ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Dr Raphael Bar
BR Consulting

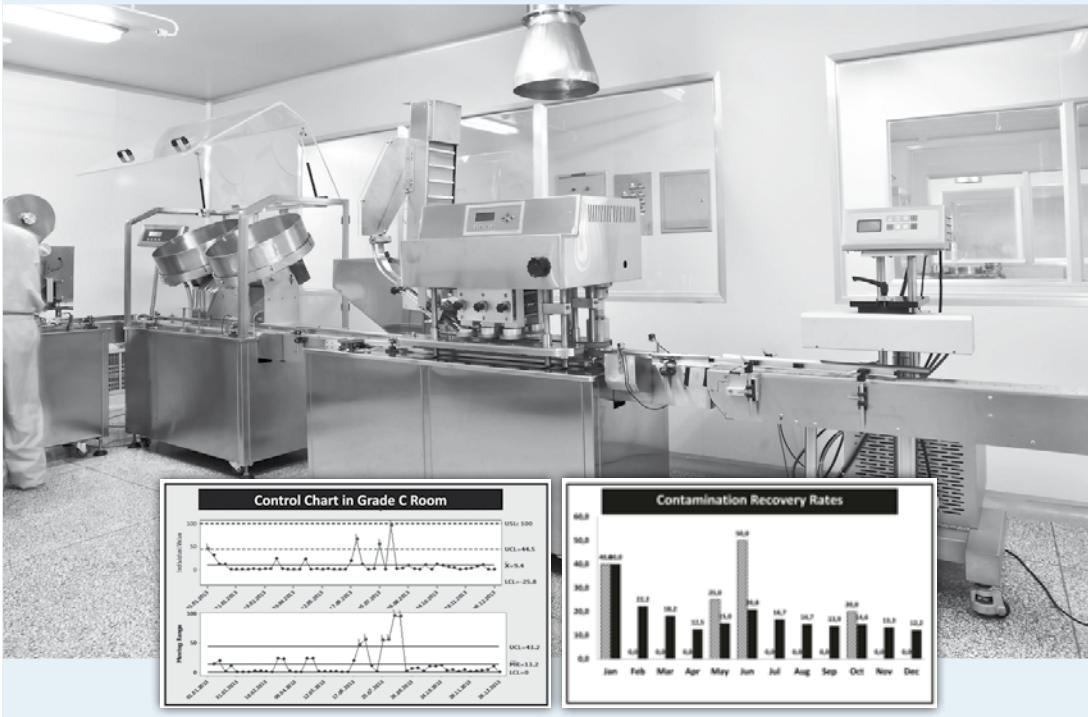
Sinéad Cowman
Lonza

Michael Schiffer
CSL Behring

Environmental Monitoring

Trending, Analysis and Data Management

Live Online Training on 09/10 November 2021



A Special Training on Efficient Data Management and Interpretation

Highlights

- Regulations and Infra Structure
- Tools like MODA and Minitab
- Charting, Trending and approaches for Interpretation
- Data Variability
- 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 assessment in investigation

Objective

This Live Online Training will first 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 ISO 14664 changes.
- 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 newly 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 (Dec. 2017), 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

Programme

Environmental Monitoring: Introduction and Regulations

- Overview of current regulations
- Draft Annex 1

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 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

Contamination Recovery Rates

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

Overview of Control Charts of Individual Microbial Counts

- Moving range (mR)
- Control charts of individual data (XmR)
- Calculation of control limits
- The three-way chart
  - Examples of three-way charts

Trending Tool Applications

- Trending tool examples from industries
- Data collection tools
- Reaction and measures on negative trends
- Responsibilities

Overview of Control Charts of Attributes (Microbial Counts)

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

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

Investigation and Risk Assessment

- Practical aspects of Environmental Monitoring
- How to set up an structured EM program and gain strong data
- Risk-based approach
- Handling of big data amounts
- EM program examples from Industrial clean rooms

How to Minimize False Alarms in Environmental Monitoring Data

- Why we need to minimize false alarms
- Why traditional SPC rules are rarely met for microbial data
- State of control versus state of statistical control
- Practical SPC rules
- 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

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

Moderators

Raphael Bar and Axel Schroeder

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 thirteen years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.

Sinéad Cowman
EU Business Development Manager – Informatics, Lonza

Sinéad studied Microbiology at Trinity College Dublin and has over 20 years' experience in QC Microbiology. She joined Lonza in 2005 to manage their endotoxin business in Ireland and for the past 10 years has been involved in their informatics division. She has worked with many organizations from small biotech to global pharmaceutical companies to implement and validate a paperless solution for QC Microbiology and help them achieve an automated integrated approach to data collection and evaluation. She recently completed a PGDip in Strategy and Innovation at Oxford University and is focused on driving the strategic direction of informatics at Lonza..

Michael Schiffer
Senior Manager Global R&D, CSL Behring, Switzerland

Michael Schiffer worked at Novartis from 2013 to 2020 in various functions in the area of fill & finish of commercial and clinical biopharmaceuticals and their launch. After his start in microbiological quality assurance and then working as a process expert in manufacturing, he headed a quality control laboratory for chemical-physical release and stability testing. Since 2020 within Research and Development at CSL Behring in the Global Pathogen Safety department, he provides global support to general matters related to Pathogen Safety and leads the scientific support team for Switzerland.

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Reservation Form (Please complete in full)

Environmental Monitoring - Trending, Analysis and Data Management
Live Online Training on 09/10 November 2021

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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If you cannot attend the conference you have two options:
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- Cancellation until 1 weeks prior to the conference 50 %
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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 http://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, 09 November 2021,
09.00 – 18.00 h CET
Wednesday, 10 November 2021,
09.00 – 16.30 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer 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 € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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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