Live Online Conference on 25-26 November 2021

Endotoxin and Pyrogen Testing

From Routine Testing to Alternative Methodology

Picture: Charles River Laboratories

This Live Online Conference is part of PharmaLab 21 LIVE ONLINE
Analytics•Bioanalytics•Microbiology
22-26 November 2021

Highlights

- Pharmacopoeial Strategies
- Inspection Experiences
- rFC – Alternative Testing
- Automation and High Speed Testing
- MAT Experiences

Speakers

Dr Reyes Candau-Chacon, **FDA**
Dr Emmanuelle Charton, **EDQM**
Dr Viviane Grunert da Fonseca, **Roche**
Carmen Marin Delgado de Robles, **Roche**
Anne-Claire Erba, **Merck**
Dr Rainer Gallitzendörfer, **Government of Upper Bavaria**
Dr Eelo Gitz, **Sanquin**
Dr Stefan Haberstock, **Tecan**
Dr Michael Kracklauer, **Microcoat Biotechnologie**
Prof. Dr. Nico Lachmann, **Medical University Hannover**
Ruth Noe, **Lonza**
Arnaud Paris, **bioMérieux**
Sophia Pfeiffer, **Boehringer Ingelheim**
Nicola Reid, **CRL**
Dr Shahjahan Shaid, **GSK Vaccines**
Shabnam Solati, **CTL-MAT**
Dr Ingo Spreitzer, **PEI**
Dr Sandra Stoppelkamp, **University Tübingen**
David Wadsworth, **Suez**
Veronika Wills, **ACC**

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Endotoxin and Pyrogen Testing

25 November 2021, 09.00 - 17.30 h CET
26 November 2021, 09.00 - 13.30 h CET

Objectives

This Live Online Conference will inform you about current developments in Endotoxin and Pyrogen testing as well as the practical use of established test methods like LAL for Endotoxin testing including:

- International regulatory developments
- Feasibility of new and innovative products and methods
- Special issues like masking/LER
- Testing of critical substances
- Application of alternative testing methods – MAT or RFC

Background

Testing for Endotoxins and Pyrogens is a critical in-process and final release test for parenteral products. Different approaches have been developed over the last few decades to provide solutions for the breadth of product range that is tested for endotoxins and pyrogens: RPT, LAL, MAT. With the LAL test method as the established, compendial methodology for bacterial endotoxins with harmonization of the EP, USP and JP. Due to the importance of these tests, they are under ongoing scrutiny by industry and regulators to ensure testing efficacy and safe manufacturing and release of products into the market.
Novel medicinal products such as cellular and gene therapies and combinations with medical devices as well as complex biopharma formulations pose testing challenges and require in-depth knowledge and expertise in the field of Endotoxins and Pyrogens. In addition, as the choice of solutions offered by suppliers for endotoxin testing becomes wider (e.g. recombinant factor C, ELISA-based test kits, automated LAL cartridge technology) it is important to get a data driven understanding of the advantages and limitations of each approach.
So not only the discussions on low endotoxin recovery and endotoxin masking are important. Additionally the need for future innovations within BET that provide solutions to current challenges with modern pharmaceutical and biopharmaceutical products for the day-to-day testing should be in our focus.
Enough reasons to attend this Endotoxin and Pyrogen Session at PharmaLab 2021.

Target Group

This Live Online Conference is addressed to all persons from

- Pharmaceutical manufacturers
- Biopharmaceutical companies
- Contract laboratories
- Tissue establishments
- Authorities who are involved in Endotoxin- and Pyrogen Testing.

