EUROPEAN MICROBIOLOGY CONFERENCE

Live Online Conference on 3 - 5 May 2022

3 Tracks: Control of Cell- and Gene-Based Products/ATMPs, Current Trends in Endotoxin and Pyrogen Testing, Robotic Isolators

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

Background

In the current era, where conferences and seminars are mainly held online and virtually, new approaches and structures are needed to offer participants optimal value and expert input. Therefore, the ECA Academy has decided to offer the European Microbiology Conference 2022, which has been an integral part of the European conference landscape since 2008, in a special topic-focused format. During 2.5 days, 3 topics will be offered, which can be booked individually or in combination.

Microbiological Control of Cell- and Gene-Based Products/ATMPs | 03 May

Objectives

The number of cell-, tissue- or gene-based advanced therapy medicinal products (ATMPs) in research, development and production is steadily increasing. Due to the very different characteristics of the biological materials, the often small batches, the limited shelf life or the bio-safety requirements of the manufacturing environment, conventional control methods can often only be used to a limited extent. Alternative approaches for microbiological control, independent whether we are talking about sterility testing, endotoxin detection or others, are often necessary for such products.

The following conference will provide insight into how pharmacopoeias deal with this, the experiences and expectations of regulatory authorities and how microbiological control and testing strategies and methods are implemented in industry and laboratories. During the Q&A-session you will also have the opportunity to ask the speakers your individual questions.

Target Audience

This track provides information for all industry, authority or laboratory personnel involved in the microbiological control of cell and tissue products or gene therapeutics.

Highlights

- EP and USP - Pharmacopoeial Aspects
- Bacterial and Viral Safety
- Alternative Sterility Testing
- Control of mRNA Products

Moderators

Dr Sven M. Deutschmann, Roche, Chair of the ECA Pharmaceutical Microbiology Working Group & Axel Schroeder, Concept Heidelberg

Programme

Welcome and and Organisationals
Axel H. Schroeder, Concept Heidelberg

Introduction - Overview ATMPs -MTS / MTO-Products
Dr Sven M. Deutschmann, Head of gASAT "Adventitious Agents Testing & Alternative Microbiological Methods" Roche Diagnostics, Germany

E2E Perspective to the Identification of Pre-cQAs of GT products
Dr Roland Pach, Global Analytical Expert CGT & External Collaborations, F. Hoffman – La Roche, Switzerland

European Pharmacopoeia Perspective
Solène Le Maux, Scientific programme manager - European Directorate for the Quality of Medicines & Healthcare (EDQM) chez Conseil de l'Europe, France

Introduction to the new USP Chapter on Microbial Control Strategies for Cell and Gene Therapy Products
Dr David Rösti, Global Subject Matter Expert, Novartis Switzerland

Bacterial Safety of ATMP
Dr Oleg Krut, Head section Microbiological Safety, Paul-Ehrlich-Institut, Federal institute for Vaccines and Biomedicines

An Alternative Sterility Testing Approach
Joseph Pierquin, Chief Technical Officer, RedBerry, France

Viral Safety Concepts for ATMPs
Dr Johannes Blümel, Head of Virus Safety Section, Paul-Ehrlich-Institut, Federal institute for Vaccines and Biomedicines

Contamination Control of Therapeutic Virus Production
Dr Michael Ruffing, SME Adventitious Agents Biologicals, Boehringer Ingelheim

Microbial Control Strategy for Autogene Cevumeran a cell-free, individualized, mRNA based ATMP
Friedrich von Wintzingerode, PhD, Microbiology and QC Lead Individualized Therapies

Aseptic Process Validation in the Cocoon® Platform
Laura Sands, Head of Regulatory Affairs Personalized Medicine, Lonza

Current Trends in Endotoxin and Pyrogen Testing | 04 May

Objectives

For several years now, the field of endotoxin and pyrogen testing has been subject to a high pressure of change. Especially in Europe, also as a consequence of the 3R strategy of the European Union, alternative test methods have found their way into pharmacopoeias. The comparison of existing methods and alternative test methods, the experiences with pitfalls and possibilities but also limitations still leads to a lively discussion.

Learn about the latest trends and developments in this conference. International experts from industry and laboratories as well as representatives from EDQM will report on current requirements, implementation in practice, establishment of new methods and where these can also be a challenge.

Target Audience

This track provides information for all industry, authority or laboratory personnel involved in endotoxin and Pyrogen testing and implementation of detection methods.

Highlights

- Pharmacopoeial Background
- Endotoxin Removal
- Detecion in Novel Products
- Assessing Performance with Real Contamination
- Analyzing Endotoxin in Complex Samples
- MAT Experiences

Moderators

Dr Johannes Reich, Managing Director, Microcoat, Member of The ECA Pharmaceutical Microbiology Working Group Advisory Board & Axel Schroeder, Concept Heidelberg

Programme

Welcome and Organisationals
Axel H. Schroeder, Concept Heidelberg & Johannes Reich, Microcoat

European Pharmacopoeial Requirements and Perspectives
Emmanuelle Charton, Head of Division B, European Pharmacopoeia Department, EDQM, Council of Europe

The impact of endotoxin masking on the removal of endotoxin during manufacturing of a biopharmaceutical drug product
Jessica Stolzenberger, Head of Laboratory, Late Stage DSP Development, Boehringer Ingelheim

Challenges of endotoxin detection during development of a novel VLP
Callum Scott, Technical Transfer and Formulations Development Manager, Allergy Therapeutics UK

