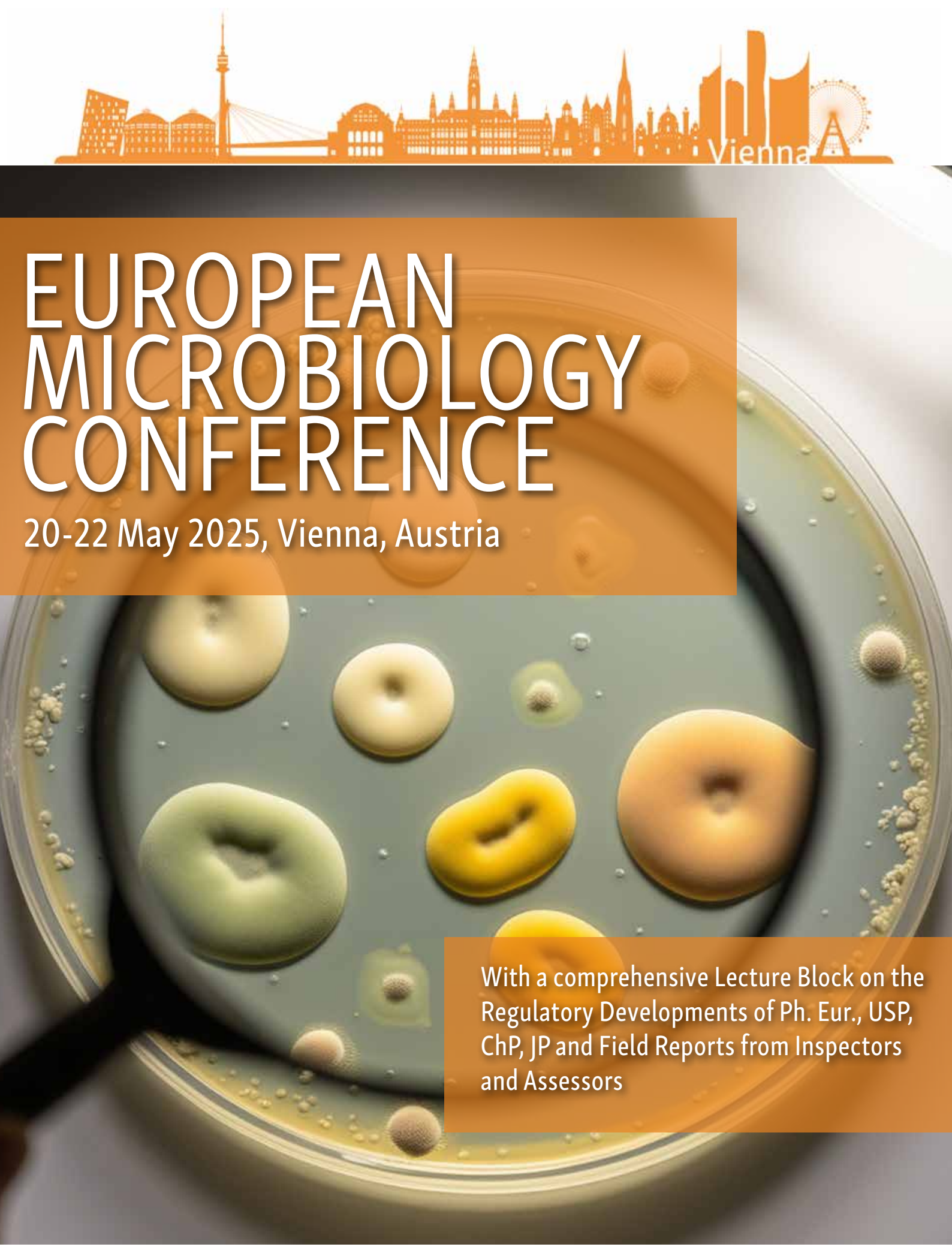


EUROPEAN MICROBIOLOGY CONFERENCE

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

Supported by ECA Academy Your GMP/GDP Information Source

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

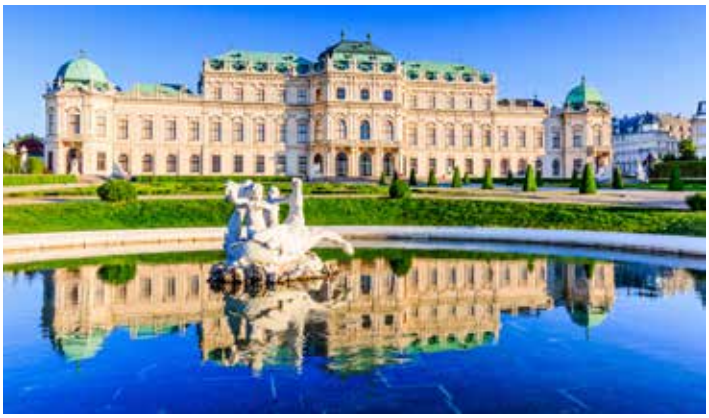
Moderators

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

- Chinese Pharmacopeia (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

- Feasibilitiy 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 Bonnevay, 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

