ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Dr Sven M. Deutschmann
Roche Diagnostics, Germany

Dr Marcel Goverde
MGP, Switzerland

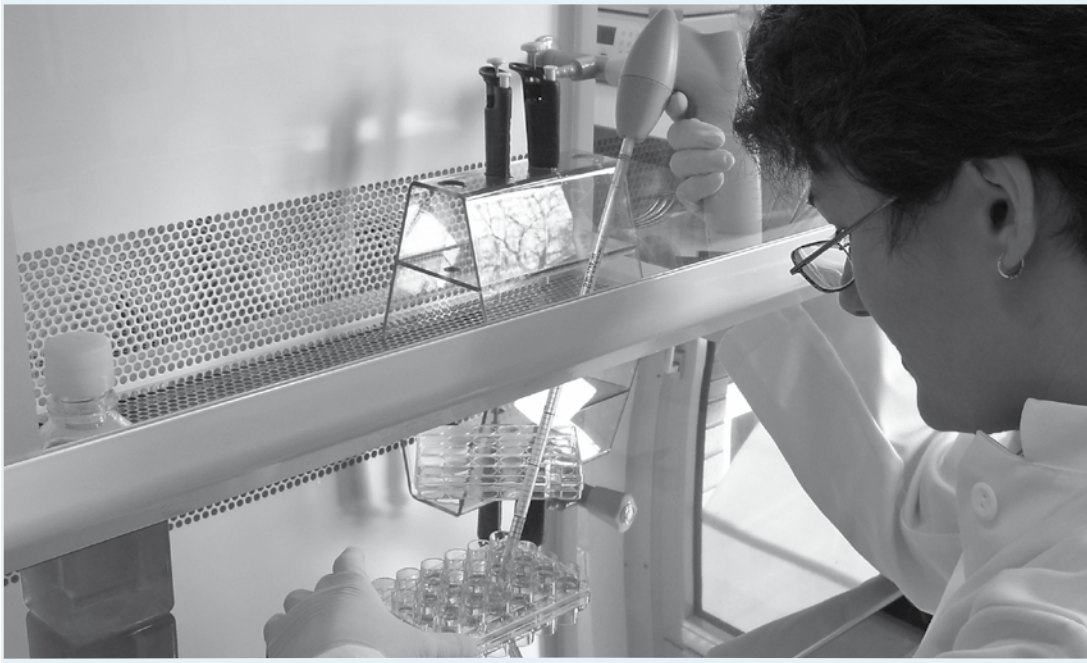
Dr Holger Kavermann
Roche Diagnostics, Germany

Dr Nicole Weyeneth
Consultant, Switzerland

Modern Microbiology Laboratory

„Best Lab Practice“

07 - 09 November 2023 | Barcelona, Spain



Highlights

- Basic Requirements for Microbiology Labs
  - Lab Layout/MST/Operator Qualification
- Compliant Microbiological Test Methods
  - Classic Methods: Limit Test / Endotoxin / Sterility / Specified MO
  - Modern Methods: RMM/LIMS
- The Real World - A Workshop Day
  - Harmonized Methods for Testing of non-sterile Products
  - Alternative Microbiological Methods
  - Risk Assessment and Trending
  - Environmental Monitoring
- Further Challenges in the Micro Lab
  - ID Techniques / OOS Handling / Change Control / Validation According EP 5.1.6.

Mastering the challenges of classic and modern microbiological methods

Objective

Most tests applied in microbiological QC are described in detail in the different Pharmacopoeias (e.g. Ph.Eur., USP, and JP). These methods are regarded as being validated. Nevertheless, the user has to demonstrate that the sample to be tested does not interfere with the method described in the pharmacopeias. In the end, it is up to you to prove that the official methods function in your environment.

The validation of microbiological test methods for your needs consumes a lot of time, money and manpower. Things can get more complicated if your products interfere with the execution of the test.

The real challenge is to fulfil both, regulatory requirements and at the same time financial targets set by your management.

During this 3-day workshop you develop strategies for a sustainable approach to perform microbiological test procedures in compliance with the regulations. This course will give you clear guidance on how to cope with these tasks besides your routine laboratory work.

The key tool of this seminar will be team work. During interactive sessions you will create procedures for the most common microbial test methods. Our experienced ECA course leaders will moderate the discussions to lead you to practice-oriented solutions.

After completion of the course you will be able to run microbiological test procedures in a compliant and at the same time efficient manner.

To guarantee optimal conditions for the exchange of opinions and experiences, **the number of participants is limited**!

