



## Speakers



Hans-Joachim Anders  
Novartis Stein, Switzerland



Dr Stefanie Bayer  
Labor LS, Germany



Arjan Langen  
GE Healthcare, The Netherlands



Axel H. Schroeder  
Concept Heidelberg, Germany

# Microbiology for Non-Microbiologists

Understand the true meaning of microbiological findings

02/03 February 2021 | Antwerp, Belgium



## 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

Workshops about microbiological  
Deviations and Trouble Shooting

## Objective

It is the aim of this course 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 course 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?

## 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

### Workshops

The objective of these workshop sessions is to give the participants some hands on experience with the fundamentals of microbial techniques and the difficulties associated with interpretation. They will also provide the chance to discuss common problems in an informal atmosphere.

#### Workshop 1: Hygienic Deviations

Participants will work in small groups on practical case studies of microbiological deviations. They will work on a root cause analysis and defining corrective and preventive actions.

#### Workshop 2:

##### Trouble shooting in the microbiological laboratory.

The focus will be on those problems that occur frequently in microbiological quality control. Practicable solution to these challenges will be discussed in small groups.

## Social Event



In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

## Speakers



**Dr Hans-Joachim Anders,**  
Novartis Pharma Stein, Switzerland

Mr 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 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 Biology at the 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 operations director at Concept Heidelberg for microbiology and biotechnology.

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

## Microbiology for Non-Microbiologists, 02/03 February 2021, Antwerp, Belgium

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

CONCEPT HEIDELBERG

P.O. Box 101764

Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg

GERMANY

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 2 weeks prior to the conference 10 %
    - Cancellation until 1 week prior to the conference 50 %
    - Cancellation within 1 week prior to the conference 100 %.
- CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount, airfare penalties or other costs incurred due to a cancellation.

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 can-

cellation 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 January 2012).

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](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

Tuesday, 02 February 2021, 09.00 h – 18.00 h  
(Registration and coffee 08.30 – 09.00 h)

Wednesday, 03 February 2021, 09.00 h – 15.30 h

## Venue

Lindner Hotel & City Lounge

Lange Kievitstraat 125

2018 Antwerp, Belgium

Phone +32 3 22777-00

Email [info.antwerpen@lindnerhotels.be](mailto:info.antwerpen@lindnerhotels.be)

## Fees (per delegate, plus VAT)

ECA Members € 1,590

APIC Members € 1,690

Non-ECA Members € 1,790

EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable

## Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## Conference language

The official conference language will be English.

## GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

## Organisation and Contact

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

CONCEPT HEIDELBERG

P.O.Box 10 17 64 | 69007 Heidelberg, Germany

Phone +49(0)62 21/84 44-0 | Fax +49(0)62 21/84 44 34

[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)

[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

For questions regarding content please contact:  
Mr Axel H. Schroeder (Operations Director) at  
+49(0)62 21/84 44 10, or at  
[schroeder@concept-heidelberg.de](mailto:schroeder@concept-heidelberg.de).

For questions regarding reservation, hotel, organisation etc. please contact:  
Mr Niklaus Thiel (Organisation Manager) at  
+49(0)62 21/84 44 43, or at  
[thiel@concept-heidelberg.de](mailto:thiel@concept-heidelberg.de).