EUROPEAN MICROBIOLOGY CONFERENCE

Live Online Conference on 5 - 6 May 2021

Speakers

Dr Eric Clement Arakel, Sartorius Lab Instruments | Dr Emmanuelle Charton, EDQM | Martin Coffey, USP/Microbiological Consulting, LLC | Tony Cundell, USP/Microbiological Consulting, LLC | Dr Jan Feuser, Boehringer Ingelheim | Dr Rainer Gallitzendörfer, Local Government of Upper Bavaria | Barbara Gerten, Merck | Jesper Hjorth, Novo Nordisk | Peter Huonker, Früh Verpackungstechnik Michaela Ann Kinney, Roche | Christian Lomb, Labor LS | Larissa Nkenmei-Pietsch, TentaMedix | Dr David Roesti, Novartis Dr Wolfgang Rudy, TentaMedix | Ioanna Venet, EDQM | Christine Weiß, Labor LS 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 would like to invite you to our European Microbiology Conference 2021. Last year we could not react so quickly to the COVID-19 pandemic and unfortunately had to cancel our conference in Barcelona. But we were able to hear some of the presentations later at virtual PharmaLab in autumn.

A face-to-face meeting is unfortunately still not feasible this spring, but in the meantime we are of course in a different position and are holding our spring conference on 05/06 May as a live online event.

This event offers you an excellent opportunity to learn about the latest developments and state of the art in science and technology in microbiological quality control. Pharmacopoeia experts, representatives of pharmaceutical quality control and contract laboratories will share their experiences with the regulatory requirements and their implementation in practice. Current developments in methodology and testing and implementation will be as much a topic as dealing with deviations and stumbling blocks. The aim is to provide pharmaceutical microbiologists with practical and applicable knowledge and „know-how".

In addition, the new chapter of the ECA Guideline for microbiological deviations will be presented to the participants in detail.
It would be a great pleasure for me if you would join us live online.

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

Overview

Highlights

- Pharmacopoeial Developments and GMP Expectations
- Burkolderia cepacia Complex – Regulatory Requirements and Methodology
- Monitoring and New Methods – from Comparison up to Validation
- Water Activity – USP and Laboratory Experiences
- Endotoxin- and Pyrogen Testing
- ECA - OOS/OOL Guide: New Chapter for Sterility Test Failures

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 ask questions in several Q & A Sessions throughout the conference.

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

- 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 ECA Pharmaceutical Microbiology Working Group

Axel H. Schroeder,
Administration Manager, Pharmaceutical Microbiology Working Group

Presentations

Implementation of European Pharmacopoeia methods: conventional methods versus alternative methods

Emmanuelle Charton, EDQM

- Conventional methods, "suitable" methods, "example" methods, "substitute" methods, "alternative" methods: how to find your own method of choice and how to implement it.
- How much flexibility is provided by Ph. Eur.?

Experiences with Burkolderia cepacia Complex

- Part 1 Laboratory Experience with existing Methods, Christian Lomb Labor LS
- Part 2 Specific Growth Media, Laurent Leblanc, bioMerieux
- Part 3 PCR, Tony Cundell, USP

Case Study - Comparison of Monitoring Systems

Peter Huonker, Früh Packaging Technology

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

Continuous microbial air monitoring for aseptic filling lines

Dr Eric Clement Arakel, Sartorius

- Continuous air sampling for 8 hours non-stop using the Gelatine-Membrane-Filtration according to Annex 1
- Presentation of a case study comparing the traditional impaction method with the filtration method with regard to microbial recovery

Water Activity Part 1 – USP <992>

Martin Coffey, USP Expert Volunteer

Water Activity Part2 - An important factor forrisk assessment

Christine Weiß, Labor LS

- Practical Experiences
- Application in the context of risk assessment

Experiences and Data from OWBA – Online Water Bioburden Analyser

Jesper Hjorth, Novo Nordisk

- Experience with different OWBA's on PW and WFI
- Comparison of online data from different water types
- Status on OWBA implementation in Novo Nordisk

VBmicro: a suitable lab device for bioburden determination of water and buffers in less than 1 hour

Dr Ulrich Zuber & Michaela Ann Kinney, Roche

- Feasibility studies
- Steps to implementation

Inspection of Micro Labs /Expectations of an Inspector on microbiological QC

Dr Rainer Gallitzendörfer, Local Government of Upper Bavaria

Performance Testing of Membrane Filters

Barbara Gerten, Merck

- The revised ISO 7704 – background and changes
- Batch testing by demonstrating the suitability in the whole system in combination with the specific culture medium
- Additional testing for new types of membrane filters or in case of problems

Microbial control in Downstream of biopharmaceutical manufacturing

Dr Jan Feuser, Boehringer Ingelheim

- General aspects of microbial control strategy
- Microbial weak spots in Downstream manufacturing
- Approaching a bioburden investigation
- Attributes of microbial assessments

Endotoxins versus pyrogen testing: how the European Pharmacopoeia texts can help

Ioana Venet, EDQM

- An overview of the sources of information on these aspects in the Ph. Eur.
- A presentation of the current requirements in the Ph. Eur. texts
- An update on the Ph. Eur. methods that can be used for the testing of pyrogens and/or endotoxins

Determination of Pyrogens: optimization of the MAT for Medical Device testing

Wolfgang Rudy & Larissa Nkenmei-Pietsch, TentaMedix GmbH

- 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

New Chapter of ECAs OOS/OOL Guide: Guidance for sterility test failures

Dr David Roesti, Novartis

- General Procedure
- Timelines
- Obvious laboratory failure prior to completion of the test 5
- Laboratory invstigation – fro, ID up Conclusion
- Level II Full scale investigation
- Batch disposition and health authority notification

Speakers at the Conference

Dr Eric Clement Arakel
Sartorius Lab Instruments
Product Manager

Dr Emmanuelle Charton
EDQM
Head of Division B

Martin Coffey
USP as an Expert Volunteer, Bausch + Lomb
Expert in pharmaceutical development

Tony Cundell
USP/Microbiological Consulting, LLC
Consulting Microbiologist

Dr Jan Feuser
Boehringer Ingelheim
Head Microbiology Lab Identification

Dr Rainer Gallitzendörfer
Local Government of Upper Bavaria
GMP Inspector

Barbara Gerten
Merck
Senior Scientist

Jesper Hjorth
Novo Nordisk
Clean Utility Professional

Peter Huonker
Früh Verpackungstechnik
Head of Quality Management

Michaela Ann Kinney
Roche
Quality Control Associate

Laurent Leblanc
bioMérieux
R&D manager for culture media solutions

Christian Lomb
Labor LS
Scientist - Department for Testing for Non Sterile Medicinal Products

Larissa Nkenmei-Pietsch
TentaMedix
Laboratory manager cell biology and in vitro toxicology

Dr David Roesti
Novartis
Technical Steward Microbiology, Manufacturing Science & Technology

Dr Wolfgang Rudy
TentaMedix
Chief Scientific Officer

Ioanna Venet
EDQM
Scientific Programme Manager

Christine Weiß
Labor LS
Head Laboratory Testing for Non Sterile Medicinal Products

Dr Ulrich Zuber
Hoffmann-La Roche
Head of environmental monitoring

Date of the Live Online Conference

Wednesday, 05 May 2021, 09.30 – 17.30 h
Thursday, 06 May 2021, 09.00 – 17.00 h
All times mentioned are CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate plus VAT)

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.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.microbiology-conference.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. 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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Reservation Form (Please complete in full)

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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 %.

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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).

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