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EUROPEAN MICROBIOLOGY CONFERENCE

27/28 June 2023, Heidelberg, Germany

+ Post-Conference Workshop – Statistics for Microbiological Validation

29/30 June 2023, Heidelberg

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

ECA Academy
Your GMP/GDP Information Source

European Microbiology Conference | 27/28 June 2023

Dear Colleagues,

After two years online, we are returning on site. Since 2008, the European Microbiology Conference of the ECA Academy in close collaboration with the ECA Pharmaceutical Microbiology Working Group has been an integral part of the European conference landscape.

For the return to the on-site conference, we have put together an interesting program that addresses various current topics, e.g. alternative and rapid microbiological methods, new demands on culture media or the testing of cell banks. The program will be rounded off by an after-conference workshop on the validation of microbiological methods using statistics.

I am particularly looking forward to once again being able to exchange ideas directly with colleagues from all over the world and to discuss current trends and developments.

Dr Sven M. Deutschmann
Chairman of ECA's Pharmaceutical Microbiology Working Group

Overview

Highlights

- Requirements on Microbiological Laboratories – an Inspectors View
- Pyrogenicity – Pharmacopoeial Developments and Detection
- Contamination Control Strategies for Non-Sterile Products and more
- Rapid/Alternative Methods – Regulatory Expectations and practical Experiences
- Modern Culture Media – Properly Qualified
- Bioindicators
- USP Update

Background

The role of pharmaceutical microbiology is getting more and more important. The microbial control concept is also increasingly in the focus of regulators during product submission and inspections. Current challenges are Endotoxin-masking effects ("Low Endotoxin Recovery"), implementation of alternative microbiological methods, control of cell-based products and the ongoing issues with contamination control – there were an increasing number of findings in the authority reports. The challenge is therefore to satisfy regulatory requirements alongside management's financial expectations.

Target Audience

This conference is of interest to professionals in microbiology from

- Pharmaceuticals and Biopharmaceutical Companies
- Academic Research Institutions
- Government Agencies
- Contract Laboratories

who are involved in

- Contamination Control
- Monitoring
- Validation
- Quality Affairs
- Regulatory Affairs
- Research and Development

Moderators

Dr Sven M. Deutschmann,
Roche, Chairman of the ECA Pharmaceutical Microbiology Working Group

Axel H. Schroeder,
Administration Manager, Pharmaceutical Microbiology Working Group

Social Event | 27 June

On 27 June, 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.

Programme

Inspection of Microbiological Laboratories

Dr Franz Schönfeld, GMP Inspectorate Upper Franconia

- Room requirements
- Equipment - qualification, calibration
- Typical findings and weak points

Case Studies on Contamination Control Strategies for Non-Sterile Manufacturing Facilities

Dr Michael Miller, Microbiology Consultants LLC

- Understand the regulatory expectations for contamination control in non-sterile manufacturing
- Review recent contamination and recall events for aqueous-based products due to contamination issues
- Discuss practical examples of strategies to remediate and prevent contamination by relevant microorganisms, including Gram-negatives

Observations related to the use of environmental isolates in microbiological quality control testing – How to handle

Brice Lantheaume, Microbiologics

- Why to include environmental isolates in pharmaceutical testing?
- Factors which make an organism objectionable
- Determining which organism to use in routine Microbiology testing

Taking a Macro view of your Microbiota: how COVID bugged your Contamination Control Strategy

Duncan Barlow, CRL

- Effect of the pandemic in terms of implementation of new procedures and disinfection processes.
- Is there an impact on industrial microflora and if so, how?
- Case Study: Identification of isolates in pharmaceutical companies before, during and after the pandemic
- Trends and Analysis

FDA's Current Regulatory Expectations for Rapid Microbiological Method Validations

Dr Michael Miller, Microbiology Consultants LLC

- Review FDA's expectations for regulatory submissions of quantitative and qualitive method validations, based on discussions held at the October 2022 Rapid Microbiology Methods workshop
- Understand how to conduct relevant validation criteria and gain FDA approval, for limit of detection, specificity, ruggedness and robustness
- Discuss when it is required to perform method suitability and equivalence studies, and when actual product is required to be tested
- Learn how to validate short shelf life products, including ATMPs, when available product is in limited supply

Evaluation for implementation of an analytical technique for microbial identification in the quality control exemplified by MALDI-TOF MS

Laura Bagschik, Roche

- Data research by a state-of-the-art market analysis
- Comparison of possible techniques and suppliers
- Cost/Benefit and business case calculations
- Conclusions and discussion of the results

