



EUROPEAN MICROBIOLOGY CONFERENCE

20-22 May 2025, Vienna, Austria

With a comprehensive Lecture Block on the Regulatory Developments of Ph. Eur., USP, ChP, JP and Field Reports from Inspectors and Assessors



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

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Dear Colleagues,

Last year again saw new developments in the field of microbiology. Especially in the regulatory area of pharmacopoeias, there are approaches worldwide to consider new techniques, implement strategies such as 3Rs and provide support in the establishment and validation of modern and alternative methods.

For this reason, the European Microbiology Conference 2025 will also address these developments in detail and focus on these global developments on the first day. Speakers from the expert groups of various pharmacopoeias such as Ph. Eur., USP, ChP and quality assessors and inspectors from various authorities will provide insights into expectations of changes and their own experiences.

In addition, individual lecture blocks with speakers from industry and laboratories will focus on relevant topics such as rapid/alternative microbiological methods, monitoring and identification or modern testing for endotoxins and pyrogens in order to provide participants with a comprehensive picture over the three days. The diverse field of speakers and the current topics will enable a comprehensive discussion of current issues with participants and speakers.

Since 2008, the European Microbiology Conference of the ECA Academy in close cooperation with the ECA Pharmaceutical Microbiology Working Group has been an integral part of the European conference landscape. After Heidelberg and Munich in the last two years, we will meet this year on 20-22 May in Vienna, Austria.

We look forward to welcoming you in Vienna



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

Overview

Highlights

- International Regulatory Updates – Ph. Eur., USP, ChP and more
- Implementation and Validation of Alternative/Rapid Microbiological Methods
- Current developments in Endotoxin and Pyrogen Testing
- Optimisation in Environmental Monitoring
- Digitization and Automation of Microbiological Testing (Sterility, Endotoxin and more)

Background

Microbiological quality assurance and control has become increasingly important with the growing role of biological drugs. Whether in relation to the need for faster methods to meet short product shelf lives, or in relation to the challenging testing for viral contamination, which was not relevant for many traditional chemical products. New approaches to pyrogen testing in the context of 3R initiatives or the problem of DNA and RNA residues in the area of analysis also influence daily work in the field of pharmaceutical microbiology. As a result, the microbial control concept applied and described in the dossier of products and the compliance to the filed microbial control concepts inspected during official Health Authority inspections is increasingly becoming the focus of regulatory authorities. The annual European Microbiology Conference provides a platform for all interested parties to keep up to date with the current challenges and share knowledge and experience with colleagues.

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

Dr Michael Miller,

Microbiological Consultants LLC

Axel H. Schroeder,

Administration Manager, Pharmaceutical Microbiology Working Group

Social Event | 20 May



On **20 May 2025**, 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.

PART 1 **REGULATORY UPDATES AND PHARMACOPOEIA DEVELOPMENTS**

The European Pharmacopoeia Unveiled: Recent Milestones and Future Directions

Dr Emmanuelle Charton, EDQM

- Bidding Farewell to the Rabbit Pyrogen Test: A New Era in Safety Testing
- The Future of Bacterial Endotoxin Testing
- Embracing Rapid Microbiological Methods

Potential Certification System for the Validation and Comparability of RMM

Dr Solène Le Maux, EDQM

- Context and development
- Principles of a potential certification system
- Stakeholder perspectives and feedback

USP Bioburden, Microbial Control and Sterility Assurance Topic Updates

Marsha Steed, USP Expert Group

USP Rapid Microbiological Methods Updates

Dr Peter Nissen, NovoNordisk, USP Microbiology Expert Group

The Pyrogen/Endotoxin Test and Sterility/Microbial Test in Chinese Pharmacopoeia

Dr Qing He, Chinese National Institutes for Food and Drug Control, Pharmacology Division

- Chinese Pharmacopoeia (ChP) in general
- The pyrogen/endotoxin test in ChP
- The sterility/microbial test in ChP

Recent Direction of Microbiological Methods toward the nineteenth Edition of Japanese Pharmacopoeia

Dr Yutaka Kikuchi, Chiba Prefectural University of Health Sciences, Department of Nutrition Faculty of Healthcare Sciences

- Overview of microbiological methods
- Rapid Microbial Methods
- Monocyte-Activation Test

Live Biotherapeutic Products and their Regulatory Framework in Europe and Serbia with a Focus on Microbiological Quality Assurance