Validation of the Monocyte Activation Test for GMP Release Testing
Jonas Van den Berg, Global Quality Manager Roche Diagnostics, Germany

Examples for a Potential Global Endotoxin and Pyrogen Test Strategy
Christoph Hansy, Global Microbiology Management, Takeda, Austria

Experience with the Shelf Life/Stability of the Control Standard Endotoxin (KSE)
Patrick Koch, Senior Scientist Microbiological Quality Control, ThermoFisher, Switzerland

Analyzing Endotoxin in Complex Samples
Luisa Burgmaier, PhD Student, University of Tübingen, Clinic of Thoracic, Cardiac and Vascular Surgery, Clinical Research Laboratory, Tübingen, Germany

Nanoparticles and Test Interference in BET
Speaker to be announced

Importance of Formulation when Assessing Performance with Real Contamination
Alan Hoffmeister, Charles River Laboratories, Senior Global Technology and Market Development Manager, UK

rFC Implementation Strategy and Endotoxin Technology Roadmap in Sanofi Pasteur
Thierry Bonnevay, Global Microbiology Analytical Expert, Sanofi Pasteur

Robotic Isolators – Challenges and Modern Monitoring Systems | 05 May

Objectives

Aseptic production has always been complex and cost-intensive and the risk of contamination high. To minimise the risks, the techniques used have become increasingly sophisticated, from simple cleanrooms, sterile workbenches and RABS to the classic isloators. With the new possibilities of automation, digitalisation and rapid microbiological methods, there are currently even more opportunities to minimise contamination risks and optimise processes. This also, or especially, plays a role in the production of novel therapies with biological starting materials, which often have small batch sizes.

One possible method is the use of modern isolators, without gloves, automated and in combination with modern real time or online monitoring systems. However, when establishing such systems, the user is faced with the challenge that the currently valid regulatory requirements were often oriented towards the previous systems and are difficult to apply across the board for modern systems, either because given limits were derived from the less sensitive systems or because comparability of the results is difficult or impossible to achieve due to the different methodologies.

This workshop will provide an insight into the view of a GMP inspector, an introduction to available techniques and systems, as well as industry experience in implementation and the hurdles that may be encountered in regulatory acceptance.

Target Audience

This track provides information for all industry, authority or laboratory personnel involved in the qualification of isolator systems and the implementation of modern monitoring systems

Highlights

- Technical Principles of Robotic/Gloveless Isolators
- Challenges of Modern Monitoring
- Implementation Experiences
- Inspectors Point of View
- Perspective and Experience of Recent Inspections

Moderators

Dr. Wolfang Eder, Roche Diagnostics, & Axel Schroeder, Concept Heidelberg

Programme

Technical Principles and Challenges

Short Presentations about Robotic Isolator Systems

- Functional principle and background
  Christian Siegmund, Network Technical Implementation Lead for Modular Gloveless Isolator Filler F. Hoffmann-La Roche, Switzerland
- Challenges in Aseptic Filling
  Thomas Thurn, Director Drug Product Clinical Supply Chain Cilag, Switzerland
- Robotic Fill & Finish
  Ute Schleyer, Project Manager Site and Plant Development, Vetter, Germany

Challenges and Hurdles – Modern Monitoring in Isolators and Implementation Experiences with Authorities

Short Presentations on current Experiences

- Monitoring for Viables in Closed Robotic Isolators
  Winnie Madsen, Isolator filler specialist, Novo Nordisk, Denmark
- Health Authority Expectations Regarding Gloveless Isolator Implementation
  Kevin Gadient, Senior Director Manufacturing Operations, Emergent, USA
- Process Controls for Gloveless Isolator Systems
  Hoang Phan, Network Technology Lead Genentech, USA
- Challenges and requirements during introduction of a continuous monitoring system for viable particles in a new robotic filling line
  Ruth Barensteiner, Principal Scientist Compliance, Cilag, Switzerland

Personal View and Expectations of a GMP Inspector

Dr Daniel Müller, GMP Inspector Local Government of Baden Württemberg, Germany

CMO Perspective and Experience of Recent Inspections

Youwen Pan, WuXi Biologics, China

Panel Discussions and Q&A with Speakers and Experts

Date of the Live Online Conference

Tuesday, 03 May 2022, 09.00 - 17.30 h
Wednesday, 04 May 2022, 09.00 - 17.30 h
Thursday, 05 May 2022, 13.30 - 17.30 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)

1 Day Ticket
ECA Members EUR 890.- | APIC Members EUR 940.-
Non-ECA Members EUR 990.- | EU GMP Inspectorates EUR 495.-

2 Days Ticket
ECA Members EUR 1590.- | APIC Members EUR 1690.-
Non-ECA Members EUR 1790.- | EU GMP Inspectorates EUR 895.-

Half Day Ticket (Day 3)
ECA Members EUR 640.- | APIC Members EUR 665.-
Non-ECA Members EUR 690.- | EU GMP Inspectorates EUR 345.-

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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For questions regarding organisation:
Nicole Bach (Organisation Manager) at +49(0)62 21/84 44 22 or at bach@concept-heidelberg.de.

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Reservation Form (Please complete in full)

European Microbiology Conference
Live Online Conference on 03-05 May 2022

- ☐ **Day 1 (03 May 2022): Microbiological Control of Cell- and Gene-Based Products/ATMPs**
- ☐ **Day 2 (04 May 2022): Endotoxin and Pyrogen Testing – Current Trends**
- ☐ **Day 3 (05 May 2022, Half Day): Robotic Isolators – Challenges and Modern Monitoring Systems**

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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 %.

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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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