EU GMP Annex 1 – Extended active viable air sampling

Dr Gunter Neuer, Becton Dickinson

- Impact of the EU GMP Annex 1 regards active air sampling
- Influencing factors
- Results of active, continuous air sampling - duration and limitations

EPAA-EDQM Conference "Ending in Vivo Testing for Pyrogenicity"

Dr Sven M. Deutschmann, Roche

- EU-Council's and EDQM's Perspective
- Industry Perspective
- Regulatory Session

Development of a cell culture model for the detection of bacterial pyrogenic contamination in parenteral drugs using digital PCR

Nicole Paland, Minerva Biolabs

- Available test methods - what is measured?
- Nucleic acid amplification techniques (NAT) using digital PCR (dPCR)
- What is measured with the technique?

The Application of Next Generation Sequencing (NGS) in Pharmaceutical and Biopharmaceutical Manufacturing

Dr Christine E. Farrance, CRL

- Technology and bioinformatic (data analysis) overview
- Regulatory requirements that can be met with NGS
- Current commercial applications in Charles River
- Additional applications under development
- The need for GMP compliant reference libraries

Halal Culture Media for Media-Fill and other applications

Adele Gisselmann and Dr Andreas Bubert, Merck Life Science

- Principles of Media-Fill tests and culture media for environmental control
- General background of halal certified culture media
- Potential risk for contamination in halal manufacturing facilities

Properly Qualified Media – A must have for EM and a successful Contamination Control Strategy

Juliane Hornung, Labor LS

- Growth media in the context of CCS
- Which aspects of media need to be qualified?
- Growth Promotion Testing and Growth Controls
- Validation of Shelf-life
- Neutralizing Properties

For updates, please visit the conference website at https://www.microbiology-conference.org/.

Microbiological Growth Studies versus Preservative Efficacy Testing

Christian Lomb, Labor LS

- Presentation of different types of growth studies
- Differences between growth studies and the preservative efficacy test
- Case studies

Optimising Gaseous Decontamination Cycles for Sterility Test Isolators

Miriam Guest, Astra Zeneca

- The use of Vapour Phase Hydrogen Peroxide in Sterility Test Isolators
- Introduction to Enzyme Indicator Technology
- How the use of Enzyme Indicators has optimised cycle design and increased efficiency
- Considerations for Implementation

ASEPTING PROCESSING – Biological Indicators for Vaporized Hydrogen Peroxide (VH2O2) Process

Maria Luisa Bernuzzi, MesaLabs

- Understanding critical characteristics of a biological indicator designed for VH2O2 decontamination processes
- Challenges and best practices for accurate outcomes and interpretation of your results

Update on USP Microbiology General Chapters

Marsha Steed, Resilience, USP Mircobiology Expert Committee

- Sharing the latest revisions and proposed revisions
- Overview of proposed activities
- Current activities and priorities

Post-Conference Workshop – Statistics for Microbiological Validation

Highlights

- Regulatory Background
- Statistical Analysis in line with Guidelines
- Quantitative Methods
- Qualitative Methods

Please note that for the participation, a laptop is needed for the practical exercises.

Target Audience

This conference is of interest to professionals in microbiology from

- Pharmaceuticals and Biopharmaceutical Companies
- Academic Research Institutions
- Government Agencies
- Contract Service Laboratories

who are involved in implementation and validation of microbiological test methods.

Programme

Speakers

Pieta IJzerman-Boon, Principal Statistician MSD
Prof. Edwin van den Heuvel, University of Technology, Eindhoven, The Netherlands

Abstract

For the validation of microbiological test methods several experiments must be performed to demonstrate that the new method is capable of detecting and counting organisms in test samples and at least as good as the compendial method. To quantify the performance, statistical methods form an indispensable tool. This workshop will provide information on the types of experiments and the statistical analyses that may be performed to estimate the validation parameters of the new alternative or rapid methods. The methods will be illustrated on real cases using software.