Dr Milanka Setina, Biological Drug Quality Assessor, Medicines and Medical Devices Agency of Serbia

- Overview of Live Biotherapeutic Products (LBPs) and their unique role in healthcare
- European regulatory landscape for LBPs
- Regulatory perspectives on LBPs in Serbia
- Key microbiological quality considerations: purity, and contamination control

Inspection of Microbiological Quality Control Laboratories - Expectations and Findings

Dr Rainer Gallitzendörfer, GMP Inspector

- Overview of the legal framework in the EU
- Inspections - why, what and how
- Lab tour - expectations and typical findings



PART 2 **ENVIRONMENTAL MONITORING**

Contact News - Validating Contact Plates Methodology?

Karola Schühle, PharmaMedia Müller

- Possible pitfalls in contact sampling
- Detection of micro-organisms
- Impact of human handling
- Disinfectant residues

Lessons Learned from the Implementation of an Automated EM System at a Single Temperature

Niels Visschers & Jeroen van Wiik, MSD

- Global implementation of automated EM system (3P) using single temperature
- Equipment qualification and method validation strategy- Challenges/opportunities and lessons learned of the equipment qualification will be discussed
- Detailed approach on statistical parameters for method validation, e.g. numbers replicates, selection of strains, etc.

Advances in Microbial Identification Technologies: Focus on the BioMerieux VITEK MS Prime for Field Strains and Molds

Melanie Braun and Marius Pfister, Labor LS

- Results and findings of a recent comprehensive identification study with the VITEK MS Prime
- Identification of molds with the VITEK MS Maldi ToF - an alternative to microscopic and molecular biological identification?
- LS-pedia - The step towards a comprehensive service offering scientific information, know-how and microbiological identification

PART 3 ALTERNATIVE AND RAPID METHODS

Hands-On Learning on Performing Statistical Calculations for Quantitative and Qualitative Rapid Method Validation Criteria

Dr Michael Miller, Microbiology Consultants

- Understand available statistical models for demonstrating comparability
- Match the appropriate statistical models with data sets shared by the presenter
- Perform the analyses and conclude whether the data demonstrate comparability

From traditional to Rapid Method in Sterility Testing: Keep Control of your Digitalized Data

Nicolas Lelievre, Merck

- Traditional method: example of digitalization and data traceability all along the testing process
- Rapid method: shorten your time to result while complying with data integrity requirement".

Evaluation of an Alternative Microbiological Technique Based on Microcalorimetry

Nathalie Vendur, Roche

- Feasibilities studies – e.g. impact of different growth media on the TTR
- Product-specific evaluation studies
- LOD-evaluation

Mycobacteria techno Roadmap from Sanofi Vaccine

Dr Thierry Bonnevey, Sanofi

- Generalities on Mycobacteria, regulations and Mycobacteria, history of mycobacteria testing,
- Limitations of Ph.Eur. Method 2.6.2 Mycobacteria and their validation, all alternative than microbiological culture to Mycobacteria testing,
- NAT : development validation of NAT Mycobacteria, conclusion and perspectives

Validation of a new Solid Phase Cytometry (SPC) for Rapid Sterility Testing in Pharmaceuticals

Silvia Scotti, Eurofins,

Pauline Silberreiss, Redberry

- Advantage of rapid sterility testing with SPC
- Applicability of Red One™ technology (solid-phase cytometry) for a 4-day alternative sterility test
- Evaluation of criteria against pharmacopoeial standards, including a comparability study with the compendial 14-day method 14-day method

Sterility Testing of a Cell Based Product with new Development of Solid Phase Cytometry (ScanRDI)

Dr Hans Joachim Anders, Novartis

- Starting point validation of a cell-based product with pre-enrichment culture - a short method introduction
- Open topics before implementation
- Improvements regarding system setup (tablet, pictures)
- Direct detection without pre-enrichment - Overview of Cell burst method with Scan RDI
- Design and result



PART 4 ENDOTOXIN AND PYROGEN TESTING

Automating Endotoxin Testing in a GMP Environment with the PyroTec® PRO

Ole Siebenmorgen, Roche

- Why did we decide to implement an automated system for endotoxin testing?
- How was the implementation strategy?
- What is our experience with routine testing in a GMP environment?

