



## Speakers



**Arjan Langen**  
GE Healthcare, The Netherlands



**Chris Randell**  
CooperVision, UK



**Dr Björn Wiese**  
Janssen Cilag, Switzerland

# Environmental Monitoring

## Compliant and Reasonable

18/19 June 2024 | Copenhagen, Denmark



Picture: MBV AG - Microbiology and Bioanalytic

## Highlights

- Environmental Monitoring. Why Do We Do It – What Does it Tell Us?
- Relevant Guidelines Including the New EU GMP Annex 1
- Non-viable (particulate) Air Monitoring
- Environmental Monitoring for Non-Steriles
- Clean Rooms - RABS - Isolator: Points to Consider
- Surface | Personnel | Air Monitoring
- Deviation Management for Environmental Monitoring
- Microbiological Methods
- Investigations | Documentation | Trending

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Workshops / Case Study:

- How to Establish an Environmental Monitoring Programme
- Interpretation of OOS Results
- Case Study: Trending of Environmental Monitoring Results

## 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, the new EU GMP Annex 1 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 training 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 Audience

This ECA Training Course is directed at staff from Production, Quality Assurance and Quality Control who is responsible for the planning and implementation of environmental monitoring programmes. It is also valuable for decision makers who have to deal with environmental monitoring data within the framework of product release.

## Programme

### Environmental Monitoring

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- Why do we do it – what does it tell us?

### Relevant Guidelines

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

### Surface / Personnel Monitoring

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

### Viable Air Monitoring

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

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

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- 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

### Non-viable (particulate) Air Monitoring

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- 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



## Workshop

### How to Establish an Environmental Monitoring Programme / Use of FMEA to Determine Sample Points in Routine Monitoring

- 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



## 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

## 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

## Environmental Monitoring for Medical Devices

- Environmental Monitoring requirements considering ISO and AAMI
  - Classified Cleanrooms
  - Controlled Environment
- Real life example
- What to do when excursions occur?

## Environmental Monitoring for Non-Steriles

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

## 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



## 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

## Investigations / Documentation

- The information content of “variable” data versus quantitative limits
- Published and practical limits
- The information content of qualitative data
- Communicating with technical management and higher management

## Speakers



Arjan Langen  
GE Healthcare, The Netherlands

Arjan Langen has over 20 years of experience within the field of pharmaceutical microbiology. Currently he is a Director Sterility Assurance at GE Healthcare, responsible for the global Sterility Assurance program. Besides he was a member of the ECA Annex 1 task force that worked on the detailed review of the draft revision text of Annex 1. He is microbiologist by training, qualified IRCA/QCI auditor and Green Belt certified.



Chris Randell  
CooperVision, Eastleigh, 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  
Janssen Cilag, Schaffhausen  
Switzerland

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. From 2011 to 2022 he was Director Sterilization Technology and Analytical Testing at Zimmer Biomet. Since September 2022 he leads the Community of Practice for Sterilization Technologies at Janssen Cilag, Schaffhausen.

Reservation Form (Please complete in full)

## Environmental Monitoring, 18/19 June 2024, Copenhagen | Denmark

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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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 July 2022).

German law shall apply. Court of jurisdiction is Heidelberg.

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## Date of the Training Course

Tuesday, 18 June 2024, 09.00 – 17.30 h)

(Registration and coffee, 08.30 – 09.00 h)

Wednesday, 19 June 2024, 08.30 – 16.00 h

## Venue

Radisson Blu Scandinavia Hotel

Amager Boulevard 70

2300 Copenhagen S, Denmark

Phone +45 (0)33 96 50 00

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## Fees (per delegate plus VAT)

ECA Members € 1,690

APIC Members € 1,790

Non-ECA Members € 1,890

EU GMP Inspectorates € 945

The conference fee is payable in advance after receipt of invoice.

## Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. 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).

## Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

## Conference language

The official conference language will be English.

## Social Event



In 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.

## 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

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### For questions regarding reservation, hotel, organisation etc. please contact:

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