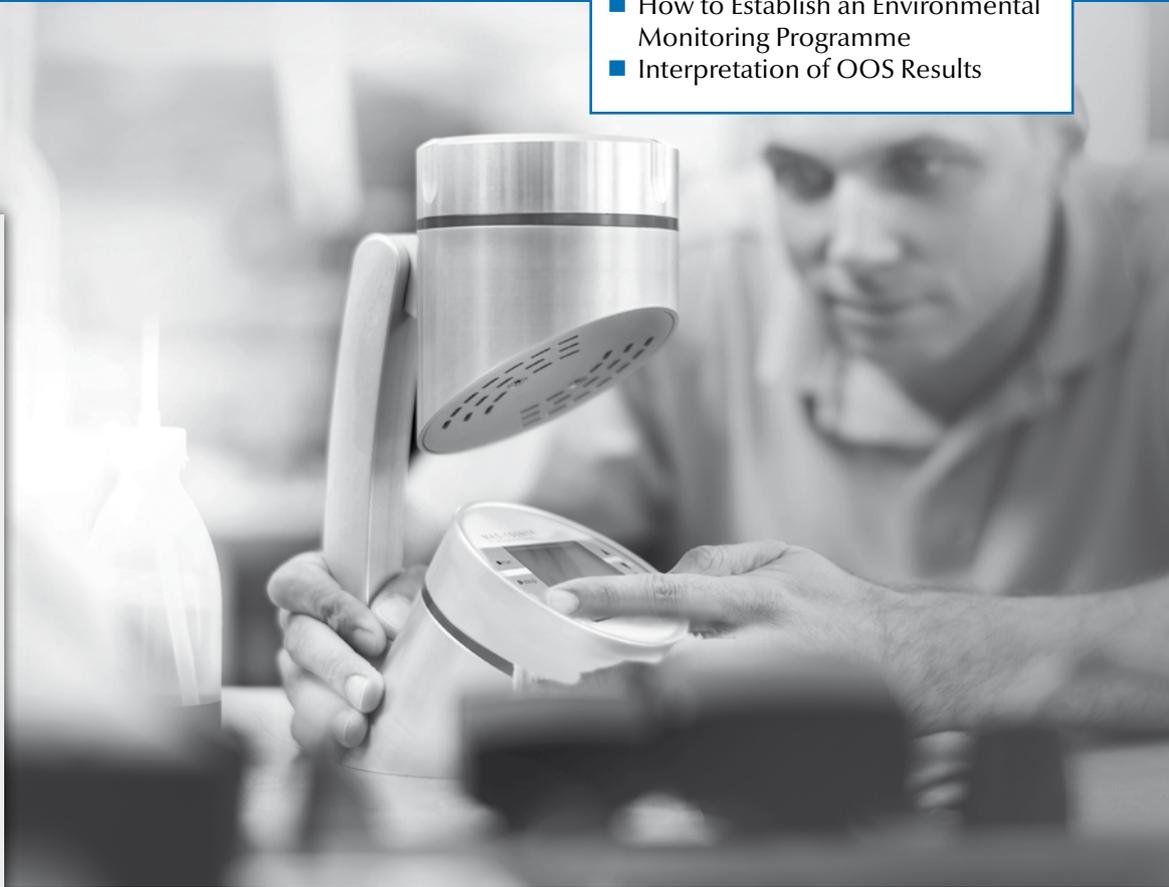
**Colin Booth**  
*Binding Site Group Ltd, UK*



**Christopher Randell**  
*CooperVision, UK*



**Dr Björn Wiese**  
*Zimmer Biomet GmbH, Switzerland*



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28-29 May 2019, Copenhagen, Denmark

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## 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

# Environmental Monitoring

28-29 May 2019, 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 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.



## 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 you 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

Binding Site Group 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, now Thermo Fisher Scientific, where he was Vice President Science and Technology. Since 2017 he is Director Regulatory and Quality Assurance for The Binding Site, a specialist IVD company making diagnostics test for Cancer diagnostics.



Christopher Randell

CooperVision, UK

Chris has been working in the pharmaceutical and medical device industry for over 27 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 Senior QA Manager for CooperVision.



Dr Björn Wiese

Zimmer Biomet GmbH, Switzerland

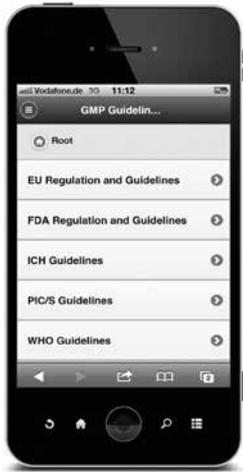
From 1996 to 2000 Björn Wiese worked as project manager in R&D of Danisco Ingredients, Niebüll, Germany, and developed start up cultures. Since November 2000, he had been head of the microbiology department of Hameln Pharmaceuticals, Hameln, Germany. From 2005 - 2010 Björn worked at the pharmaceutical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

## 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](http://www.gmp-compliance.org). Just follow the link „Conferences“ on the homepage.

## Use the GMP App at no costs!



The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app

just enter [app.gmp-compliance.org](http://app.gmp-compliance.org) in your browser and the WebApp opens immediately.

## Lufthansa is Mobility Partner for all ECA Events



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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!

## GMP/GDP In-house Training Courses

Are you interested in a GMP/GDP training course at your facility for a larger group of people?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP: APIs (ICH Q7), Medicinal Products, Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity

You will find a time schedule for each training course at [www.gmp-compliance.com](http://www.gmp-compliance.com), button "Inhouse Training"

We also offer in-house training courses for Qualified Persons. Please contact us for more information: [info@gmp-compliance.org](mailto:info@gmp-compliance.org)

We will be happy to design further GMP training courses for you on request.

## GMP/GDP 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 modules:

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- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity Manager

On the internet at [www.gmp-compliance.org](http://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](mailto: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](mailto:info@concept-heidelberg.de)



Internet:  
[www.gmp-compliance.org](http://www.gmp-compliance.org)



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Reservation Form (Please complete in full)

### Environmental Monitoring

28-29 May 2019, Copenhagen, Denmark

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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City Zip Code

Country

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E-Mail (please fill in)

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D-69007 Heidelberg

GERMANY

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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 %
    - within 1 week prior to the conference 50 %
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- CONCEPT HEIDELBERG reserves the right to change the materials, in-

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**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!) (As of January 2012)

German law shall apply. Court of jurisdiction is Heidelberg.

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#### Date

Tuesday, 28 May 2019, 09.00 - 17.45 h  
(Registration and coffee, 08.30 - 09.00 h)  
Wednesday, 29 May 2019, 08.30 - 16.00 h

#### Venue

Radisson Blu Scandinavia Hotel  
Amager Boulevard 70  
2300 Copenhagen S, Denmark  
Phone +45 33 96 50 00  
[scandinavia.meetings.events@radissonblu.com](mailto:scandinavia.meetings.events@radissonblu.com)

#### 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.

#### 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](http://www.gmp-compliance.org).

#### 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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**For questions regarding content please contact:**  
Dr Andreas Mangel (Operations Director) at +49 (0)62 21 / 84 44 41, or by e-mail at [mangel@concept-heidelberg.de](mailto:mangel@concept-heidelberg.de).

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