



# EUROPEAN MICROBIOLOGY CONFERENCE

26/27 June 2024, Munich, Germany

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

25 June 2024, Munich

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This conference is recognised for the ECA GMP Certification Programme „Certified Microbiological Laboratory Manager“. Please find more details at [www.gmp-certification.eu](http://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*

- 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 & Jacob Sonne-Hansen, Fujifilm*

- General overview of the challenges associated with protein A chromatography resins necessitate the development of effective sanitization approaches capable of addressing routine maintenance and responding to bacterial contamination events.
- Review of case studies from different Biophorum members:
  - Sanofi Case study: Upscaling a Peracetic Acid cleaning method for protein A chromatography resin for application as a non-routine cleaning method involving PAA solution to remediate a column contamination.
  - Other Biophorum case studies - TBD

### 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

## 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 $\beta$ -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- $\beta$ -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 organism 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

#### Implementing Next Generation Sequencing technology under GMP

*Snehit Mhatre, Eurofins*

- Scope of NGS in BioPharmaceutical market: Microbiome & Live Biotherapeutic Products
- Difficulties in implementing NGS under GMP
- Recommendations and guidelines

#### 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*

- Current NGS applications for QC Micro
- Future NGS applications for QC Micro
- NGS challenges

#### Possibilities of NGS in virus safety in accordance to ICH Q5a R2

*Anna Liznar, Pathoquest*

- Viral Safety of Cell Banks: Decluttering Animal-based Assays
- Replacing Animal-based Tests with a single GMP NGS Test (iDTECT Transcriptome)
- Ensuring Detectability: Assay Controls and Adoption to different Matrixes

## Speakers



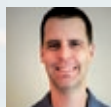
**Dr Hans Joachim Anders**

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/Sterility Assurance Lead



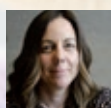
**Dr Sven M. Deutschmann**

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



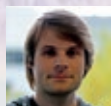
**Dr Qing He**

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



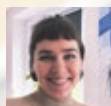
**Dr Oleg Krut**

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



**Laurent Leblanc**

bioMérieux  
3P Ecosystem R&D Sr. Manager



**Anna Liznar**

Pathoquest  
NGS Solution Specialist, Business Development



**Dr Frank Mertens**

Saercon  
Founder and Director



**Snehit Mhatre**

Eurofins  
Senior Scientific Director Microbiome



**Dr Michael Miller**

Microbiology Consultants, LLC  
President



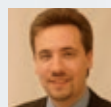
**Jeanne Moldenhauer**

Excellent Pharma Consulting  
Chief Science Officer



**Jim Polarine**

Steris Corporation  
Senior Technical Service Manager



**Dr David Roesti**

Novartis  
Technical Steward Microbiology, Manufacturing Science&Technology



**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



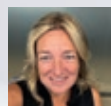
**Saori Shikama**

Takeda



**Jacob Sonne-Hansen**

Fujifilm  
Principal Scientist, Ph.D, Process Science



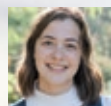
**Marsha Steed**

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](http://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.

### 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](mailto:info@concept-heidelberg.de)  
[www.concept-heidelberg.de](http://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](mailto:schroeder@concept-heidelberg.de).

### For questions regarding organisation:

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

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69007 Heidelberg  
Germany

### 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**

☐ Mr ☐ Ms ☐ Mx ☐ Dr

Title, first name, surname

Company

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Important: Please indicate your company's VAT ID Number

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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.

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