EUROPEAN MICROBIOLOGY CONFERENCE

6 - 7 May 2020 | Barcelona, Spain

Pre-Conference Workshop:
Validation of Alternative/
Rapid Microbiological Methods | 5 May

Speakers

Dr Emmanuell Charton, EDQM | Dr Marja Claassen, MSD | Jordi Iglesias Cullell, CRL | Dr Sven M. Deutschmann, Roche

Dr Elena Ferber, Labor LS Stefan Gärtner, Labor LS | Mike Gajdiss, Lonza | Dr Viviane Grunert da Fonseca, Roche

Peter Huonker, Früh Verpackungstechnik | Dr Pieta IJzerman-Boon, MSD | Dr Michael Miller, Microbiology Consultants LLC

Dr Kai Nesemann, Sartorius Maria Eugenia Giribets Parra, Boehringer Ingelheim | Dr Wolfgang Rudy, TentaMedix

Dr Michael Ruffing, Boehringer Ingelheim Alexandra Stärk, Novartis Pharma Stein

Dr Steffanie Strathdee, UCSD Department of Medicine | Dr Ulrich Zuber, Hoffmann-La Roche

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

ECA Academy
Your GMP/GDP Information Source

European Microbiology Conference

Dear Colleague,

I cordially invite you to the European Microbiology Conference (EMC) and the Workshop on Alternative/Rapid Microbiological Methods 2020 of the ECA Academy in Barcelona, Spain.
The conference has been taking place for 12 years now. The positive feedback of the participants and speakers made the EMC an annual event which informs about current developments and trends in pharmaceutical microbiology with lectures and workshops. In 2020, EMC will be combined with a pre-conference workshop on the validation of alternative microbiological methods, focusing on statistical approaches for the validation.
These two events will provide you with an excellent opportunity to keep abreast of the latest developments and the state of the art in science and technology in microbiological quality control. Pharmacopoeia experts, pharmaceutical quality control representatives and contract laboratories will share their experiences on what the current challenges and achievements are and how they have ultimately implemented appropriate microbiological quality control concepts in their companies. The aim of this conference and workshop is therefore to provide the pharmaceutical microbiologist with practical and applicable knowledge and „know-how". It also provides a forum for interesting and open discussions between speakers, regulators and your industry colleagues.

It would be a great pleasure for me if you would join us in Barcelona.

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

Pre-Conference Workshop: Validation of Alternative/Rapid Methods | 5 May

Objectives

In this year's workshop, different approaches for the validation of alternative microbiological methods will be presented on the basis of case studies by microbiologists and statisticians. In particular, the statistical approach will be considered and subsequently the advantages and disadvantages will be discussed. What were the experiences of the scientists, what solutions were pursued and how was the validation carried out?

Background

In a lecture on the European Pharmacopoeia Chapter 5.1.6, the EDQM defined Alternative Methods for Control of Microbiological Quality: "The aim is to facilitate the implementation and use of alternative microbiological methods (AMM) where this can lead to cost-effective microbiological control and improved assurance for the quality of pharmaceutical products.

Even if the validation of alternative microbiological methods does not always prove to be easy, especially when it comes to demonstrating comparability with existing compendial methods, implementation in QC laboratories is making progress. It has been found that the collection, analysis and evaluation of the data obtained is of great importance for the validation of alternative and rapid methods. Especially if the results of the alternative methods cannot be presented in the classical cfu, the authority expects "use of statistics to demonstrate equivalency between an alternative and a growth-based compendial method."

However, there may be different statistical approaches that can be used in the validation process, depending on the method or which microbiological test is affected.

Target Audience

- Microbiologists from pharmaceutical and biopharmaceutical industry
- Manufacturer of medical devices
- Responsible QC/QA staff
- Experts from contract laboratories
- Manufacturer and suppliers of BI
- Responsible Authorities

Presentations | 5 May

Alternative methods in the European Pharmacopoeia

Dr Emmanuell Charton, EDQM

- Relevant texts
- Current expectations

Non-inferiority testing for RMM validation: Two use cases

Dr Viviane Grunert da Fonseca, Roche Diagnostics

- Qualitative sterility test: Validation with respect to equivalence
- Quantitative automated colony counter: Validation with respect to accuracy & precision

Validating a Rapid Sterility Test: Practical Strategies to Ensure Regulatory Compliance

