ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers


Jonas van den Berg
Roche


Dr Thierry Bonnevay
Sanofi Pasteur


Luisa Burgmaier
University of Tübingen


Emmanuelle Charton
EDQM


Christoph Hansy
Takeda


Alan Hoffmeister
Charles River Laboratories


Patrick Koch
ThermoFisher


Dr Callum Scott
Allergy Therapeutics


Jessica Stolzenberger
Boehringer Ingelheim

Current Trends in Endotoxin and Pyrogen Testing

A Part of the European Microbiology Conference 2022

Live Online Training on 04 May 2022

Highlights

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

Complete Conference (03-05 May 2022) 3 Tracks: Control of Cell- and Gene-Based Products/ATMP, Trend in Endotoxin and Pyrogen Testing, Robotic Isolators

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.

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.

Target Audience

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

Moderators

Dr Johannes Reich
Managing Director, Microcoat, Member of The ECA Pharmaceutical Microbiology Working Group Advisory Board

Axel Schroeder
Concept Heidelberg

Programme

Welcome and and Organisationals
Axel H. Schroeder

European Pharmacopoeial Requirements and Perspectives
Dr Emmanuelle Charton, EDQM, Council of Europe

- Bacterial Endotoxin test using recombinant Factor C: latest news
- Recent revision of general chapter 2.6.30 Monocyte Activation Test
- Towards an Animal-free Pyrogenicity testing strategy

The impact of endotoxin masking on the removal of endotoxin during manufacturing of a biopharmaceutical drug product
Jessica Stolzenberger, Boehringer Ingelheim

- Low endotoxin recovery
- Endotoxin removal
- Downstream processing
- Endotoxin, Lipopolysaccharide

Challenges of endotoxin detection during development of a novel VLP
Callum Scott, Allergy Therapeutics

- Issues associated with the introduction of a MAT during the pre-clinical phase of development
- Use of a MAT to release batches of Drug Substance & Drug Product

Validation of the Monocyte Activation Test for GMP Release Testing
Jonas van den Berg, Roche

- Considerations for method development
- MAT validation strategy
- Results for generic validation and product-specific validation of the MAT

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

- Main Challenges related to BET and Pyrogen Testing
- Benefits from a Global Testing Strategy
- Examples

Experience with the shelf life/stability of the control standard endotoxin (KSE)
Patrick Koch, ThermoFisher

- What are control standards
- Stability study
- Results and conclusion

Analyzing endotoxin in complex samples
Luisa Burgmaier, University of Tübingen

- Blood plasma as a challenging sample matrix
- Complex contamination of samples
- Comparison of methods for analyzing samples

Nanoparticles and test interference in BET [complex sample matrix]
Speaker to be announced

Importance of formulation when assessing performance with real contamination
Alan Hoffmeister, Charles River Laboratories

- How formulation effects recovery
- Factors to consider
- Critical elements or convenience?

rFC implementation strategy and Endotoxin technology roadmap in Sanofi Pasteur
Thierry Bonnevay, Sanofi Pasteur

- Evolution of pharmacopoeias and regulation around endotoxins testing and rFC assays
- Presentation of different solutions and data comparing different LAL based assays and rFC assays on different matrices
- Strategy for middle and long term implementation of rFC inside Sanofi

Speakers

Jonas van den Berg
Roche

Jonas has a background in life sciences and holds a PhD from the University of Groningen. In his role as Quality Manager within Global Quality Control he is involved in the implementation of new QC technologies. He is the project lead for the implementation of the Monocyte Activation Test, as well as other rapid microbiological methods at Roche.

Dr Thierry Bonnevay
Sanofi Pasteur

Thierry holds a PhD from Université Claude Bernard Lyon 1. 1998 he started in analytical bacteriology at Marcx L'Etoile. After differnt positions in bacteriology he is today Microbiology Platform Head and Global Microbiology Analytical Expert.

Luisa Burgmaier
University of Tübingen

Luise holds an M.Sc. in Biotechnology from University of Applied Sciences Weihenstephan-Triesdorf, Freising, Germany. Currently she is PhD student at the University of Tübingen in an cooperation with Microcoat Biotechnolgie in Bernried, working on Endotoxin Analytics.

Emmanuelle Charton
European Directorate for the Quality of Medicines and HealthCare (EDQM)

Emmanuelle CHARTON holds a PhD in biochemistry from the Institut National Agronomique de Paris-Grignon. Since 2006 she is Head of Division B in the European Pharmacopoeia department at the EDQM. Her work experience includes QA/QC in a facility for the production of parenteral products and preparation to GMP inspections in a global pharmaceutical company, research and development in biochemistry in a global company selling food and chemicals. She has over 27 years' experience at the EDQM, including as scientific administrator to the groups of experts in the fields of biology and microbiology and as a supervisor to the corresponding work in the EDQM laboratory.

Christoph Hansy
Takeda

Christoph Hansy is currently member of the Global Microbiology Management Team at Takeda, Vienna, Austria. In his current postion, he provides expertise and technical leadership in microbiological matters. He has experience with BET and Rabbit Pyrogen Testing. In his current global role, he addresses the changing perspective on the strategic component of endotoxin and pyrogen testing. Evaluation of improvement opportunities for the BET facility is one of his core tasks.

Alan Hoffmeister
Charles River Laboratories

Alan's experience with the Bacterial Endotoxins Test (BET) dates to 1988, since when he has been actively involved in all aspects of the assay. Alan is experienced in BET topics including, amongst others, LAL Methodologies, Product Validations, Interference Matrices, Data Integrity and BET Regulatory Affairs. He has also contributed to the development of BET protocols, technical guides and fact sheets internally as well as for clients and industry organisations.

Patrick Koch
ThermoFisher

Patrick completed his training as a biology laboratory technician in microbiology and pharmacology at the Sandoz-Wander SBSW school for biology laboratory technicians in Bern. He is also He is also an industrial technician in pharmaceutical production and a trainer for biology laboratory technicians. Since 1995 he has been working in QC in laboratories of the pharmaceutical industry such as Novartis and CSL in various functions.

Dr Callum Scott
Allergy Therapeutics

Callum holds a PhD in Molecular Microbiology from Heriot-Watt University. Following a Post-Doctoral Research Fellowship with the University of Aberdeen, and after two years as a lecturer in Applied Science, he became a Development Manager for vaccine development within Benchmark Animal Health. Since 2020, Callum has been a Technical Transfer and Formulations Development Manager with Allergy Therapeutics (UK) Ltd.

Jessica Stolzenberger
Boehringer Ingelheim

Jessica studied at the University of Applied Sciences in Furtwangen. 2004 she startet at Boehringer as Technical Assistant, Process Science Biberach. Since 2016 she is Head of Late Stage DSD III Late Stage DSP Development.

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GERMANY

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**

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

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General terms and conditions
If you cannot attend the conference you have two options:
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2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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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).
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.

Date of the Live Online Training

Wednesday, 04 May 2022, 09.00 h - 17.30 h 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 email 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 Day 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 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.gmp-compliance.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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