ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

## Speakers

**Arjan Langen**
GE Healthcare, The Netherlands

**Chris Randell**
CooperVision, UK

**Dr Björn Wiese**
Janssen Cilag, Switzerland

# Environmental Monitoring

## Compliant and Reasonable

## Live Online Training on 16/17 May 2023

Picture: MBV AG - Microbiology and Bioanalytic

## Highlights

- Environmental Monitoring. Why Do We Do It – What Does it Tell Us?
- Relevant Guidelines Including EU GMP Annex 1 Revision
- 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

Workshops / Case Studies:
- How to Establish an Environmental Monitoring Programme
- Interpretation of OOS Results
- 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.


Picture: Heipha

In practice, environmental monitoring programmes sometimes develop into time-consuming, cost- and personnel-intensive measures. Therefore, it is the aim of this Live Online Training to provide the participants with pragmatic recommendations for the creation and implementation of environmental monitoring programmes.

Within the framework of this Live Online Training, 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 Live Online Training 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

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

## Relevant Guidelines

- 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

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

## 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?

## 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

## 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

## Workshop / Case Study

**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 occurs?

## 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 / Case Study

**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 is a member of the ECA Annex 1 task force that works 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

Between 2000 and 2005, 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.

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CONCEPT HEIDELBERG
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Fax +49 (0) 62 21/84 44 34

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Reservation Form (Please complete in full)

## Live Online Training: Environmental Monitoring
16/17 May 2023

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

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German law shall apply. Court of jurisdiction is Heidelberg.

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## Date of the Live Online Training
Tuesday, 16 May 2023, 09.00 – 17.00 h
Wednesday, 17 May 2023, 09.00 – 16.00 h

All times mentioned are CEST.

## Technical Requirements
We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

## 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.

## Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org

## Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

## Conference language
The official conference language will be English.

## You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

## Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

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

**For questions regarding organisation etc. please contact:**
Ms Isabell Helm (Organisation Manager) at
+49(0)62 21/84 44 49, or at
helm@concept-heidelberg.de.

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