Dr Michael Miller, Microbiology Consultants LLC

- Review recent regulatory policies and compendial guidance for rapid sterility testing
- Understand the required validation parameters including limit of detection, specificity, method suitability and equivalence
- Consider sampling strategies when compendial requirements cannot be met
- Discuss the impact of short-life products on detection time
- Debate the need for using stressed microorganisms
- Provide examples of real-life rapid sterility validation data

Validation Approach for an Alternative Method in Pharmaceutical QC

Dr Marja Claassen & Dr Pieta IJzerman-Boon, MSD

From visual counting to automation of water monitoring with the Growth DirectTM

Maria Eugenia Giribets Parra, Boehringer Ingelheim

- Build your business case to show the impact of automation in your lab
- Define your validation strategy: dos and don'ts
- The Growth DirectTM in routine: benefits and opportunities

European Microbiology Conference | 6-7 May

Highlights

- Regulatory Developments and Authorities Expectation
- Contamination Control Strategy for a new Launch Product
- Monitoring and New Methods – from Comparison up to Validation
- Testing of ATMP – Endotoxins, Mycoplasma and More
- MAT Multiplexing Platform
- ECA – New OOS/OOT Guide for Endotoxin Testing

Objectives

This event offers you a unique possibility to become acquainted with ongoing regulatory requirements, the development of microbiological methods for quality and process control as well as with the recent experiences in microbial contamination control.

Speakers from different scopes of pharmaceutical microbiology will give you the chance to get to know the different views on versatile microbiological topics. Also, as a participant you will have ample opportunity to discuss your specific issues with speakers and other participants.

Background

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

- Pharmaceutical 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 ECA Pharmaceutical Microbiology Working Group
Dr Michael Miller,
Microbiology Consultants LLC

Presentations

Keynote

Necessity is the Mother of Invention: Why Phage Therapy is Making a Comeback in the West

Steffanie Strathdee, PhD, UCSD Department of Medicine

- The presenter will describe her family's personal story as it relates to the current revitalization of phage therapy
- The presenter will briefly describe the strange history of phage therapy and why it was 'forgotten' in the West
- The presenter will discuss current and future prospects for phage therapy using natural, genetically engineered and synthetic phage

Current activities with relevance to microbiology

Dr Emmanuelle Charton, EDQM

- Rapid methods
- BET/rFc/MAT
- Extraneous agents
- others

Evaluation of Next Generation Sequencing (NGS) for Adventitious Virus Testing

Dr Michael Ruffing, Boehringer Ingelheim

- Current Regulatory Background and Activities
- Replacing compendial Methods – Case Studies

Definition of a microbiological contamination control strategy for a new launch product

Alexandra Stärk, Novartis

- Relevant parameters of a microbiological contamination control strategy
- Critical and non-critical process parameters
- Required validation studies

Development and validation of a rapid sterility test using BacT/ALERT Dual T

Dr Marja Claassen & Dr Pieta IJzerman-Boon, MSD

- Development of method to enable detection of Cutibacterium acnes
- Design of experiments for solving diminished mold detection
- Validation of improved method according to Ph.Eur. 5.1.6 and USP<1223>
- Innovative statistical validation approach to demonstrate non-inferiority with compendial method

Rapid Microbiological Methods for Bioburden testing of air and water and the long way towards implementation

Dr Ulrich Zuber, Roche

- Devices for online monitoring of water and air
- Feasibility studies
- Steps to implementation
- Oppportunities for RMM due to the new version of Annex 1

Growth Direct System Experiences

Mike Gajdiss, Lonza

Continuous microbiological air monitoring

Dr Kai Nesemann, Sartorius

Case Study - Comparison of Monitoring Systems

Peter Huonker, Early Packaging Technology

- Application area and function
- Comparison of two monitoring systems – Valimon from ValiSys and Labwatch Monitoring from GE (Amphenol)
- Pros/Cons

Rapid microbial test for short shelf life pharmaceuticals

Dr Kai Nesemann, Sartorius

Determination of Pyrogens from Medical Devices/MAT Multiplexing

Dr Wolfgang Rudy, TentaMedix

- Endotoxin vs. Non Endotoxin Pyrogen detection in vitro
- Monocyte Activation Test as in vitro replacement of the Rabbit Pyrogen Test
- Pyrogens and Medical Devices
- Cytokine multiplexing

Pyrogen Detection on cellular prepartions and other short shelf life pharmaceuticals

