Modern Microbiology Laboratory
Pharmacopoeial and GMP Compliance

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
Objectives

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

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

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 of chapter Ph. Eur. 5.1.6
- Revision of chapter 5.1.6
- Validation process
- Accuracy, Precision, Specificity, LOD, LOQ, Linearity, Range, Robustness

Module 2:
Compliant Microbiological Test Methods

Microbial Limit 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:
Future 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

Colin Booth,  
The Binding Site, UK  
Colin Booth was the manager of pharmaceutical microbiology of Glaxo Wellcome Research and Development based in the UK where he was responsible for all the microbiology associated with the development of all Glaxo Wellcome new products. In 2002 he joined Oxoid Limited and became Vice President Science and Technology until 2008. Following he became Global Director Quality Assurance and Regulatory Affairs of Thermo Fisher Microbiology. In 2015 he founded his own consultancy QMS - Quality Microbiology Solutions. Since 2017 Director Regulatory and Quality Assurance for “The Binding Site” a specialist IVD company making diagnostics tests for Cancer diagnosis.

Marcel Goverde,  
MGP Consulting, Switzerland  
Marcel Goverde has attended the University of Basel, where he majored in biology. After one year of working for the agro biological department of Novartis, he led a development project on sustainability and education in Costa Rica. After returning to Switzerland he earned his PhD in ecology at the University of Basel where he subsequently was employed as an academic tutor. 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. Furthermore he is a member of the working group 1 from the European Directorate for the Quality of Medicines (EDQM) which is in charge for microbiological and statistical methods.

Arjan Langen,  
MSD, The Netherlands  
Arjan Langen was manager of Microbiological Quality Control and Quality Assurance officer at Intervet International in The Netherlands before he joined Nobilon International. At Nobilon he was appointed Quality Assurance Manager, responsible for the cGMP approval of the new multi-purpose vaccine production facility in Boxmeer, The Netherlands. In 2008 Arjan became Director Compliance at DSM Pharmaceutical products and in 2009 he founded his own company for training and consulting in the field of pharmaceutical microbiology. In 2011 he became Pharmaceutical Specialist at MSD. His current position is Production Specialist IPT Pharma Outbound at MSD Animal Health. He is a member of the PDA and a member of the Dutch Society of Pharmaceutical Microbiology.

Michael Schiffer,  
Process Expert, Novartis Pharma Stein, Switzerland  

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.
Organisation and Contact

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

For questions regarding content:
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.:
Ms Katja Kramer (Organisation Manager) at +49-62 21 / 84 44 16, or per e-mail at kramer@concept-heidelberg.de.

Social Event

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

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, button “Inhouse Training”

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

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

Use the GMP App at no costs!

The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine.

To open the app just enter app.gmp-compliance.org in your browser and the WebApp opens immediately.
Reservation Form (Please complete in full)

Modern Microbiology Laboratory
11 – 13 September 2018, Hamburg, Germany

Mr.  Ms.

Company

Title, first name, surname

Department

Important: Please indicate your company’s VAT ID Number

Street/P.O. Box

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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 %
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