ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Dr Raphael Bar
BR Consulting

Susan Cleary
Novatek International

Michael Schiffer
CSL Behring

Martin Schoepperle
Lonza

Environmental Monitoring

Trending, Analysis and Data Management

Live Online Training on 12/13 November 2024

A Special Training on Efficient Data Management and Interpretation

Highlights

- Regulations and Infra Structure
- Dos and Don'ts for setting up an efficient monitoring program for trending and analysis
- Tools like Novatek Environmental Monitoring System, MODA and Minitab
- Charting, Trending and approaches for Interpretation
- Data Variability and Control Charts
- How to minimize false alarms in environmental monitoring data
- Strategy and Tools for detecting Trends
- Real-time continuous LIF monitoring of viable and inert particles
- Risk Management and investigation

Programme

Objective

This practical course will present the basic methodology of evaluating the Environmental Monitoring (EM) data using elementary Statistical Process Control (SPC) tools as well as empirical approaches to set microbial control limits for clean rooms. This course will address the following issues:

- Overview of controlled rooms classifications, elements of an EM program and present EU and FDA regulations including the recent EU GMP Annex 1 update.
- How to organize and present an abundant amount of microbial data in meaningful graphs
- To understand how action and alert control limits are set
- How to demonstrate that the environmental microbial monitoring process is under a ***state of control***
- How to calculate and plot the proposed ***Contamination Recovery Rates*** in USP Chapter <1116>
- To detect a trend in the environmental microbial monitoring process
- How to apply risk assessment in investigations

All above issues will be demonstrated on examples and case studies of microbial counts generated in controlled rooms of manufacturing facilities of sterile products.

A prior knowledge of control charts is an advantage.

Background

Regulatory agencies require from manufacturing companies of pharmaceuticals and biopharmaceuticals, particularly of sterile drug products, to maintain an environmental monitoring program, whereby particulates as well as microorganisms in either air samples (active and passive sampling) or in surfaces (contact plates) are routinely tested and monitored.
Thus, a multitude of environmental microbial data is generated on a routine basis and it is recorded in a manner permitting trend evaluation. But collecting EM data is only the first challenge. The following challenge for the responsible person in quality is charting, analyzing data, setting action and alert limits, interpreting the overall monitoring process behaviour, detecting a trend or shift in contamination levels, monitoring excursion rates and contamination recovery rates, while conducting an ongoing risk analysis. According to the recent revision of EU Annex 1 (2022), results from monitoring should be considered when reviewing batch documentation for finished product release. Therefore, this course is aimed at providing empirical tools for charting and trending EM data.

Target Audience

- Environmental Monitoring personnel in facilities of pharmaceuticals, biopharmaceuticals and medical devices
- Microbiologists
- Quality Assurance / Regulatory Affairs personnel
- Production Managers / QC Managers
- Senior Management

Moderators

Raphael Bar and Axel Schroeder

Programme

Environmental Monitoring: Introduction, Regulations and Practical Aspects

- Overview of current regulations, EU Annex 1 (2022)
- Practical aspects of environmental monitoring
- How to set up a structured EM program to gain strong data and handle big data amounts
- Industry best practices

Variability of Data

- Standard deviation of a sample and of population
- Histogram
- Standard deviations of the mean range
- Relation between standard deviation and range
- Short-term variation versus global variation
- Separating the signal from noise

Overview of Control Charts of Attributes (Microbial Counts)

- Poisson Distribution
- c Chart
- u Chart
- I-MR versus c Chart

Contamination Recovery Rates

- Contamination recovery rates (USP approach <1116>)
- Plotting recovery rates and excursion rates
- Demonstration of contamination recovery rates per USP <1116>

Overview of Control Charts of Individual Microbial Counts

- Moving range (*m*R)
- Control charts of individual data (X*m*R)
- Calculation of control limits

Trending Tool Applications

- Trending tool examples from industries
- Data collection tools
- Investigation and risk assessment for negative trends

Overview Control Charts of Grouped Data

- Plotting Run chart and control chart (Process Behavior Chart)
- Computation of three-sigma Control limits
- Control charts of average, range and standard deviation
- The three-way chart
- Examples of three-way charts

Demonstration of Building Control Charts of Real-Life Microbial Counts in Classified Rooms (with StatGraphics®)

Interactive Case Studies

- In this case study, Michael Schiffer will deepen and discuss in detail the contents of previous lectures using practical examples.

