ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Sven M. Deutschmann
Roche Diagnostics GmbH, Germany

Sabrina Schmidt
Novartis Pharma Stein AG,
Switzerland

Dr Holger Kavermann
Roche Diagnostics GmbH, Germany

Arjan Langen
GE Healthcare, The Netherlands

Modern Microbiology Laboratory

Pharmacopoeial and GMP Compliance

Live Online Training from 07 - 09 December 2021

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

Module 1:
Basic Requirements for Microbiological Laboratories

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

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

Module 2:
Compliant Microbiological Test Methods

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

Tests for Specified Microorganisms

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

Bacterial Endotoxins/Test Validation

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

Testing of Pharmaceutical Water

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

The Test of Sterility

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

Programme Day 2

Rapid Microbiological Methods

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

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

Module 3:
Further Challenges in Modern Microbiological Labs

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?

Training and Qualification of Analysts

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

Disinfection – Efficacy Testing and Validation

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

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

Programme Day 3

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

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).

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.

Environmental Monitoring – Set-Up and Deviations

This presentation 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.

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.

Speakers

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".

Sabrina Schmidt
Novartis Pharma Stein AG, Switzerland

Sabrina Schmidt is currently Sr. QA Expert / QA Team Leader SU QA/QC, QA Ops Microbiology Solids Novartis Technical Operations in Stein, Switzerland. She worked for Eurofins from 2000 to 2005. In 2013, she became Senior QA Specialist at Novartis and has held the position of QA Expert/Teamlead QA Microbiology since 2017. In the course of her work, she has gained diverse experience in the field of microbiological monitoring, QA and QC of non-sterile products.

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.

Date of the Live Online Training

Tuesday, 07 December 2021, 09.00 – 18.00 h CET
Wednesday, 08 December 2021, 09.00 – 17.00 h CET
Thursday, 09 December 2021, 09.00 – 13.30 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 € 1,790
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.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

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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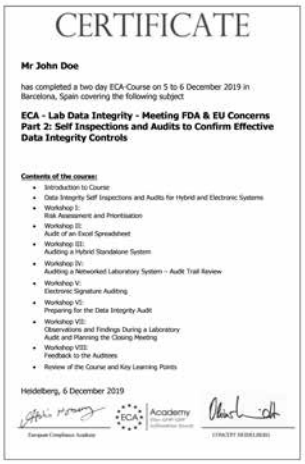
Your Benefit

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.


CERTIFICATE

Mr John Doe

has completed a two day ECA-Course on 5 to 6 December 2019 in Barcelona, Spain covering the following subject

ECA - Lab Data Integrity - Meeting FDA & EU Concerns Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

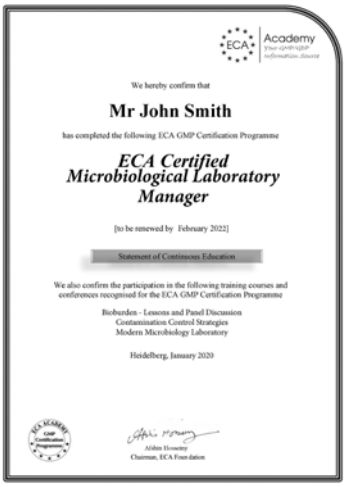
Contents of the course:

- Introduction to Course
- Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Workshop I: Risk Assessment and Prioritisation
- Workshop II: Audit of an Excel Spreadsheet
- Workshop III: Auditing a Hybrid Standalone System
- Workshop IV: Auditing a Networked Laboratory System – Audit Trail Review
- Workshop V: Electronic Signature Auditing
- Workshop VI: Preparing for the Data Integrity Audit
- Workshop VII: Observations and Findings During a Laboratory Audit and Planning the Closing Meeting
- Workshop VIII: Feedback to the Auditees
- Review of the Course and Key Learning Points

Heidelberg, 6 December 2019

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. 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. Please find more information at www.gmp-certification.org


ECA Academy

We hereby confirm that

Mr John Smith

has completed the following ECA GMP Certification Programme

ECA Certified Microbiological Laboratory Manager

[to be renewed by February 2022]

Statement of Continuous Education

We also confirm the participation in the following training courses and conferences recognised for the ECA GMP Certification Programme

Bioburden - Lessons and Panel Discussion
Contamination Control Strategies
Modern Microbiology Laboratory

Heidelberg, January 2020

Achim Hoensky
Chairman, ECA Foundation

WA/29032021

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

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P.O. Box 101764
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GERMANY

Reservation Form (Please complete in full)

Modern Microbiology Laboratory, Live Online Training from 07 - 09 December 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)

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 weeks 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 HEIDELBERGwill 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 cancellation 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). 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.