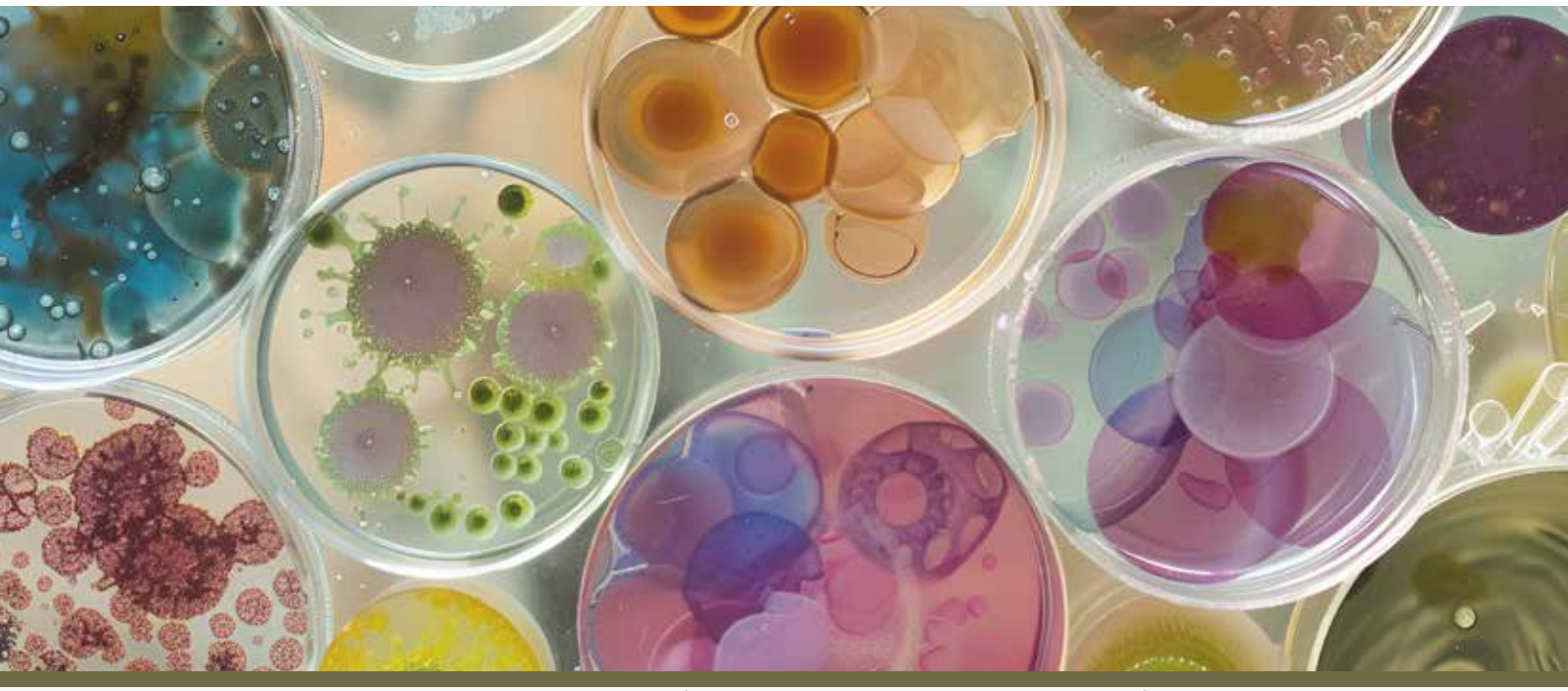
PART 5
GENERAL MICROBIOLOGICAL DEVELOPMENTS

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 Bonnevay
Sanofi

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

Dr Rainer Gallitzendörfer
GMP Inspector

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 Directorate for the Quality of Medicines and HealthCare (EDQM)

Dr Michael Miller
President,
Microbiology Consultants LLC

Dr Peter Nissen
Senior Principal Scientist, Microbiology, USP Microbiology Expert Group/
NovoNordisk

Dr Jelena Novaković Jovanović
QC Manager, Biological Department,
Galenika

Marius Pfister
Specialist Manager of Microbiological Service,
Labor LS

Katharina Schlereth
Head of Department,
Labor LS

Karola Schühle
Head Research and Development,
PMM - Pharma Media Müller

Silvia Scotti
Senior Project Manager - Innovation Projects, Eurofins

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 MicroBio LLC

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 Vienna

Phone +43 (1) 878 08 0
parkhotel.schoenbrunn@austria-trend.at

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.

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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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.

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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