



Speakers



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Modern Microbiology Laboratory

Pharmacopoeial and GMP Compliance



Live Online Training from 08 - 10 December 2020



Highlights

- Basic Requirements for Microbiology Labs
 - Lab Lay Out/MST/Operator Qualification
- Compliant Microbiological Test Methods
 - Classic Methods: Limit Test/Endotoxin/Sterility/Specified MO
 - Modern Methods: RMM/LIMS
- Further Challenges in the Micro Lab
 - ID Techniques/OOS Handling/Change Control/ Validation According EP 5.1.6.
- The Real World - A Case Studies Day
 - Harmonized methods for testing of non-sterile products
 - Trending and risk assessment
 - Environmental monitoring
 - Rapid Microbiological Methods

Mastering the challenges of classic and
modern microbiological methods

Objective

Most of the tests used in microbiological quality control are described in detail in the various pharmacopoeias (e.g. EP, USP and JP). These methods are generally considered validated - but not yet for your products!

Ultimately it is up to you to prove that the official methods work in your environment and for your product. The validation of microbiological test methods for your needs requires a lot of time, money and personnel. However, it can also become unexpectedly complicated when your own product interferes with the test method or effects such as masking for endotoxins prevent detection. Also special challenges, such as very short shelf life or extremely small batches may require a different or adapted method

The real challenge is to meet both regulatory requirements and the financial targets set by your management.

During this three-day online training, you will be introduced to classical and alternative methods as well as strategies for a sustainable approach to implement and perform microbiological testing procedures in compliance with regulations. This course gives you clear guidance on how to perform these tasks in addition to your routine laboratory work.

A key element of this seminar will be case studies and practical examples. Our experienced ECA course instructors, some of whom are members of the Pharmacopoeia expert groups, will present their experience to guide you to practical solutions. The training also offers the opportunity to submit questions throughout the seminar, which will be answered in special Q&A sessions.

This course will provide practical guidance on implementing the harmonized test methods as well as alternative microbiological methods!

Target Audience

This GMP Training is designed for microbiologists, managers and supervisors of pharmaceutical microbiological laboratories.

Furthermore, the course will be of interest to personnel from quality control, quality assurance, regulatory affairs and contract laboratories involved in the microbiological aspects of the production and testing of medicinal products.

Programme Day 1

09.00 – 09.15 h Welcome and Organisationals

Module 1: Basic Requirements for Microbiological Laboratories

09.15 – 10.15 h
Lab Layout and Equipment Qualification

- Clean and dirty concepts
- Avoiding cross contamination
- Lay out requirements for a PCR lab
- Equipment qualification – points to consider for a microbiological lab

10.15 – 11.00 h
Method Suitability Test vs. Microbiological Method Validation

- Designing a MST strategy
- Worked examples of MST, creams, liquids, tablets.
- MST for difficult formulations
- Transferring methods to other laboratories, what do you need?
- Microbial cultures, selection and maintenance
- Microbiological media: how to make it, store it and test it
- Background and revision of chapter Ph. Eur. 5.1.6
- Validation process
- Accuracy, precision, specificity, LOD, LOQ, linearity, range, robustness
- Case study for the Milliflex Quantum System

11.00 – 11.15 h Break

Module 2: Compliant Microbiological Test Methods

11.15 – 12.00
Microbial Enumeration Test for Non-Sterile Products

- The harmonised approach USP/Ph.Eur. /JP
- Relevant parameters in the test procedure
- Choosing the most suitable test method
- Microbial quality of excipients, APIs and final dosage forms
- Defining alert levels based on historical data
- The approach of risk assessment testing



12.00 – 12.30 h
Questions and Answers

12.30 – 13.30 h Break

13.30 – 14.15 h
Tests for Specified Microorganisms

- Testing methods
- Challenges concerning the suitability testing
- How to choose the right growth media supplier
- What are objectionable micro-organisms

14.15 – 15.15 h
Bacterial Endotoxins/Test Validation

- Principles of the techniques
 - Gel-clot techniques
 - Photometric techniques
- Preparatory testing / validation tests
- LER


15.15 – 15.30 h Break

15.30 – 16.15 h
Testing of Pharmaceutical Water

- Regulation and requirements for pharmaceutical water
- Validation of water systems
- Water testing & deviation handling

16.15 – 17.15 h
The Test of Sterility

- Media
- Method suitability tests
- Test procedures
 - Membrane filtration method
 - Direct transfer or direct inoculation method

 17.15 – 18.00 h
Questions and Answers

Programme Day 2

09.00 – 09.45 h
Rapid Microbiological Methods

- Overview on the current RMMs
- Limitations and benefits of the different RMM?

