ECA Academy
Your GMP/GDP Information Source

Microbiology for Non-Microbiologists

Understand the true meaning of microbiological findings

Workshops about microbiological deviations and trouble shooting

13-14 June 2018, Copenhagen, Denmark

SPEAKERS:

Dr Stefanie Bayer
Labor L+S AG, Germany

Colin Booth
The Binding Site, UK

Arjan Langen
MSD, The Netherlands

Axel Schroeder
Concept Heidelberg, Germany

LEARNING GOALS:

- Acquire a Basic Knowledge in Microbiology
- Develop an Understanding for the Meaning of Microbiology for the Quality of Medicinal Products
- Get familiar with typical microbiological Tests in the Pharmaceutical Industry
- Learn to interpret microbiological Data correctly
- Case studies on Deviations and Trouble Shooting

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

It is the aim of this course to familiarise responsible personnel from production, quality assurance and engineering with microbiological questions. The participants **learn how to interpret microbiological data** and which consequences these have for the production.

Background

The quality of drugs and the quality assurance during production are above all determined by their microbiological characteristics. The microbiological requirements on drugs are laid down in various regulations. When an authority inspects a company, it will focus its attention on these and on the requirements made on hygiene.

In their daily work, the responsible personnel in the production units has to understand microbiological results and evaluate their significance for further decisions. However, in practice **many microbiological results are misinterpreted** and thus often the wrong conclusions are drawn from them. When asked for the most frequent misinterpretations of microbiological results, pharmaceutical microbiologists gave the following answers.

- The difference between bioburden and sterility testing (are they the same?)
- The use of disinfectants guarantees the sterility of the object, surface, culture treated.
- The distribution of microorganisms in a sample or on a surface is uniform.
- Motile microorganisms can swim hundreds of meters in an hour causing contamination problems in remote parts of the facility.
- How can different media formulations give different results?
- Microbial tests described in the Pharmacopoeias can always be validated, no matter what the matrix is, how aggressive it is, e.g. NaOH, how high the concentrations of antibiotics are etc.
- Identification results are absolute and unequivocal, especially when computer-generated.
- Underestimating the importance of cleaning prior to disinfection.
- Environmental monitoring results provide an accurate risk assessment during production.
- How can clean room surfaces not be heavily contaminated when the air counts are out of specification?
- How can endotoxins be present when the bioburden is nil?
- How can the titre of a virus reference standard change according to the detection cell line used?
- WFI is sterile.
- Filters are absolute.
- UV light disinfects and is capable of sterilising surfaces and water.

This listing appears to cover all aspects of microbiology from the interpretation of straightforward issues concerning environmental monitoring, bioburden results and identifications – through to the more complex issues surrounding virology results for the biologics/biotech people.

The misinterpretation of microbiological results often gives rise to the following misunderstandings:

- Huge environmental monitoring programmes (more is better).
- Rejection of batches due to minor out-of- specification results.
- Delayed registration objectives and to attend appeal hearings.
- Numerous contamination incidents due to the application of inappropriate solutions to problems.
- Senseless promises made to regulatory authorities without scientific rationale based on the concept of quality.

Target Group

This course is designed for responsible personnel from **production, quality assurance, regulatory affairs and engineering** that has to make judgements, release products and take actions on the basis of the microbiological data supplied.

Programme

The Characteristics of Microorganisms

- Fungi
- Bacteria
- Mycoplasma
- Viruses
- Cellular organisation, function
- Products; toxins, endotoxins, antibiotics, enzymes

Microbial Growth

- How it occurs
- What is required for growth?
- Growth kinetics – laboratory culture versus nature
- Effect of stress factors on growth

Microbial Identification Techniques

- What is the significance of a name?
- Distribution of microorganisms in nature, raw materials and water
- Distribution of microorganisms in pharmaceutical facilities

Detection Methods and their Limitations

- What can be detected by:
  - The sterility test
  - The bioburden test in its various forms. Membrane filtration, pour plate, spread plate,MPN
  - The test for specified organisms
  - The endotoxin test
- Limits of detection and factors effecting limits of detection

Validation of Microbial Test Methods

- Basic principles of validating a microbial test system
- What approaches can you take when a microbial assay test cannot be validated?

Cleaning, Sanitation, Disinfection

- Why cleaning before disinfection?
- The difference between cleaning and disinfection
- Disinfectants and their efficacy
- Methods of disinfection
- Disinfection validation

Environmental Monitoring

- Sampling techniques
  - air sampling
  - surfaces
  - settle plates
- Technical limitations and interpretation of results
- Is there a relationship between high results and contaminated product?

How to Handle Microbiological OOS Results

- Typical Out-Of-Specification results
  - Sterility testing
  - Bioburden
  - Endotoxin testing
  - Cleanroom monitoring
- Investigation of Causal Connection
  - Laboratory failure investigations
  - Sampling/process/production failure investigation
  - Type of microorganisms
  - Deviations/incidents/assessment
  - Deviation/investigation report
- Retesting/Reanalysis/Resampling
  - Definitions
  - Calculation of mean values
  - Rejection/Release

Sterilisation Methods

- Principles and kinetics of sterilisation
- Selection of sterilisation method
- Types of sterilisation methods
- Validation of the sterilisation process

Workshops

The objective of these workshop sessions is to give the participants some hands on experience with the fundamentals of microbial techniques and the difficulties associated with interpretation. They will also provide the chance to discuss common problems in an informal atmosphere.

Workshop 1: Hygienic Deviations

Participants will work in small groups on practical case studies of microbiological deviations. They will work on a root cause analysis and defining corrective and preventive actions.

Workshop 2: Trouble shooting in the microbiological laboratory.

The focus will be on those problems that occur frequently in microbiological quality control. Practicable solution to these challenges will be discussed in small groups.

Speakers

Dr Stefanie Bayer, *Labor L+S AG, Germany*
Stefanie studied Microbiology and Biochemistry at the University of Würzburg and received her doctoral degree in microbiology at the University Hospital Erlangen. For two years, she collected work experience in the molecular biology department of a medical diagnostic laboratory before she joined Labor L+S AG in 2012. There she is responsible as division manager for molecular biology analyses with focus on microbial identification.

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.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.

Arjan Langen, *MSD, The Netherlands*
Arjan Langen is responsible for sterile manufacturing of new products at MSD, Oss. He is a member of the PDA and a member of the Dutch Society of Pharmaceutical Microbiology.

Axel H. Schroeder, *Concept Heidelberg*
Axel Schroeder studied Biology at the Ruprecht-Karls University Heidelberg. From 1994 to 2005 he worked as specialist for Industrial Hygiene and Contamination control at Henkel/Ecolab. Between 2005 and 2008 he was engaged at Basan GmbH as Key Account Manager for Pharmaceuticals and Biotechnology. Since 2008 he has been operations director at Concept Heidelberg for microbiology and biotechnology.

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.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Microbiology for Non-Microbiologists,
13-14 June 2018, Copenhagen, Denmark

☐ 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)

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If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- until 1 weeks prior to the conference 50 %
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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.

Date

Wednesday, 13 June 2018, 09.00 h – 18.00 h
(Registration and coffee 0830 – 09.00 h)
Thursday, 14 June 2018, 09.00 h – 15.30 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
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Scandinavia.meetings.events@radissonblu.com

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
Including: Conference documentation, lunch on both days, all refreshments, social event on the first day. The registration fee is payable in advance after receipt of invoice. VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form with all further information when you have registered for the course. 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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