Programme Day 1 - 25 November 2021

Towards an Animal-free Pyrogenicity Testing Strategy in the European Pharmacopoeia

- Strategy for the removal of the test for Pyrogens from 59 texts of the Ph. Eur.
- The new general chapter 5.1.13 Pyrogenicity
- Incentive to develop and implement a monocyte activation test as a replacement of the rabbit pyrogens test
- Challenges ahead

Dr Emmanuelle Charton, EDQM

Inspection Experiences

Dr Rainer Gallitzendörfer, GMP Inpector, Government of Upper Bavaria

Regulatory Perspectives in Europe, USA and Japan on the Validation and Industrial Implementation of the rFC Method

- Review the different status in Ph. Eur., USP and JP on the adoption of rFC specific chapters as a compendial method
- What does "validation" mean for the rFC method vs LAL method with the interpretation of the Ph. Eur 2.6.32 chapter
- FDA vs USP perspective in the US for rFC adoption
- Real pharmaceutical industry case of an industry adoption of the rFC method according to the Ph. Eur 2.6.32 chapter

Arnaud Paris, bioMérieux

Sustainability in Bacterial Endotoxin Testing – A Holistic Approach

- Overview of most current findings on the equivalency of recombinant reagents as collected within a large-scale comparability study of end products
- Statistical evaluation of the obtained data as well as results of suitability testing on a wide range of product categories
- Determination whether recombinant reagents may be used in addition to LAL reagents for testing of products in order to assure their safety and purity

Veronika Wills, ACC

The Journey of LER

- Regulatory requirements in case of LER
- Comparison of BET methods in a LER product
- Development and validation of an dedicated sample preparation
- Automation of the sample preparation protocol

Dr Michael Kracklauer, Microcoat

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FDA Perspective on Pyrogen Detection Systems

- Compendial and alternative pyrogen detection test. Method limitations
- FDA position on the use of non-compendial pyrogen detection test
- Recombinant Factor C: case studies
- Monocyte Activation Test: case studies

Dr Reyes Candau-Chacon, FDA

Horseshoe Crab Conservation and Reducing LAL in Testing

- The status of the Atlantic Horseshoe Crabs
- What is affecting their population
- What methods may be used for Bacterial Endotoxin Testing that can reduce the need for this valuable resource

Nicola Reid, Charels River Laboratories

Fully Automated, High Speed & High Throughput Endotoxin Testing with the Fluent Gx and rFC

- Latest generation liquid handling technology for a completely compliant endotoxin quantification and detection
- 100% Fully Automated with no need for manual standard preparations with animal free recombinant Factor C assays
- High Throughput endpoint detection
- Barcode scanning and FluentControl Gx functionality allow full sample and process traceability and data integrity for regulated needs
- Introspect software and Connect App give full overview on instrument performance and allow status monitoring from remote via mobile phone

Dr Stefan Haberstock, Tecan

Centripetal Microfluidic Automation for Optimized Endotoxin Testing

- Brief (5 min) overview of centripetal microfluidics - what is it and how does it work?
- Validation needs for a microfluidic system/platform
- Analytical method suitability optimisation via centripetal microfluidics
- How to automate and optimise endotoxin assay setup with centripetal microfluidics

David Wadsworth, Suez

Error-Proofing and Futureproofing: Part Deux

- Use of robotics to perform routine endotoxin detection assays in a high throughput pharmaceutical Quality Control Laboratory improves compliance by increasing the right first time testing rate
- Significant savings in resources may also be found when using a larger volume recombinant liquid reagent, instead of reconstituting multiple lyophilized vials of classical LAL reagents.
- We compare manual and automated assay setup and performance of both a kinetic LAL assay and a recombinant Factor C assay
- The savings and enhanced accuracy are demonstrated for both validation testing and routine use of a recombinant endotoxin detection assay coupled with robotics

Ruth Noe, Lonza

Scalable Generation of Fully Defined Monocyte/Macrophages from Human iPSC to Assess Pyrogens in Parenteral drugs and Medical Products

- Human Induced pluripotent stem cells (iPSC) can be generated from every donor, have unlimited self-renewal potential and can be differentiated towards immune cells
- Fully defined iPSC-derived macrophages (iMono/Mac) can be produced continuously in scalable numbers using bioreactors
- iMono/Mac share hallmarks with in vivo counterparts and are generated by standardized conditions
- iMono/Mac display superior sensitivity to pyrogen stimulation with a broad dynamic range compared to other cell sources used so far within the MAT.