09.45 – 10.30 h
Environmental Monitoring


- Monitoring of non-sterile processes
- Aseptic manufacture:
 - developing a programme
 - interpreting data
 - regulatory requirements
- Monitoring methods; air, surface, people
- A complete programme for a sterile product

10.30 – 10.45 h Break

Module 3:
Further Challenges in Modern Microbiological Labs

10.45 – 11.45 h
Identification Techniques – Phenotypic / Genotypic

- Phenotypic and genotypic identification techniques- advantages and limitations
- A change from phenotypic to genotypic identification and the surprises
- New methods - what's in sight?

 11.45 – 12.15 h
Questions and Answers

12.15 – 13.15 h Break

13.15 – 14.15 h
Training and Qualification of Analysts

- A structured training programme for microbiologists - what they need to know and why


14.15 – 15.15 h
Disinfection – Efficacy Testing and Validation

- Antimicrobial agents and their efficacy
- Testing methods
- Efficacy testing against isolates
- Validation approach
- Guidelines

15.15 – 15.30 h Break

15.30 – 16.30 h
Change Control

- Capturing changes in your process.
- When is a change not a change?
- Change control after the event!
- Your change control process, making it robust

 16.30 - 17.00 h
Questions and Answers

Programme Day 3

09.00 – 09.45 h

Dealing with OOS Results

- How do we define alert and action limits?
- How should we react on Out-Of-Specification results?
- How can we perform a proper Failure Investigation?

Module 4:

The Real World - Case Studies and Examples

09.45 – 10.30 h

Risk Assessment and Trending

This part of day 3 will give you an insight in trending of microbiological data and principles of microbiological risk assessments. It will cover the regulatory background like ICH Q9 and make you familiar with risk identification tools like FMEA (Failure Mode and Effects Analysis) or FTA (Fault Tree Analysis).

10.30 – 10.45 h Break

10.45 – 11.30 h

The Harmonized Methods for Testing of Non-Sterile Products

The goal of this session is to encourage the participants to think globally when analyzing microbiology problems. Microbiology problems are subtle and often multifactorial in their origin. The examples will show you tips and tricks in testing methods and a possibility to discuss the issues of the implementation of the harmonized methods like growth promotion testing, creating an implementation concept and necessary investments.

11.30 – 12.15 h

Environmental Monitoring – Set-Up and Deviations

The last presentation of the day gives you an understanding of how to set-up an environmental monitoring programme, and how to handle excursions. The discussions will focus on initial qualification vs. routine monitoring, how many samples are reasonable, reporting structure of environmental monitoring data, corrective actions and the impact of environmental data on product release.

12.15 – 13.00 h

Rapid Microbiological Methods – Regulatory Background and Implementation

This session offers you a unique possibility to evaluate the new developments in RMM systems to extend the experiences in validation and implementation of these systems in pharmaceutical industry. Furthermore you will learn more about the expectations of European and US authorities.



13.00 – 13.30 h

Questions and Answers



Sven M. Deutschmann,
Roche Diagnostics GmbH, Germany

Sven M. Deutschmann studied biology at the University of Brunswick. In 1995 he joined Roche Diagnostics GmbH. Currently, Sven Deutschmann is Head of Global ASAT Adventitious Agents Testing & Alternative Microbiological Methods, Global Analytical Science & Technology. (gASAT). Besides his local and global responsibilities he is a member of several microbiological expert groups, e.g at the German Pharmacopeia Commission, in the Working Parties "Bacterial Endotoxins", and Expert Group 1 "Biological Methods and Statistical Analysis" of the European Pharmacopeia Commissions. In addition, he is chairman of the Advisory Board of the ECA "Pharmaceutical Microbiology Working Group".



Marcel Goverde,
MGP Consulting, Switzerland

Marcel Goverde has attended the University of Basel, where he majored in biology. From 2002 to 2010 he was leading the quality control lab for non-sterile products as well as the lab for research & development of microbiological methods at F. Hoffmann-La Roche Ltd in Basel. From 2010-2011 he worked as microbiological expert at Novartis. In 2011 he started his own company for consulting, training and project management in microbiology.



Dr Holger Kavermann,
Roche Diagnostics GmbH, Germany

Holger Kavermann studied microbiology at the University of Göttingen and obtained his PhD in medical microbiology at the University of Munich. In 2003 he joined Roche Diagnostics GmbH, as Manager QC responsible for the microbiological and cell biological analytics of QC and In-Process-Control samples in the production of biotechnological derived active pharmaceutical ingredients. Since 2013 he has been heading the QC Department for Environmental Monitoring and Cleaning Validation.



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.

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Reservation Form (Please complete in full)



Modern Microbiology Laboratory, Live Online Training from 08 - 10 December 2020

Title, first name, surname

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Date of the Live Online Training

Tuesday, 08 December. 2020, 09:00 – 18.00 h CET
Wednesday, 09 December 2020, 09.00 – 17.00 h CET
Thursday, 10 December 2020, 09.00 – 13:30 h CET

Technical Requirements

For our Live Online Trainings 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 € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
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.

Your Benefit



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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