EUROPEAN MICROBIOLOGY CONFERENCE

26/27 June 2024, Munich, Germany

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

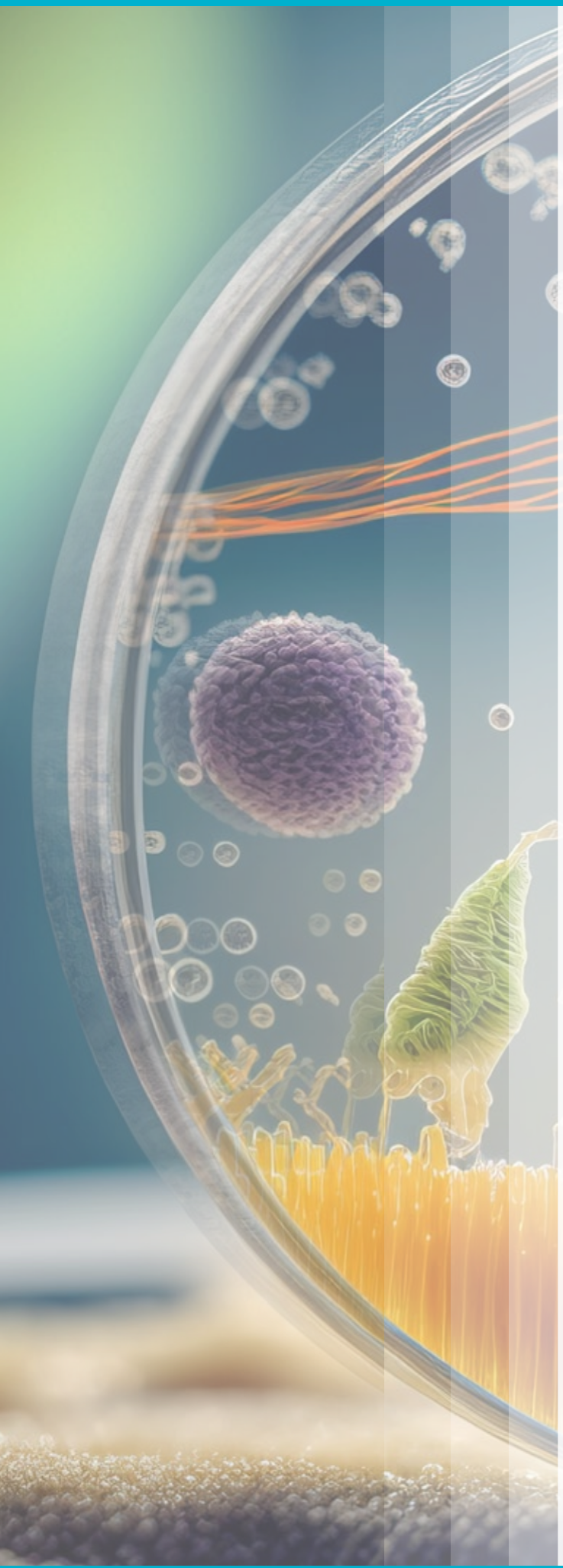
25 June 2024, Munich

Book conference and workshop 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

Supported by BioPhorum

ECA Academy Your GMP/GDP Information Source



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

- General overview of the RMM chapters under drafting
- General principles of the revised <72> and <73> chapters
- Drafting and reviewing process within the USP microbiology expert committee

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

Dr Michael Miller, Microbiology Consultants

- Understand what's new in the 2024 Technical Report and how it compares with current regulatory and pharmacopoeia guidance
- Review new recommendations for validation and statistical analysis
- Provide instruction on how to apply the guidance for short-life products and ATMPs

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

Robin De Scheemaeker, Sanofi

Use of Physics-Methods for Contamination Control (Space-Charge Electret / Nanoflashing)

Jeanne Moldenhauer, Excellent Pharma Consulting

- New physics-based technologies provide advantageous methods of contamination control without the disadvantages of many current systems
- Identification of a new phenomenon that occurred in nature, that can now be used on demand and in a controlled fashion to inactivate microorganisms, viruses, and pollen
- Presentation of real data from international laboratories and sites showing the effectiveness of this technology
- Discussion of other potential applications

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

Dr Michael Miller, Microbiology Consultants

- Review most common water systems, designs and microbial specifications
- Identify design flaws and maintenance issues that lead to contamination and biofilm
- Provide recommendations for gaps with a focus on contamination case studies

A Disinfectant Field Trial that Meets Annex I Guidance

Jim Polarine, Steris Corporation

- A field trial of biopharmaceutical disinfectants - a component for a CCS
- Ready-to-use quaternary ammonium disinfectant and a hydrogen peroxide/peracetic acid sporicide used to control bioburden in a new cleanroom after construction.
- Impact of material flow, engineering controls, supplies and operating procedures
- EM Data evaluation and synopsis

Taxonomy, Nomenclature, Genealogy of Type Culture Strains

Miriam Guest, Charles River Laboratories

- Understanding the use of test strains in QC Micro
- Variation in recommended test organisms in the Pharmacopoeia
- Understanding the importance Taxonomy and Nomenclature