Prof. Dr. Nico Lachmann, Medical University Hannover

Programme Day 2 - 26 November 2021

The Monocyte Activation Test (MAT) Can Predict Reactions to Medical Devices in Contact with Blood

- Material-induced inflammation
- In vitro / in vivo
- Patient safety

Dr Sandra Stoppelkamp, University Tübingen

Waive and Replace the Rabbit Pyrogen Test in Lifecycle Vaccine Release

- Rabbit pyrogen tests are still mentioned as requires test in the European Pharmacopeia for several Vaccines
- The European and International regulatory landscape is changing and allowing the use of alternatives
- Several alternatives are present as LAL/TAL/rFC and MAT
- In certain cases the consistency approach allows to waive the assay instead of a replacement
- A decision tree with examples will be shown for the 3 stated options

Dr Shahjahan Shaid, GSK Vaccines

Method Validation Strategy for Endotoxin Testing of Water Samples with Recombinant Factor C in Adherence to 3R Principle for Animal Welfare

- To avoid animal testing and contribute to sustainability initiatives, recombinant factor C (rFC) was evaluated for endotoxin testing in monoclonal antibody and water sample matrices. Comparative testing with both the LAL and rFC assay demonstrated suitable endotoxin detection and support implementation of rFC as an endotoxin test method
- The method validation strategy provides an overview and experimental study design justification according to the guidance in USP <1225> and Ph. Eur. 2.6.32. Overview of the method validation strategy will include evaluation of the following parameters: inhibition and enhancement, accuracy, precision, specificity, linearity, range and limit of quantitation, robustness, method suitability, and comparability.
- The benefit of this presentation is to share method validation strategy for rFC for endotoxin testing in accordance with EU and US regulatory requirements. The benefit includes discussion on which aspects of method validation parameters should be evaluated by sample testing or by scientific literature rationale

Carmen Marín Delgado de Robles, Roche Diagnostics
Dr Viviane Grunert da Fonseca, Roche Diagnostics

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From Cell Preparation to ELISA Execution: Key Aspects for a Successful Implementation of the MAT

- Cryoprotectants - to wash or not to wash?
- FBS vs human AB serum as source of serum: What to use when?
- Highest sensitivity or being able to measure pyrogenic contaminations around the CLC: Fine-tuning the ELISA dilution
- Expression of the LOD, MVD and pyrogen concentrations: Let's standardiz

Dr Eelo Gitz, Sanquin

MAT - Identifying Innate Immune Response Modulating Impurities

Sophia Pfeiffer, Boehringer Ingelheim

Feasibility of the Monocyte Activation Test for Cell-Based Samples

- Evaluation of the feasibility of Monocyte Activation Test for cell-based samples
- Relevance of testing cell-based samples
- Several types of cell-based products evaluated, including cells in suspension and adherent cells
- Hints for sample preparation in case of challenging assay

Anne-Clair Erba, Merck

Monocyte Activation Test: Understanding and Mitigating Patient Safety Risks Arising from the Synergistic Effects of Mixed Pyrogens

- Presenting the MAT as an in-vitro, human-specific, sensitive and reproducible pyrogen test
- Explaining its recent traction — that is, due to EP's mandate to use MAT as NEP risk assessment for BET or replacement of RPT as stand-alone release assay
- Detailing what synergistic effects of mixed pyrogens are, their serious risks to patient safety, and MAT's unique efficacy in their detection and quantification

Shabnam Solati, CTL-MAT

Next-generation Monocyte Activation Test: Increasing Accuracy/Reliability for High Throughput Sample Testing

- MAT automation systems can help to increase accuracy/robustness/reliability, and improve sample throughput in the laboratory
- The strength of the MAT is the biological reaction to NEPs. How can we optimize the MAT assay layout to focus more on NEP detection?
- Single donors batches vs. pooled donor batches: Donor variation, friend or foe

Dr Koen Marijt, MAT-Research

Speakers

Dr Reyes Candau-Chacon, FDA, USA
Reyes Candau-Chacon, PhD is a microbiologist in Branch 2 of the Division of Biotechnology Manufactruing (DBM), Office of Pharmaceutical Quality, CDER). DBM evaluates the microbial quality and sterility assurance as well as the facility compliance status of biological license applications. This is conducted in a comprehensive manner and includes reviewing the microbiology aspects of the BLA as well as inspecting the manufacturing facilities. In addition, the division participates in writing guidelines, policies, and procedures.

