ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Dr Sven M. Deutschmann
Roche Diagnostics, Germany

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MGP, Switzerland

Dr Marcel Goverde
MGP, Switzerland

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Roche Diagnostics, Germany

Modern Microbiology Laboratory

„Best Lab Practice“

Live Online Training on 10 - 12 December 2024

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
- Further Challenges in the Micro Lab
  - ID Techniques/OOS Handling/Change Control/ Validation According EP 5.1.6.
- The Real World - Case Studies and Examples
  - Harmonized Methods for Testing of non-sterile Products
  - Alternative Microbiological Methods
  - Risk Assessment and Trending
  - Environmental Monitoring

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 Live Online Training 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 Live Online 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.

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

Programme

Module 1:
Basic Requirements for Microbiological Laboratories

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 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?

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

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

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 4:
The Real World - Case Studies and Examples

Trending and Risk Assessment

This session 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).

Harmonized Methods for Testing of Non-Sterile Products

The goal in this par tis to encourage the participants to think globally when analyzing microbiology problems. Microbiology problems are subtle and often multifactorial in their origin. We 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 track 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

Rapid Microbiological Methods – Regulatory Background and Implementation

This part offers additional information and 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.

Date of the Live Online Training

Tuesday, 10 December. 2024, 09.00 – 18.00 h CET
Wednesday, 11 December 2024, 09.00 – 17.00 h CET
Thursday, 12 December 2024, 09.00 – 13.30 h CET

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 € 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.

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.

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 21191.

Conference language

The official conference language will be English.

You cannot attend the Live Online Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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Interested? You can find all recorded events at www.gmp-compliance.org/recordings.

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

WA/08052024

Speakers

Dr Sven M. Deutschmann
Roche Diagnostics GmbH, Germany

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.

Emine Floret
MGP, Switzerland

Emine Floret started her professional career at Eurofins, France, in microbiological food control. She then worked at Solvias, France and Idorsia Pharmaceuticals Ltd in pharmaceutical microbiological quality control. Since May 2024, she has been working at MGP Consulting GmbH as Senior Project Manager in the field of quality control microbiology and hygiene.

Dr Marcel Goverde
MGP Consulting, Switzerland

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

In 2003, Dr Kavermann 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.

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Reservation Form (Please complete in full)

Modern Microbiology Laboratory
Live Online Training on 10 - 12 December 2024

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 %.

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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.