



EUROPEAN MICROBIOLOGY CONFERENCE

26/27 June 2024, Munich, Germany

+ Pre-Conference Workshop – Next Generation Sequencing (NGS)

25 June 2024, Munich

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together and save 400 €!



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,

After last year's wonderful conference in Heidelberg, we are once again offering you the opportunity to meet face-to-face, listen to exciting presentations and discuss current topics in microbiology with colleagues 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.

For the second time after the pandemic and again on site, we have selected a series of interesting lectures. On the one hand, we will be looking at current developments in pharmacopoeias on topics such as alternative methods, endotoxins/pyrogens and bioburden, and on the other, we will be addressing the dilemma of temperatures during the incubation of microorganisms and monitoring requirements. Another

block of lectures will deal with questions of contamination control under the aspects of the current GMP guidelines.

This year, we are placing a special focus on the topic of Next Generation Sequencing (NGS), i.e. the activities of PharmEur in this field, the impact of ICH Q5A(R2) and the experiences of users, with our own pre-conference workshop.

We look forward to welcoming you in Munich.



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

Overview

Highlights

- Pharmacopoeial Developments – From alternative Testing and Modern Methods
- Contamination Control – Monitoring, Disinfection and more
- Method Validation and Interpretation of Results
- Monitoring – Challenges with Temperatures and more
- Endotoxin and Pyrogen – USP, Ph.Eur. and Chinese Pharmacopoeia
- Bioindicators

Background

The role of pharmaceutical microbiology is getting more and more important. The microbial control concept is 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 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

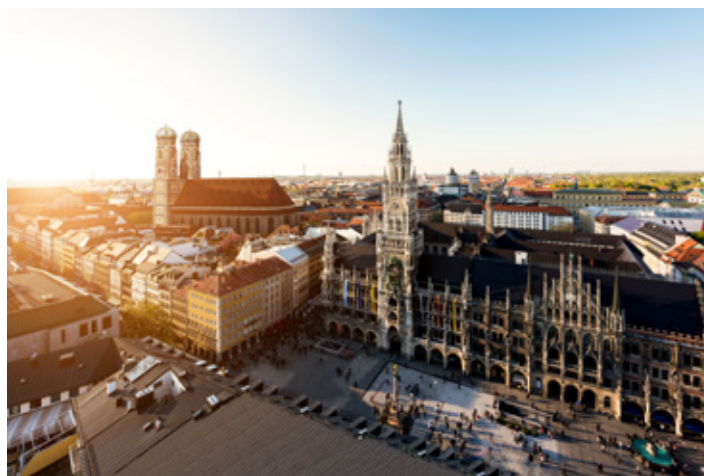
- Contamination Control
- Monitoring
- Validation
- Quality Affairs
- Regulatory Affairs
- Research and Development

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 | 26 June



On 26 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

Overview and Future Plans of the USP Rapid Microbiological Methods Subcommittee

Dr David Roesti, Novartis

Revision of Technical Report 33 – Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods

Dr Michael Miller, Microbiology Consultants

Remediation of Contaminated Protein A Chromatography Resin; Case Studies from BioPhorum Members

Robin De Scheemaeker, Sanofi

Use of Physics-Methods for Contamination Control

Dr Jeanne Moldenhauer, Excellent Pharma Consulting

Contamination Control Strategies for Pharmaceutical Grade Water systems: Keeping it Clean and Preventing Biofilms

Dr Michael Miller, Microbiology Consultants

A Disinfectant Field Trial that Meets Annex I Guidance

Jim Polarine, Steris Corporation

Taxonomy, Nomenclature, Genealogy of Type Culture Strains

To be announced

Appearance or Reality? Interpretation and Significance of Microbiological Results

Dr Frank Mertens, Saercon

Primary Validation of Flow Cytometry as At-Line Bioburden Monitoring

Dr Jürgen Illerhaus, BWT

EM Incubation Temperature – a View on a Dilemma for a QC Micro Lab

Dr Hans Joachim Anders, Novartis

Fact Checking On The Behavior Of Environmental Microbial Organisms In A Single Temperature Incubation Regime

Laurent Leblanc, bioMérieux

USP Updates on Bioburden and Endotoxins

Marsha Steed, Member USP Microbiology Expert Group

Latest Progress of Pyrogen/Endotoxin Test in Chinese Pharmacopoeia

Dr Qing He, National Institutes for Food and Drug Control

Effect of Container Types and Material on Endotoxin and β -Glucan Recovery

Dr Bernhard Illies, Microcoat

Sterilization Science; a Positive Biological Indicator (BI) Result at the End of the Proper Incubation Time: How Managing it

Luisa Bernuzzi, Mesa Labs

Pre-Conference Workshop – Next Generation Sequencing (NGS)

Objectives

This workshop will address the existing and announced relevant regulations, present the collected comments of the ECA NGS Task Force where applicable and furthermore experts from industry, laboratories and service providers will report on their experiences with NGS.

