ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Dr Raphael Bar
BR Consulting

Susan Cleary
Novatek International

Josh Magnus
Magnus Solutions

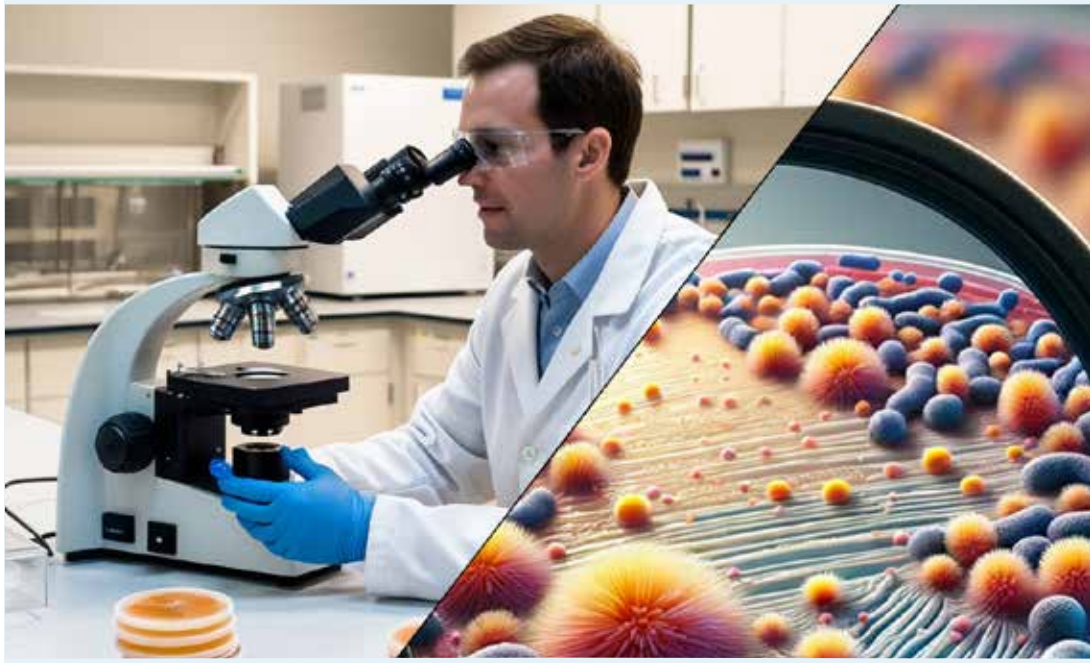
Michael Schiffer
CSL Behring

Staci Williams
Lonza

Environmental Monitoring Data

Trending, Analysis and AI

Live Online Training on 11-13 November 2025



From traditional SPC to Artificial Intelligence (AI)

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
- Artificial Intelligence for Trend Analysis, Detection of Variations and Contamination Prediction

NEW: incl. AI application

Objective

This practical course will present the basic methodology of evaluating 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
- How 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>
- How to detect a trend in the environmental microbial monitoring process
- How to apply risk assessment in investigations

All issues above will be demonstrated using 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 authorities require manufacturing companies of pharmaceuticals and biopharmaceuticals, particularly of sterile drug products, to maintain an environmental monitoring program. Particulates as well as microorganisms in either air samples (active and passive sampling) or on surfaces (contact plates) should be 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 initial challenge. The following challenge for the responsible person in quality is charting and analysing data, setting action and alert limits, interpreting the overall monitoring process behaviour, detecting trends or shifts 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 con-sidered 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 Dr Gerhard Becker

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

Leveraging AI for Smarter Cleanroom Data Analysis – Introduction and Practical Applications

- Introduction to AI in cleanroom operations, environmental monitoring, and aseptic processing.
- How AI enhances trend analysis, real-time data interpretation, and contamination prediction.
- Practical applications of AI in data-driven risk assessment, process optimization, and quality control.

Live Demo & Case Studies – AI in Microbiological Data Analysis

- Step-by-step walkthrough of AI-driven microbial trend analysis.
- How AI detects variations, predicts contamination risks, and reduces false alarms.
- Interactive discussion on applying AI solutions in participants' cleanroom environments.

The Future of AI in Cleanroom Monitoring – Tools, Implementation Strategies & What's Next

- Overview of AI-powered cleanroom monitoring solutions and emerging technologies.
- How to integrate AI into existing environmental monitoring programs without disrupting compliance.
- Future trends: AI + IoT for continuous monitoring, predictive contamination control, and process automation.
- Final discussion: What's next for AI in regulatory compliance and GMP environments?

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.

Josh Magnus, Magnus Solutions, Israel

Josh Magnus is a sterile manufacturing and cleanroom expert, specializing in environmental monitoring, aseptic processing, and contamination control. He is the Founder and CEO of Magnus Solutions, a consulting and training firm providing regulatory guidance, cleanroom services, and aseptic training for the pharmaceutical, medical device, and compounding industries.

With prior roles as Aseptic Expert and Training Manager at Teva Pharmaceuticals and Head of Cleanroom Services at HY Labs Israel, Josh has led environmental monitoring initiatives, developed risk-based contamination strategies,

and trained hundreds of industry professionals in GMP cleanroom operations. He has also served as an SME for FDA, EU, and IMH audits, specializing in EM data interpretation and process optimization.

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.

Staci Williams, Lonza

Staci is a Key Account Manager in Lonza's Informatics division, specializing in the MODA platform. She supports clients in digital transformation for their quality and manufacturing processes. Before joining Lonza, she held various quality-focused roles, ensuring GMP compliance in biologics, vaccines, and cell and gene therapy manufacturing. She holds a Bachelor's degree in Biochemistry from New York University and a Master's degree in Regulatory Science from Johns Hopkins University.

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Reservation Form (Please complete in full)

Environmental Monitoring Data – Trending, Analysis and AI
Live Online Training on 11-13 November 2025

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 %
- Cancellation within 2 weeks prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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, 11 November 2025, 09.00 - 17.00 h
Wednesday, 12 November 2025, 09.00 - 17.00 h
Thursday, 13 November 2025, 09.00 - 13.00 h
All times mentioned are 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 € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,245
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22142.

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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