Stefan Gärtner, Labor LS

- Regulatory requirements
- Test Methods and Strategies
- Test Interferences
- Low Endotoxin Recovery

Strategies for validating nucleic acid-based techniques for testing for the absence of Mycoplasma

Dr Elena Ferber, Labor LS

- Characteristics of mycoplasmas
- NAT-Techniques
- Strategies for validation/suitability tests
- Pitfalls and practical examples

The new ECA OOS/OOT Guide on Endotoxin Testing

Jordi Iglesias Cullell, CRL

- OOS/OOT/Atypic versus Invalid
- Define a OOS flowchart
- Organizational tools for conducting Investigations
- OOS investigation Check-List

Speakers at the conference

Dr Emmanuelle Charton
European Pharmacopoeia Dept., EDQM, Council of Europe
Head of Division B

Dr Marja Claassen
MSD
Senior microbiological specialist

Jordi Iglesias Cullell
Charles River Laboratories
Technology Market and Development Manager

Dr Sven M. Deutschmann
Roche, Head of gASAT "Adventitious Agents Testing & Alternative Microbiological Methods"

Dr Elena Ferber
Labor LS
Head Molecular Biology

Stefan Gärtner
Labor LS
Head Department Sterility Testing

Mike Gajdiss
Lonza
Microbiologist, Quality Control

Dr Viviane Grunert da Fonseca
Roche

Peter Huonker
Früh Verpackungstechnik
Head of Quality Management

Dr Pieta IJzerman-Boon
MSD
Principal Statistican

Dr Michael Miller
Microbiology Consultants LLC
President

Dr Kai Nesemann
Sartorius

Maria Eugenia Giribets Parra
Boehringer Ingelheim

Dr Wolfgang Rudy
TentaMedix
Director Virology & Contamination Detection

Dr Michael Ruffing
Boehringer Ingelheim, Laboratory Head Biopharmaceuticals QC Services, Virology & Contamination Detection

Alexandra Stärk
Novartis Pharma Stein
Technical Stewart Sterility Assurance / Microbiology

Steffanie Strathdee, PhD
UCSD Department of Medicine, Associate Dean of Global Health Sciences, Harold Simon Professor, Co-Director, Center for Innovative Phage Applications and Therapeutics

Dr Ulrich Zuber
Hoffmann-La Roche
Head of Environmental Monitoring

Social Event | 6 May

On 6 May, 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.

Dates

Workshop Validation of Alternative/Rapid Microbiological Methods
Tuesday, 5 May 2020, 09.30 - 16.30 h
(Registration and coffee 09.00 – 09.30 h)

European Microbiology Conference
Wednesday, 6 May 2020, 09.30 – 18.00 h
(Registration and coffee 09.00 – 09.30 h)
Thursday, 7 May 2020, 09.00 – 16.30 h

Venue

Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona
Spain
Tel. +34 (93) 503 53 00
Fax +34 (93) 490 60 45
sants@barcelo.com

Fees (per delegate plus VAT)
European Microbiology Conference
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 6 May, lunch on both days and all refreshments during the conferences. VAT is reclaimable.

European Microbiology Conference combined with Workshop
ECA Members € 2,180
APIC Members € 2,280
Non-ECA Members € 2,380
EU GMP Inspectorates € 1,190
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 6 May, lunch on three days and all refreshments.
VAT is reclaimable.

Workshop Validation of Alternative/Rapid Microbiological Methods
ECA Members € 890
APIC Members € 940
Non-ECA Members € 990
EU GMP Inspectorates € 445
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on 5 May and all refreshments during the conference. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. 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.

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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D-69007 Heidelberg, Germany
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For questions regarding content:
Mr Axel Schroeder (Operations Director) at +49 (0) 62 21/84 44 10 or via email at schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Niklaus Thiel (Organisation Manager) at +49 (0) 62 21/84 44 43 or via email at thiel@concept-heidelberg.de.

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CONCEPT HEIDELBERG
P.O. Box 10 17 64
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69007 Heidelberg
Germany

Reservation Form (Please complete in full)

☐ **European Microbiology Conference**
6-7 May 2020, Barcelona, Spain
☐ **Workshop Validation of Alternative/Rapid Microbiological Methods**
5 May 2020, Barcelona, Spain
☐ **European Microbiology Conference AND Workshop**
5-7 May 2020, Barcelona, Spain

☐ Mr ☐ Ms

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Company Department

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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 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week 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 HEIDELBERGwill 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 January 2012).

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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