ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Dr Hans-Joachim Anders
Novartis Stein, Switzerland

Dr Stefanie Bayer
Labor LS, Germany

Arjan Langen
GE Healthcare, The Netherlands

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Concept Heidelberg, Germany

Microbiology for Non-Microbiologists

Understand the „true“meaning of microbiological findings

Live Online Training on 02/03 February 2021

Highlights

- Acquire a basic knowledge in microbiology
- Develop an understanding for the meaning of microbiology for the quality of medicinal products
- Get familiar with typical microbiological tests in the pharmaceutical industry
- Learn to interpret microbiological data correctly
- Case studies on deviations and trouble shooting

Examples and Case Studies of Microbiological Deviations and Trouble Shooting

Objective

It is the aim of this Live Online Training to familiarise responsible personnel from production, quality assurance and engineering with microbiological questions. The participants learn how to interpret microbiological data and which consequences these have for the production.

Background

The quality of drugs and the quality assurance during production are above all determined by their microbiological characteristics. The microbiological requirements on drugs are laid down in various regulations. When an authority inspects a company, it will focus its attention on these and on the requirements made on hygiene.

In their daily work, the responsible personnel in the production units has to understand microbiological results and evaluate their significance for further decisions. However, in practice many microbiological results are misinterpreted and thus often the wrong conclusions are drawn from them. When asked for the most frequent misinterpretations of microbiological results, pharmaceutical microbiologists gave the following answers.

- The difference between bioburden and sterility testing (are they the same?)
- The use of disinfectants guarantees the sterility of the object, surface, culture treated.
- The distribution of microorganisms in a sample or on a surface is uniform.
- Motile microorganisms can swim hundreds of meters in an hour causing contamination problems in remote parts of the facility.
- How can different media formulations give different results?
- Microbial tests described in the Pharmacopoeias can always be validated, no matter what the matrix is, how aggressive it is, e.g. NaOH, how high the concentrations of antibiotics are etc.
- Identification results are absolute and unequivocal, especially when computer-generated.
- Underestimating the importance of cleaning prior to disinfection.
- Environmental monitoring results provide an accurate risk assessment during production.
- How can clean room surfaces not be heavily contaminated when the air counts are out of specification?
- How can endotoxins be present when the bioburden is nil?
- How can the titre of a virus reference standard change according to the detection cell line used?
- WFI is sterile.
- Filters are absolute.
- UV light disinfects and is capable of sterilising surfaces and water.

This listing appears to cover all aspects of microbiology from the interpretation of straightforward issues concerning environmental monitoring, bioburden results and identifications – through to the more complex issues surrounding virology results for the biologics/biotech people.

The misinterpretation of microbiological results often gives rise to the following misunderstandings:

- Huge environmental monitoring programmes (more is better).
- Rejection of batches due to minor out-of- specification results.
- Delayed registration objectives and to attend appeal hearings.
- Numerous contamination incidents due to the application of inappropriate solutions to problems.
- Senseless promises made to regulatory authorities without scientific rationale based on the concept of quality.

Target Audience

This Live Online Training is designed for responsible personnel from production, quality assurance, regulatory affairs and engineering that has to make judgements, release products and take actions on the basis of the microbiological data supplied.

Programme

The Characteristics of Microorganisms

- Fungi
- Bacteria
- Mycoplasma
- Viruses
- Cellular organisation, function
- Products, toxins, endotoxins, antibiotics, enzymes

Microbial Growth

- How it occurs
- What is required for growth?
- Growth kinetics – laboratory culture versus nature
- Effect of stress factors on growth

Microbial Identification Techniques

- What is the significance of a name?
- Distribution of microorganisms in nature, raw materials and water
- Distribution of microorganisms in pharmaceutical facilities

Detection Methods and their Limitations

- What can be detected by:
  - The sterility test
  - The bioburden test in its various forms. Membrane filtration, pour plate, spread plate, MPN
  - The test for specified organisms
  - The endotoxin test
- Limits of detection and factors effecting limits of detection
- Validation of Microbial Test Methods
- Basic principles of validating a microbial test system
- What approaches can you take when a microbial assay test cannot be validated?

Cleaning, Sanitation, Disinfection

- Why cleaning before disinfection?
- The difference between cleaning and disinfection
- Disinfectants and their efficacy
- Methods of disinfection
- Disinfection validation

Environmental Monitoring

- Sampling techniques
  - air sampling | surfaces | settle plates
- Technical limitations and interpretation of results
- Is there a relationship between high results and contaminated product?

Pharmaceutical Water - Microbiological Control and Deviation Management

- Regulatory requirements
- Warning and action limits
- Measures to be taken when warning and action limits are exceeded
- Repeated non-conforming results
- Examples of warning and action limit exceedance
- Source of microbial contamination, Biofilms

How to Handle Microbiological OOS Results

- Typical Out-Of-Specification results
  - Sterility testing
  - Bioburden
  - Endotoxin testing
  - Cleanroom monitoring
- Investigation of Causal Connection
  - Laboratory failure investigations
  - Sampling/process/production failure investigation
  - Type of microorganisms
  - Deviations/incidents/assessment
  - Deviation/investigation report
- Retesting/Reanalysis/Resampling
  - Definitions
  - Calculation of mean values
  - Rejection/Release

Sterilisation Methods

- Principles and kinetics of sterilisation
- Selection of sterilisation method
- Types of sterilisation methods
- Validation of the sterilisation process

Examples and Case Studies Sessions

The objective of these special sessions is to give the participants some hands on experience with the fundamentals of microbial techniques and the difficulties associated with interpretation. Real cases will show sources of contamination, ways of root cause analysis and defining corrective and preventive actions.

Speakers

Dr Hans-Joachim Anders
Novartis Pharma Stein, Switzerland

Dr Anders is a microbiologist and team leader in Analytical Science & Technology in the field of microbiological quality control, i.e. method validation, microbiological identification, etc, at Novartis in Stein. He has several years of experiences in water testing, validation of Rapid Micro Methods up to contamination control issues.

Dr Stefanie Bayer
Labor LS, Germany

Stefanie studied Microbiology and Biochemistry at the University of Würzburg and received her doctoral degree in microbiology at the University Hospital Erlangen. For two years, she collected work experience in the molecular biology department of a medical diagnostic laboratory before she joined Labor LS in 2012. There she is responsible as division manager for molecular biology analyses with focus on microbial identification.

Arjan Langen
Director Sterility Assurance, GE Healthcare, The Netherlands

Arjan Langen has over 20 years of experience within the field of pharmaceutical microbiology. He worked for several pharmaceutical and biotech companies (Nobilon, DSM, MSD) and had various local and global roles within QC, QA, manufacturing and auditing. 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.

Axel H. Schroeder
Concept Heidelberg, Germany

Axel Schroeder studied in Biology at Ruprecht-Karls University Heidelberg. From 1994 to 2005 he worked as specialist for Industrial Hygiene and Contamination control at Henkel/Ecolab.. Between 2005 and 2008 he was engaged at Basan GmbH as Key Account Manager for Pharmaceuticals and Biotechnology. Since 2008 he has been operation director at Concept Heidelberg for microbiology and biotechnology.

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Reservation Form (Please complete in full)

Microbiology for Non-Microbiologists, Live Online Training on 02/03 February 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

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Date of the Live Online Training

Tuesday, 02 February 2021, 09.00 h – 17.30 h CET
Wednesday, 03 February 2021, 09.00 h – 16.00 CET

Technical Requirements

For our 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 email 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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