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

Target Audience

This GMP Workshop 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

Module 1:
Basic Requirements for Microbiological Laboratories

Training and Qualification of Analysts

- A structured training programme for microbiologists - what they need to know and why
  - Training – What and Why?
  - Training – How?
  - Training – Effectiveness check
  - Training – For cleanroom operators

Lab Layout and Equipment Qualification

- Clean and dirty concepts
- Avoiding cross contamination
- Layout requirements for a PCR Lab
- Equipment qualification – points to consider for a microbiological Lab

Method Suitability Test vs. Microbiological Method Validation

- When do we perform an MST and when validation?
- Validation according to Ph. Eur. chapter 5.1.6
- 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

- Microbial enumeration test according to the harmonised methods
- Relevant parameters in the test procedure
- Choosing the most suitable test method
- Microbial quality of excipients, API 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
- Challenges with the growth promotion test
- How to evaluate objectionable micro-organisms

Bacterial Endotoxins/Test Validation

- Introduction
- Test principles
- Methods and method validation
- Trouble shooting

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

Alternative Microbiological Methods

- Introduction
- Overview of Alternative (Rapid) Microbiological Methods
- Potential applications

Environmental Monitoring

- Guidelines
- Clean room classification
- Monitoring methods and instruments
- Monitoring program based on a risk assessment
- Interpreting and trending data

Module 4:
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?

Dealing with Alert, Action and OOS Results Guidelines

- Alert and action excursions EM and UM
- Alert, action and OOS excursions product
- Limit excursion assessments and laboratory investigations

Disinfection – Efficacy Testing and Validation

- Guidelines
- Antimicrobial agents and their efficacy
- Efficacy studies - disinfectants, surfaces and isolates
- Disinfectant strategy - testing and validation

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

Module 3:
The Real World - A Workshop Day

Interactive Sessions
These interactive sessions are an excellent forum for fruitful discussions. You will develop testing and validation strategies that can be transferred directly to your lab. The ECA course leaders take care that you stay focused on the pre-defined exercises.

1. The Harmonized Methods for Testing of non-sterile Products
The goal of this workshop is to encourage the participants to think globally when analysing microbiology problems. Microbiology problems are subtle and often multifactorial in their origin. The workshop 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.

2. Alternative Microbiological Methods
This workshop offers the opportunity to exchange information with colleagues and the moderator of the workshop about their experience in the validation, implementation, and submission of alternative microbiological methods.

In an introductory lecture you will learn more about the expectations of the European and US authorities. The following Q&A round can be used to exchange knowledge regarding the validation and submission of e.g. alternative PCR-based Adventitious Agents detection methods, alternative sterility tests, or automated colony counting devices.

3. Risk Assessment and Trending
This workshop 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)

4. Environmental Monitoring
The workshop gives you an understanding on how to set-up an environmental monitoring program based on room classification and risk assessments. The focus will be set on routine monitoring including sample location and frequency, data trending and evaluation. Further laboratory assessment during excursions and manufacturing contaminations will be discussed.

Please select 3 workshops when registering!

Speakers

Dr 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 is member of the "Analytical Science"-Chapter within the Quality and Compliance Organisation of Roche's Pharma Technical Operations Unit. Besides his global responsibilities within Roche he is involved in various external, legislative functions, e. g. as a member of the German Pharmacopeia Commission and its "Microbiology" Committee and of various working and expert groups of the European Pharmacopeia Commission, such as the "BET"-Working Group, the "Mycoplasma"-Working Group and the Expert Group 1 (the last two Ph. Eur. Expert Groups are chaired by him). In addition, Sven is member of a brains trust of the Federal Office in Berlin. Last, but not least he is the Chairman of the Advisory Board of the "Pharmaceutical Microbiology" Working Group of the European Compliance Academy.

Dr 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. In 2013, he became head of the QC Department for Environmental Monitoring and Cleaning Validation. Since 2017, he has been the department head for Microbiology, EM and Cleaning Analytics.

Dr Nicole Weyeneth, Freelancer, Switzerland

Nicole Weyeneth studied Biology with focus on population genetics at the University of Bern and Geneva. From 2011 until 2016 Nicole was the head of the Bioanalytics department at the CLO Interlabor Belp AG (Switzerland) managing the QC Microbiology and the QC Biochemistry. In 2017, she started as Scientist in the QC Microbiology at Biogen (Switzerland). Her responsibility was to set-up the laboratory with Rapid Microbiological Methods (RMM), including Analytical Instrument Validation in the QC Microbiology, as well as TOC and Conductivity, and implementation of RMM for QC of Utilities, EM, IPC and DS samples. From 2022 to 2023 Nicole managed the QC Microbiology at Biogen as Sr. Manager including the QC for EM and UM.

Date
Tuesday, 07 November 2023, 09.00 – 18.00 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday, 08 November 2023, 09.00 – 18.00 h
Thursday, 09 November 2023, 08.30 – 13.30 h

Venue
Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Email sants@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145

The fee is payable in advance after receipt of invoice and includes conference documentation (as download), dinner on the first day, lunch on first and second day and all refreshments during the conference. 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.

Presentations / Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

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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For questions regarding organisation etc. please contact:
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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.

Participant's comment:

"The conference was really good and applicable. I will absolutely recommend it to anyone from pharmaceutical industry. Really well done job! And very experienced speakers!"
Sandi Pusnik, Lek Pharmaceuticals d.d., Slovenia

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.

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

NEWS

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GERMANY

Reservation Form (Please complete in full)

Modern Microbiology Laboratory, 07 - 09 November 2023,Barcelona,Spain

Please choose 3 out of 4 workshops in Module 3:
☐ *Harmonized methods for testing of non-sterile products*
☐ *Alternative Microbiological Methods*
☐ *Risk Assessment and Trending*
☐ *Environmental Monitoring*

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks 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.