This course will provide practice-oriented guidance on implementing the harmonised test methods!

Microbiological Best Laboratory Practice

Mastering the Challenges of Pharmacopoeias

17-19 March 2015, Vienna, Austria

SPEAKERS:

Colin Booth
Oxoid, UK

Dr Sven M. Deutschmann
Roche Diagnostics, Germany

Dr Marcel Goverde
MGP Consulting, Switzerland

Dr Holger Kavermann
Roche Diagnostics, Germany

Arjan Langen
MSD, The Netherlands

LEARNING GOALS:

- Two Modules:
  - Validation according to the Pharmacopoeias
  - The Real World
- Develop testing and validation strategies in four interactive Sessions:
  - Harmonized methods for testing of non-sterile products
  - Specified organisms
  - Endotoxin testing
  - Environmental monitoring
- Latest Trends in Microbiological Quality Control

ECA ACADEMY

This education course is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager“. Please find details at www.gmp-certification.eu

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Objectives

Most tests applied in microbiological QC are described in detail in the different Pharmacopoeias (e.g. EP, USP, 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 to the validation of microbiological test procedures. 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 cope with the validation of 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!

Target Group

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: 17 March 2015
Validation According to the Pharmacopoeias

Validation Requirements
- Designing a validation strategy
- Worked examples of validation, creams, liquids, tablets
- Sterility test validation, why do so many laboratories get it wrong?
- Validation of difficult formulations
- Validation and robustness - are they the same thing?
- Transferring methods to other laboratories, what validation do you need?

Colin Booth

Materials Needed for the Validation
- Microbial cultures, selection and maintenance
- Microbiological media: how to make it, store it and test it
- Routine validation of your QC laboratory instruments.
- Managing your stock, laboratory inventory.

Colin Booth

The Test of Sterility: Critical Parameters for a Validation of the Test Procedures
- Media
- Validation tests
- Test procedures
  - Membrane filtration method
  - Direct transfer or direct inoculation method

Sven M Deutschmann

Bacterial Endotoxins/Test Validation
- Principles of the techniques
  - Gel-clot techniques
  - Photometric techniques
- Preparatory testing / validation tests

Colin Booth

Tests for Specified Microorganisms
- Implementation of the harmonised methods
- Challenges concerning the suitability testing
- How to choose the right growth media supplier
- What are objectionable micro-organisms

Marcel Goverde

Disinfection – Efficacy testing and Validation
- Antimicrobial Agents and their Efficacy
- Testing Methods
- Efficacy testing against Isolates
- Validation Approach
- Guidelines

Arajan Langen

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
- Suitability test: what should we report?
- Microbial quality of excipients, API and final dosage forms
- The approach of risk assessment testing

Marcel Goverde

Module 2: 18-19 March 2015
The Real World

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 analyzing 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.
Marcel Goverde

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.
Sven M. Deutschmann, Holger Kavermann

Endotoxin Testing
Routine endotoxin testing should be straightforward, sometime there are problems in the assay, we will explore examples of faults that have occurred in routine testing, and how to fix them. However the major part of this workshop will be to work through problems of validating the assay both in Gel Clot and in the Kinetic Chromogenic assays. We will review data from real examples and discuss the options for resolution of the issues.
Colin Booth

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.
Arjan Langen

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

Sven M. Deutschmann, Marcel Goverde

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?

Sven M. Deutschmann

Change Control and Training of New Personnel
- Capturing changes in your process
- When is a change not a change?
- Change control after the event
- Your change control process, making it robust
- A structured training programme for microbiologists, what they need to know and why

Colin Booth

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?

Holger Kavermann

Speakers

Colin Booth, *Oxoid, UK*
Colin 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 where he is now Vice President Science and Technology. He is an ECA Advisory Board Member covering the field of Development Microbiology.

Dr Sven M. Deutschmann, *Roche Diagnostics GmbH, Germany*
In 1995 he joined Boehringer Mannheim GmbH, now Roche Diagnostics GmbH, as Manager QC. He was responsible for the microbiological and cell biological analytics of QC and In-Process-Control samples in the production of biotechnologically derived active pharmaceutical ingredients and for the environmental monitoring program in the production areas. Since 2001 he is Director of the Microbiology QC Department. Dr Deutschmann is member of the Microbiology Commission of the German Pharmacopoeia Commissions and specialist resp. member in several Working Parties of the Pharmacopoeia Commissions. Recently, he was appointed Chairman of ECA's Working Group for Rapid Microbiological Methods (RMM).

Dr 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. 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. Furthermore he is a member of the working party for Modern Microbiological Methods (MMM) from the European Directorate for the Quality of Medicines (EDQM).

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. He is responsible for the microbiological and cell biological analytics of QC and In-Process-Control samples in the production of biotechnological derived active pharmaceutical ingredients.

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 in The Netherlands, being responsible for sterile manufacturing of new products in Oss. He is a member of the PDA and a member of the Dutch Society of Pharmaceutical Microbiology.

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.

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

Tuesday 17 March 2015, 09:00 – 17:30 h
(Registration and coffee 8:30 – 9:00 h)
Wednesday 18 March 2015, 09.00 – 17:30 h
Thursday 19 March 2015, 08.30 – 13:00 h

Venue

Austria Trend Hotel
Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110
Fax +43/1/891109 050

Fees (per delegate plus VAT)

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

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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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D-69007 Heidelberg, Germany
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E-mail: info@concept-heidelberg.de
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For questions regarding content:
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schroeder@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager)
at +49-62 21 / 84 44 18, or per e-mail at
grimm@concept-heidelberg.de.

What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?

During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

Lufthansa is Mobility Partner for all ECA Events

Lufthansa Mobility Partner

As an ECA course or conference attendee, you will **receive up to 20% discounted travel fares** (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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Please choose **3 out of 4** workshops:
- ☐ Harmonized methods for testing of non-sterile products
- ☐ Rapid Microbiological Methods
- ☐ Endotoxin testing
- ☐ Environmental monitoring

☐ 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 weeks prior to the conference 50 %
- 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 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)

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.