Advancing Pyrogen Testing for Vaccines with Inherent Pyrogenicity: Development of the Reporter Cell-Based Monocyte Activation Test (MAT)

Sijai Yi, MSD

- An overview of the novel reporter cell-based MAT method and its advantages
- Validation of the reporter cell line as an effective MAT testing system for detecting a wide range of endotoxin and non-endotoxin pyrogens
- Case study review from MSD:
 - Qualification of a product-specific MAT method for vaccines with inherent pyrogenicity
 - Development of pass/fail specification strategies for MAT methods applicable to vaccines with inherent pyrogenicity

Overcoming High Viscosity in MAT product-Specific Validations

Dr Eva Kritikou, MAT Research

- Monocyte activation testing of highly viscous products
- Temperature modifications during or after cell incubation
- Product incubation duration adjustments
- pH alterations
- Alternatives for product-specific validation testing

Impact of LPS Mutants on Endotoxin Masking: Influence of Detection Systems and Sample Matrices

Dr Bernhard Illes, Microcoat Biotechnology

- Introduction to LPS mutants
- Understanding the effect of LPS structures (mutants) on the mechanism of LER
- Comparison of endotoxin detection of LPS mutants in different assay systems (LAL, rFC and MAT)
- LER investigations of different LPS mutants in DP and sample matrices

PART 5 GENERAL MICROBIOLOGICAL DEVELOPMENTS

Validation/Verification of Biological Methods (MLT, Sterility, BET, Assays)

Dr Jelena Novaković Jovanović, Galenika

- Are all methods employed in biological laboratory validated using same principle?
- Suitability test for microbiological methods
- Validation of BET testing
- Validation of bioassays
- How to overcome challenges in validation/verification process

Benefits of Digitization in Sterility Testing"

Katharina Schlereth, Labor LS

- Integration of the isolator in laboratory information management systems (LIMS)
- Digitization of testing process and integration into LIMS
- Risk Reduction by digitization



Speakers



Dr Hans Joachim Anders
Quality Team Lead Analytical Science & Technology
Microbiology, Novartis



Melanie Braun
Head Microbiological Services,
Labor LS



Thierry Bonnevey
Sanofi



Dr Emmanuelle Charton
Head of Division B in the European
Pharmacopoeia department, (EDQM)



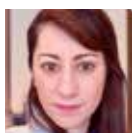
Dr Qing He
Research Fellow Pharmacology Division, Chinese National
Institutes for Food and Drug Control



Dr Bernhard Illes
Project Leader Endotoxin Services,
Microcoat Biotechnologie GmbH



Dr Yukata Kikuchi
Professor of Department of Nutrition, Faculty of
Healthcare Sciences, Chiba Prefectural University of
Health Sciences



Dr Eva Kritikou
MAT Research



Nicolas Lelievre
Regional Application & Commercial Tactics Manager,
Merck



Dr Solène Le Maux
Scientific Programme Manager, European
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Dr Michael Miller
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Katharina Schlereth
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Karola Schühle
Head Research and Development,
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Silvia Scotti
Senior Project Manager - Innovation
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Dr Milanka Setina
Pharmaceutical Quality Assessor,
Medicines and Medical Devices Agency
of Serbia



Ole Siebenmorgen
QC Technology Expert Microbiology,
Roche



Pauline Silberreiss
Research Scientist,
Redberry



Marsha Steed
Sterility Assurance Expert Sr. Consultant/CEO/
Founder, USP Microbiology Expert Group/ Steed
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Natalie Vendur
Roche



Niels Visschers
Sr. Specialist MSD Global Center of
Expertise Microbiology & AVA, MSD



Jeroen van Wiik
MSD



Dr Sijia Yi
Associate Principal Scientist,
MSD

European Microbiology Conference | 20-22 May 2025

Date

Tuesday, 20 May 2025, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Wednesday, 21 May 2025, 09.00 – 17.30 h
Thursday, 22 May 2025, 09.00 – 17.00 h

All times mentioned are CEST

Venue

Austria Trend
Parkhotel Schönbrunn
Hietzinger Hauptstr. 10-14
1130 Wien

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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.

Conference Language

The official conference language will be English.

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.

Registration

You can register either by using the QR code, by e-mail or online at www.microbiology-conference.org.



Fees (per delegate plus VAT)

ECA Members EUR 2,290
APIC Members EUR 2,390
Non-ECA Members EUR 2,490
EU GMP Inspectorates EUR 1,245

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

It includes conference documentation, dinner on 20 May, lunch on all three days and all refreshments.

Organisation and Contact

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

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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 %.

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