ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

Speakers

Arjan Langen
GE Healthcare, The Netherlands

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Environmental Monitoring

Compliant and Reasonable

22/23 September 2020 | Copenhagen, Denmark

Highlights

- 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

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

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.
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
- USP <1116>
- FDA Aseptic Processing Guide
- ISO 14644 and ISO13824
- An overview about the most important guidances

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

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?

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

Surface / Personnel Monitoring

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

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

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

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 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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GERMANY

Reservation Form (Please complete in full)

Environmental Monitoring, 22/23 September 2020, Copenhagen, Denmark

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

E-Mail (Please fill in)

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Date
Tuesday, 22 September 2020, 09.00 – 17.45 h
(Registration and coffee, 08.30 – 09.00 h)
Wednesday, 23 September 2020, 08.30 – 16.00 h

Venue
Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45(0)33 96 50 00
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/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.

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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