Facts or Fake? Interpretation and significance of microbiological test results

Dr Frank Mertens, Saercon

- (In-)Accuracy of microbial count
- Definition of specifications and limits
- Some general challenges for identification methods

Primary Validation of Flow Cytometry as Online Bioburden Monitoring

Dr Jürgen Illerhaus, BWT

- Presentation of the method and its applications
- Fundamental questions for RMMs... What do we really measure and how can the data be interpreted?
- Primary validation as the basis for further validation

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

Dr Hans Joachim Anders, Novartis

- Requirements - How useful are the guidelines?
- Monitoring or release criteria?
- Audit experiences
- Thoughts on the choice and validation of an incubation regime
- Results of comparative studies

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

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

Laurent Leblanc, bioMérieux

- Overview of the regulatory landscape
- Common incubation practices and microorganisms recovery challenges
- Presentation of the "One media / One temperature" initiative
- Result of an exploratory study of the impact of incubation temperature in the 30-35°C range

USP Updates on Bioburden, Endotoxins and Sterility Assurance/Microbial Control

Marsha Steed, JYA/Steed MicroBio

- General principles of <1119> Bioburden Monitoring and <1119.1> Bioburden Test
- General principles of <86> Bacterial Endotoxins Test Using Recombinant Reagents
- Sterility Assurance and Microbial Control Subcommittee Updates

Latest Progress of Pyrogen/Endotoxin Test in Chinese Pharmacopoeia

Dr Qing He, National Institutes for Food and Drug Control

- A brief introduction of NIFDC and CP
- Development and requirement of pyrogen/endotoxin test in CP
- Latest progress of pyrogen/endotoxin test based on 3Rs in CP

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

Dr Bernhard Illes, Microcoat

- Introduction to endotoxin masking
- Understanding of container material (inert vs. influential) contribution to reduced endotoxin recoveries
- Case studies with container dependent endotoxin recovery in drug formulations and of 1-3-ß-D-Glucans
- Strategies to discover and prevent the influence of container effects

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

Luisa Bernuzzi, Mesa Labs

- ISO and the USP expectations for a positive BI result
- What to do if the identified orgamism is a BI organism
- What to do if not
- Conclusions and root cause analysis

Pre-Conference Workshop – Next Generation Sequencing (NGS)

Objectives

This workshop will deal with the existing and announced relevant regulations in pharmacopoeias and guidelines and will present the collected comments of the ECA NGS Task Force on the planned Draft Ph.Eur. 2.6.41, which is to be published shortly. In addition, experts from industry, laboratories and service companies 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

- Introduction
- Comments from ECA "NGS"-Task Force

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

Dr Astrid Schwantes, PEI

- Updates in ICH Q5A(R2) with focus on the testing strategy and testing methods (including NGS)
- NGS application to different biomedicinal products

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

- NGS typing to identify relationships between food pathogen isolates.
- The legal context of using NGS in official controls for food safety.
- Connecting data from the human and food domain in the Netherlands and internationally.

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

Dr Stefan Emler, Smart Gene

- Apps for easy processing of NGS datasets by non-bioinformaticians in routine laboratories
- Meaningful, accurate and reproducible results also for QM/QC tests in biopharmaceutical production
- AI-curated proprietary "Centroid" reference sequence databases with validated content and up-to-date nomenclature to support high-resolution identification of >16,000 bacterial species and >40,000 fungal species
- User protocols and audit trails for full traceability of analyses

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

Caroline Rosseel, Thermo Fisher Scientific

- Ion Torrent NGS Technology Overview
- The Advantage of NGS on Microbial ID and on Viral Safety Testing
- Ion Torrent NGS Technology Approach for Microbial ID and for Viral Safety Testing
- Analysis Solutions with Regulatory Compliance

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

To be announced

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

Charlotte Verbart, Netherlands Food and Consumer Product Safety Authority

- Collaboration between Public health and Competent Authority on food safety.
- Traditional methods used in food-borne outbreak investigation, illustrated by the example of an outbreak of listeriosis.

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

Saori Shikama, Takeda

- Culture independent bacterial community structure analysis at cold WFI system
- High-throughput sequencing that targets full length 16S rRNA gene effectively identified dominant species

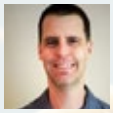
Case Studies, Data and Experience on NGS

Doug Botkin, Charles River Laboratories

Speakers

Dr Hans Joachim Anders
Novartis
Unit Head Microbiological Quality Control

Maria Luisa Bernuzzi
MesaLabs
Product and Application Engineer



Doug Botkin
Charles River Laboratories
Technology and Market Development Manager

Robin De Scheemaeker
Sanofi
Contamination Control/Steriliy Assurance Lead

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

Dr Stefan Emler
SmartGene
Founder and Director

Miriam Guest
Charles River Laboratories
Senior Principal Scientific Advisor

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 Ecosytem R&D Sr. Manager

Dr Frank Mertens
Saercon
Founder and Director

Dr Michael Miller
Microbiology Consultants, LLC
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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

Caroline Rosseel
Thermo Fisher Scientific
Sr. Product Specialist NGS

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)

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

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Sonja Nemec (Organisation Manager) at +49(0)62 21/84 44 24 or at nemec@concept-heidelberg.de.

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Reservation Form (Please complete in full)

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☐ **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 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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