Programme

Draft Ph.Eur. 2.6.41 – Content and Comments

Dr Sven M. Deutschmann, Roche

Dr Oleg Krut, PEI

Revision (R2) of Guideline ICH Q5A on Viral Safety Evaluation of Biotechnology Products

Dr Astrid Schwantes, PEI

Use of NGS to Identify Relationships in the Legal Context of Food Safety Controls

Coen van der Weijden, Netherlands Food and Consumer Product Safety Authority

GMP-Compliant Analysis of NGS Data for Detection of Contaminants, Identification of Bacterial and Fungal Strains, and Typing

Dr Stefan Emler, Smart Gene

NGS Strategies from Sample to Report for Microbial Identification and Viral Contamination Detection in Pharma

Dr Inanc D. Eserim, Thermo Fisher Scientific

Diversity of *S. epidermidis* – NGS Implementation in a GMP environment

Daniel Männle, Novartis

The way NGS is Shaping the Future of Food-Borne Outbreak Investigations in the Netherlands

Charlotte Verbart, Netherlands Food and Consumer Product Safety Authority

Bacterial community structure and dominant species in pharmaceutical manufacturing water revealed by high-throughput sequencing

Saori Shikama, Takeda

Case Studies, Data and Experience on NGS

tba, Charles River Laboratories

Speakers



Dr Hans Joachim Anders

Novartis
Unit Head Microbiological Quality Control



Maria Luisa Bernuzzi

MesaLabs
Product and Application Engineer



Robin De Scheemaker

Sanofi



Dr Sven M. Deutschmann

Roche Diagnostics
Head of Global ASAT "Adventitious Agent Testing & Alternative Microbiological Methods"



Dr Stefan Emler

SmartGene
Founder and Director



Dr Inanc D. Eserim

Thermo Fisher Scientific
Sr. Product Specialist, Translational Sales Development
NGS



Dr Qing He

Chinese National Institutes for Food and Drug Control
Research Fellow Pharmacology Division



Dr Jürgen Illerhaus

BWT
Product Marketing and Business Development Manager



Dr Bernhard Illes

Microcoat
Project Leader Endotoxin Services



Dr Oleg Krut

Paul-Ehrlich-Institut, German Federal Agency for Vaccines
and Biomedicines
Lead Microbiological Safety



Laurent Leblanc

bioMérieux
3P Ecosystem R&D Sr. Manager



Dr Daniel Männle

Novartis
Analytical Science & Technology Microbiology Specialist



Dr Frank Mertens

Saercon
Founder and Director



Dr Michael Miller

Microbiology Consultants, LLC
President



Jeanne Moldenhauer

Excellent Pharma Consulting
Chief Science Officer



Jim Polarine

Steris Corporation
Senior Technical Service Manager



Dr David Roesti

Novartis
Technical Steward Microbiology, Manufacturing
Science&Technology



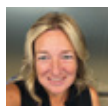
Dr Astrid Schwantes

Paul-Ehrlich-Institut, German Federal Agency for Vaccines
and Biomedicines
Regulatory Assessor Virology



Saori Shikama

Takeda



Marsha Steed

USP Microbiology Expert Group



Coen van der Weijden

Netherlands Food and Consumer Product Safety Authority
Senior/Coordinating Inspector Microbiological Food Safety



Charlotte Verbart

Netherlands Food and Consumer Product Safety Authority
Senior Advisor on Microbiological Food Safety

Dates

Pre-Conference Workshop – Next Generation Sequencing (NGS)

Tuesday, 25 June 2024, 09.00 - 17.30 h
(Registration and coffee 08.30 - 09.00 h)

European Microbiology Conference

Wednesday, 26 June 2024, 09.00 - 17.30 h
(Registration and coffee 08.30 - 09.00 h)
Thursday, 27 June 2024, 09.00 - 17.00 h

All times mentioned are CEST

Venue

HYPERION Hotel München
Truderinger Straße 13
81677 München

hyperion.muenchen@h-hotels.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)

Post-Conference Workshop – Statistics for Microbiological Validation

ECA Members EUR 990.-
APIC Members EUR 1,040.-
Non-ECA Members EUR 1,090.-
EU GMP Inspectorates EUR 545.-

Fee includes lunch and all refreshments.

European Microbiology Conference

ECA Members EUR 1,790.-
APIC Members EUR 1,890.-
Non-ECA Members EUR 1,990.-
EU GMP Inspectorates EUR 995.-

Fee includes dinner on 26 June, lunch on both days and all refreshments.

European Microbiology Conference AND Workshop

ECA Members EUR 2,480.-
APIC Members EUR 2,580.-
Non-ECA Members EUR 2,680.-
EU GMP Inspectorates EUR 1,340.-

Fee includes dinner on 26 June, lunch on all three 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

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If the billing address deviates from the specification to the right, please fill out here:

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Reservation Form (Please complete in full)

- European Microbiology Conference, 26/27 June 2024, Munich, Germany
 Pre-Conference Workshop – Next Generation Sequencing (NGS), 25 June 2024, Munich, Germany
 European Microbiology Conference AND Workshop, 25-27 June 2024, Munich, Germany

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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 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 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/ecca_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.