

# Modern Microbiology Laboratory

Pharmacopoeial and GMP Compliance

## SPEAKERS:



**Colin Booth**  
*The Binding Site, UK*



**Sven M. Deutschmann,**  
*Roche Diagnostics GmbH, Germany*



**Dr Marcel Goverde**  
*MGP, Switzerland*



**Dr Holger Kavermann**  
*Roche Diagnostics GmbH, Germany*



**Arjan Langen**  
*GE Healthcare, The Netherlands*



Mastering the challenges of classic and modern microbiological methods

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17- 19 September 2019, Munich, Germany

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## LEARNING GOALS:

- 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
  - Trending and risk assessment
  - Environmental monitoring
  - Rapid Microbiological Methods
- Further Challenges in the Micro Lab
  - ID Techniques/OOS Handling/Change Control/Validation According EP 5.1.6.



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17-19 September 2019, Munich, Germany

## Objectives

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Most tests applied in microbiological QC are described in detail in the different Pharmacopoeias (e.g. EP, USP, and JP). These methods are regarded as being validated – but not for your products!

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 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

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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

## Module 1:

### Basic Requirements for Microbiological Laboratories

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#### Training and Qualification of Analysts

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

#### Method Suitability Test - Requirements and Materials

- Designing a MST strategy
- Worked examples of MST, creams, liquids, tablets
- Sterility test validation: why do so many laboratories get it wrong?
- MST for difficult formulations
- Validation and robustness are they the same thing?
- 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

#### Method Validation According 5.1.6.

- 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

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#### 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, API and final dosage forms
- Defining alert levels based on historical data
- The approach of risk assessment testing

#### Bacterial Endotoxins/Test Validation

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

#### The Test of Sterility

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

#### Tests for Specified Microorganisms

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

### 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:

#### The Real World - A Workshop Day

#### Interactive Sessions

You will participate in 3 workshops!

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.

#### The harmonized methods for testing of non-sterile Products

The goal of this workshop is 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.

#### Rapid Microbiological Methods

This workshop 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.

#### 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)

### Environmental Monitoring

The workshop 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.

### 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 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?

#### Disinfection – Efficacy Testing and Validation

- Antimicrobial Agents and their Efficacy
- Testing Methods
- Efficacy testing against Isolates
- Validation approach
- Guidelines

#### 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

#### 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



Participant's comment on the June 2017 course:  
*"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

## Speakers

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**Colin Booth**, *The Binding Site, UK*

Colin Booth was the manager of pharmaceutical microbiology of Glaxo Wellcome Research and Development based in the UK.. In 2002 he joined Oxoid /Thermo Fisher and became Vice President Science and Technology and later Global Director Quality Assurance and Regulatory Affairs of Thermo Fisher Microbiology. Since 2017 Director Regulatory and Quality Assurance for “ The Binding Site “ a specialist IVD company making diagnostics tests for Cancer diagnosis.



**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. 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**, *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 a Sterility Assurance & QC Microbiology lead at GE Healthcare in Eindhoven – The Netherlands.

## Easy Registration

 **Reservation Form:**  
**CONCEPT HEIDELBERG**  
P.O. Box 10 17 64  
69007 Heidelberg  
Germany

 **Reservation Form:**  
+ 49 6221 84 44 34

 **e-mail:**  
info@concept-heidelberg.de

 **Internet:**  
www.gmp-compliance.org

### Date

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Tuesday, 17 September. 2019, 09.00 – 18.00 h  
(Registration and coffee 8.30 – 9.00 h)  
Wednesday, 18 September 2019, 09.00 – 18.00 h  
Thursday, 19 September 2019, 08.30 – 13.30 h

### Venue

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HYPERION Hotel München  
Truderinger Straße 13  
81677 Munich, Germany  
Phone +49(0)89-90 90 17 200  
Email: hyperion.muenchen@h-hotels.com

### Fees (per delegate plus VAT)

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ECA Members € 1,790  
APIC Members € 1,890  
Non-ECA Members € 1,990  
EU GMP Inspectorates € 995  
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on first and second day and all refreshments during the conference. VAT is reclaimable.

### Accommodation

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CONCEPT 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

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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

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The official conference language will be English.

### Organisation and Contact

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

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
D-69007 Heidelberg, Germany  
Phone +49 (0) 62 21/84 44-0  
Fax +49 (0) 62 21/84 44 34  
E-mail: 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 +49-62 21 / 84 44 10, or per e-mail at  
schroeder@concept-heidelberg.de.

**For questions regarding reservation, hotel, organisation etc. please contact:**  
Ms Sonja Geppert (Organisation Manager)  
at +49-62 21 / 84 44 16, or per e-mail at  
geppert@concept-heidelberg.de.

### Social Event

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At the end of the first day of the event, you are invited to take part in an informal dinner where you can discuss with speakers and colleagues in a relaxed atmosphere.



### GMP/GDP In-house Training Courses

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Are you interested in a GMP/GDP training course at your facility for a larger group of people? We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity

You will find a time schedule for each training course at [www.gmp-compliance.com](http://www.gmp-compliance.com), button "Inhouse Training"

We also offer in-house training courses for Qualified Persons. Please contact us for more information: [info@gmp-compliance.org](mailto:info@gmp-compliance.org)

We will be happy to design further GMP training courses for you on request.

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

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CONCEPT HEIDELBERG  
P.O. Box 101764  
Fax +49 (0) 62 21/ 84 44 34  
D-69007 Heidelberg  
GERMANY

+49 6221 84 44 34



Please choose **3 out of 4** workshops:  
 Harmonized methods for testing of non-sterile products  
 Rapid Microbiological Methods  
 Risk Assessment and Trending  
 Environmental monitoring

Reservation Form (Please complete in full)

**Modern Microbiology Laboratory**  
17-19 September 2019, Munich, Germany

Mr.     Ms.

Title, first name, surname

Company

Department

**Important: Please indicate your company's VAT ID Number**      **PO Number if applicable**

Street/P.O. Box

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 %  
- until 1 week prior to the conference 50 %  
- within 1 week prior to the conference 100 %  
CONCEPT HEIDELBERG reserves the right to change the materials, instructions, 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 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](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.