



Speakers



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Environmental Monitoring

Compliant and Reasonable



Live Online Training on 22/23 September 2020



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

Case Studies:

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

Objective

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 revised 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 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

- EU-GMP Guide Annex 1 (revision)
- 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



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 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



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
Zimmer Biomet GmbH, Winterthur, Switzerland

From 1996 to 2010 Björn Wiese worked in microbiology departments i.a. at Hameln Pharmaceuticals, Hameln, Germany and Cilag in Schaffhausen, Switzerland. 2011 he joined Zimmer GmbH now as Director Sterilization Technology and Analytical Testing.

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Environmental Monitoring Live Online Training on 22/23 September 2020

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Date of the Live Online Training

Tuesday, 22 September 2020, 09.00 – 17.00 h

Wednesday, 23 September 2020, 09.00 – 15.30 h

All times mentioned are CEST.

Technical Requirements

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Fees (per delegate plus VAT)

ECA Members € 1,490

APIC Members € 1,590

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EU GMP Inspectorates € 845

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.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at <https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars>.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training.

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