ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Dr Hans-Joachim Anders
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Microbiology for Non-Microbiologists

Understand the „true“meaning of microbiological findings

Live Online Training on 14/15 April 2026

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

Microbiological Methods: Suitability Test vs. Method Validation

- The difference between a Method Suitability Test (MST) and a Method Validation will be explained using selected examples:

- The practical realization of a MST of a Microbial Enumeration Test (Ph.Eu. 2.6.12 / USP <61>) and a Sterility Test (Ph.Eu. 2.6.1/ USP <71>) is presented
- The Method Validation of a Rapid Sterility Test according to Ph.Eu. 5.1.6 / TR33 / USP <1223> is shown

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
- Trending and Risk assessment
- Examples of warning and action limit exceedance

Sterilisation Methods

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

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

Examples and Case Studies Sessions

The aim of these special sessions is to provide participants with practical experience of the basics of microbiological deviations and trouble shootings and the difficulties associated with evaluation. On the basis of real cases, sources of contamination, possibilities of root cause analysis and the determination of corrective and preventive measures are shown.

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

Currently, Dr Bayer is responsible for the department molecular development, which focuses on the GMP-based implementation and validation of new molecular biological methods. Based on her activities, she has a broad experience in microbiological identification, molecular biological methods and validation of Rapid Micro Methods in the pharmaceutical environment.

Arjan Langen
MSD, The Netherlands
Director Quality Systems & Compliance

Arjan Langen has over 25 years of experience within the field of pharmaceutical microbiology. Until April 2025, he was 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 worked 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. Since May 2025, he is Director Quality Systems & Compliance at MSD.

Axel H. Schroeder
Concept Heidelberg, Germany

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

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Reservation Form (Please complete in full)

Microbiology for Non-Microbiologists, Live Online Training on 14/15 April 2026

Title, first name, surname

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Date of the Live Online Training

Tuesday, 14 April 2026, 09.00 h – 17.30 h CEST
Wednesday, 15 April 2026, 09.00 h – 16.00 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings 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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
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 22502. To avoid incorrect information, please give us the exact address and full name of the participant.

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.

Organisation and Contact

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