General Part

- Guidelines
- Basic Statistics
- Measurement Analysis
- Equivalence
- Statistical Detection

Quantitative Methods

- Accuracy
- LOD & LOQ
- Linearity
- Precision

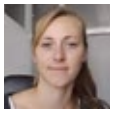
Qualitative Methods

- Accuracy
- (Generalized) Most Probable Number
- LOD
- Specificity

Workshop Dinner

On 29 June, you are cordially invited to a conference dinner. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers



Laura Bagschik
Roche
QC Biotesting

Duncan Barlow
Charles River Laboratories
Technology & Market Development Manager

Maria Luisa Bernuzzi
MesaLabs
Product and Application Engineer

Dr Andreas Bubert
Merck Life Science
Senior Global Product Manager

Dr Sven M. Deutschmann
Roche Diagnostics
Head of Global ASAT "Adventitious Agent Testing & Alternative Microbiological Methods

Dr Christine E. Farrance
Charles River Laboratories
Senior Global Scientific Affairs Liaison

Adele Gisselmann
Merck Life Science
Global Product Manager

Miriam Guest
Astra Zeneca

Prof. Edwin van den Heuvel
University of Technology, Eindhoven, The Netherlands

Dr Juliane Hornung
Labor LS
Head of Microbiology/Central Service

Pieta IJzerman-Boon
MSD
Principal Statistician

Brice Lantheaume
Microbiologics
Technical Support Specialist EMEA

Christian Lomb
Labor LS
Deputy Head of Quality Control/ Head of Microbiological Testing

Dr Michael Miller
Microbiology Consultants, LLC
President

Dr Gunter Neuer
Becton Dickinson
European Application Specialist

Nicole Paland
Minerva Biolabs
Project Manager

Dr Franz Schönfeld
Government of Upper Franconia
GMP Inspector

Marsha Steed
Resilience
Head of Microbial Contamination Control & Viral Safety

This Training Course is recognized for the GMP/ GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. **This training course is the first element for your additional certification**. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

Would you like to present your company in an exhibition or as a sponsoring partner?

We offer you the opportunity to present your company, your products and services to your target group. Thus, participants can inform themselves during the breaks and gain additional benefit from the event. Alternatively, you can also become a sponsoring partner, for example by sponsoring lunch/dinner, coffee breaks or a social event. Interested? Then find out more about the possibilities at https://www.gmp-compliance.org/training/exhibitions-and-sponsoring

Dates

European Microbiology Conference
Tuesday, 27 June 2023, 09.00 - 18.00 h
(Registration and coffee 08.30 - 09.00 h)
Wednesday, 28 June 2023, 09.00 - 17.30 h

Post-Conference Workshop – Statistics for Microbiological Validation
Thursday, 29 June 2023, 09.00 - 17.30 h
(Registration and coffee 08.30 - 09.00 h)
Friday, 30 June 2023, 08.30 - 13.00 h

All times mentioned are CEST

Venue

Heidelberg Marriott Hotel
Vangerowstr. 16
69115 Heidelberg
Phone: +49 (0) 6221/90 80
info.heidelberg@marriott.com

Accommodation

CONCEPT HEIDELBERG 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

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.microbiology-conference.org.

Fees (per delegate plus VAT)

European Microbiology Conference
ECA Members EUR 1,690.-
APIC Members EUR 1,790.-
Non-ECA Members EUR 1,890.-
EU GMP Inspectorates EUR 945.-

Fee includes dinner on 27 June, lunch on both days and all refreshments.

Post-Conference Workshop – Statistics for Microbiological Validation
ECA Members EUR 1,590.-
APIC Members EUR 1,690.-
Non-ECA Members EUR 1,790.-
EU GMP Inspectorates EUR 895.-

Fee includes dinner on 29 June, lunch on both days and all refreshments.

European Microbiology Conference AND Workshop
ECA Members EUR 3,080.-
APIC Members EUR 3,180.-
Non-ECA Members EUR 3,280.-
EU GMP Inspectorates EUR 1,640.-

Fee includes dinner on 27 and 29 June, lunch on all four days and all refreshments.

The conference fee is payable in advance after receipt of invoice. VAT is reclaimable.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference Language

The official conference language will be English.

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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Mr Axel Schroeder (Operations Director) at
+49 (0) 62 21/84 44 10 or at
schroeder@concept-heidelberg.de.

For questions regarding organisation:
Isabell Helm (Organisation Manager) at
+49(0)62 21/84 44 49 or at
helm@concept-heidelberg.de.

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

☐ **European Microbiology Conference,** 27/28 June 2023, Heidelberg, Germany
☐ **Post-Conference Workshop – Validation of Microbiological Methods,** 29/30 June 2023, Heidelberg, Germany
☐ **European Microbiology Conference AND Workshop,** 27-30 June 2023, Heidelberg, Germany

☐ Mr ☐ Ms ☐ Mx ☐ Dr

Title, first name, surname

Company Department

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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 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 %.

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 deducions 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 July 2022). 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.

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