How to Minimize False Alarms in Environmental Monitoring Data

- Part1:
  Adjusting SPC rules to pharmaceutical process data
  - Why traditional SPC rules are rarely met for microbial data
  - State of Control *versus* State of Statistical Control
  - Practical SPC rules
- Part 2:
  Detecting variation and trends in control charts
  - Examples: Control charts of real-life EM data

Data Strategies and Environmental Monitoring – MODA System

- Data requirements for the evaluation and selection of an electronic system
- How to maximise the value of your data
- Trend analysis tools and tips
- Setting alert and action limits
- Data integrity issues

Data Management and Digitalization by Novatek International

- Digitalization of Environmental Monitoring Processes
- Global EM
- Risk Based Environmental Monitoring
- Addressing EU cGMP / Annex 1 /data integrity requirements
- Smart Trending and Reporting using AI

Strategy for Monitoring a *State of Control* under Ongoing Process Verification Plan

- Phase 1 and Phase 2 in process monitoring
- Is your EM process under a state of control?
- Trending and continued process verification
- Real-time continuous LIF monitoring of viable and inert particles

Speakers

Dr Raphael Bar, BR Consulting, Israel

Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and the analytical QC Laboratory at Pharmos. He served in the Scientific Advisory Board of global PDA (USA) and is presently a board member of Israel PDA Chapter as well as a member of the organizing committee of the Israel Society for Analytical Chemistry. For the last fifteen years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.

Susan B. Cleary, Novatek International, Canada

Susan has almost 25 years of experience in designing, developing, and implementing large scale quality management and contamination control systems. Susan works with pharmaceutical, biotech, and medical device companies and specializes in data integrity and regulatory compliance for cleanroom control and is highly experienced with streamlining quality processes and digitalizing data for GMP and Annex 1 compliant systems dedicated to Cleaning Validation, Environmental Monitoring, and Utility Monitoring.

Michael Schiffer, CSL Behring, Switzerland

Michael Schiffer worked for several years at Novartis' largest biologics technical development and sterile manufacturing site with various technologies in fill & finish of commercial and clinical biopharmaceuticals. Beginning his career in microbiological quality assurance, he then transitioned into the manufacturing unit. Subsequently, he assumed leadership of a quality control laboratory. In his current position, Michael is part of CSL Behring's R&D Global Pathogen Safety department. In this capacity, he offers global support on matters pertaining to Adventitious Agents Safety and leads the scientific support team for Switzerland.

Martin Schoepperle, Lonza, Switzerland

Martin studied Biochemistry at Queensland University for Technology and got his Masters in Molecular Biology at Goethe University Frankfurt. After working in environmental monitoring and QC labs for several years he joined Lonza in 2020 as the Associate Principal Scientist where he helped establish a QC microbiology lab at the new production facility in Stein, Switzerland. Since 2021 he is part of Lonza's MODA team supporting European customers with the configuration and deployment of the system.

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Reservation Form (Please complete in full)

Environmental Monitoring - Trending, Analysis and Data Management
Live Online Training on 12/13 November 2024

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)

General terms and conditions
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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
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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.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 12 November 2024, 09.00 – 18.00 h CET
Wednesday, 13 November 2024, 09.00 – 17.00 h CET

Technical Requirements

We use Webex for our live online training courses and webinars. At 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 € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The 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.

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training...." This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
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