Dr Emmanuelle Charton, COUNCIL OF EUROPE - EDQM & Healthcare, France
Deputy Head European Pharmacopoeia Department. Head of Division B in the European Pharmacopoeia department at EDQM. The Scientific Secretariat for the elaboration of European Pharmacopoeia texts related to microbiology fall under the responsibility of her division.

Carmen Marin Delgado de Robles, Roche Diagnostics, Germany
QC Scientist Endotoxins. Passionate about new technologies that have a positive impact. Diversity and Inclusion Ambassador.

Dr Viviane Grunert da Fonseca, Roche Diagnostics, Germany
Statistical support to the nonclinical areas of chemistry, manufacturing, and controls (CMC).

Anne-Claire Erba, Merck, France
Senior R&D Scientist. Worked in R&D and QC laboratories on cellular and virology tests development and application. Also worked in viral vector bioproduction manufacturing.

Dr Rainer Gallitzendörfer, Government of Upper Bavaria, Germany
GMP Inspector. Pharmacist specialising in pharmaceutical analysis and a state-certified food chemist. Appointed by the German Accreditation Body (DAkkS) as an expert assessor for testing laboratories (DIN EN ISO/IEC 17025) in the sector committee "Health Consumer Protection" and in the subject area "Medicinal Products, Active Pharmaceutical Ingredients and Pharmacies".

Dr Eelo Gitz, Sanquin Reagents, The Netherlands
Head Product Development. During the last 6 years, he has been working on the development and production of Monocyte Activation Test (MAT) kits based on cryopreserved peripheral blood mononuclear cells (PBMC) and setting up an MAT Center of expertise at Sanquin.

Dr Stefan Haberstock, Tecan, Germany
Senior Market Manager Detection & Liquid Handling EMEA. Works as Marketing Manager for Tecan's EU sales organization with focus on liquid handling and detection automation.

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Dr Michael Kracklauer, Microcoat Biotechnologie, Germany
Project Leader Endotoxin Services.
Michael studied in Munich and Aachen. After 3 years as research associate in Munich, he joined Microcoat in 2018 as Project Leader Endotoxin Services.

Prof. Dr. Nico Lachmann, Medical University Hannover, Germany
Group leader at the "REBIRTH Research center for translational and regenerative medicine". The group of Nico Lachmann combines basic knowledge in hematology with translational approaches using immune cells to develop new cell-based therapies. Associate (W2) Professor, RESIST Cluster of Excellence, Hannover Medical School.

Dr Koen Marijt, MAT Research, The Netherlands
Lead Scientist & Co-founder of MAT research. Experienced fundamental scientist with a demonstrated history of working in the hospital & health care and biotechnology industry. Skilled in Cancer Research, T cell biology, tumor antigen discovery and monocyte activation testing (MAT).

Ruth Noe, Lonza Bioscience, UK
Senior Product Manager. Has worked supporting Bacterial Endotoxin testing products in sales, support, and SME roles and more recently as Senior Product Manager for Automation and Software solutions at Lonza BioScience.

Arnaud Paris, bioMérieux, France
Director of Scientific Affairs. Arnaud has an extensive knowledge of all the quality control of Biotechnology drugs and Cell & Gene Therapies (ATMPs).

Sophia Pfeiffer, Boehringer Ingelheim, Germany
Expert for Rapid Microbiological Methods and Endotoxin testing.

Nicola Reid, Charles River Laboratories, UK
Associate Director of Endotoxin Products. Over 20 years of experience with bacterial endotoxin testing and pharmaceutical microbiology. Involved in all aspects of the endotoxin assay.

Dr Shahjahan Shaid, GSK Vaccines, Germany
Program Manager Global QA. Expertise in in vivo and in vitro Quality release.

Shabnam Solati, CTL-MAT, The Netherlands
CEO.

Dr Ingo Spreitzer, Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines
Deputy Head of Section 1/3, "Microbial Safety and Parasitology". Duties: Pyrogen testing (rabbit and alternatives); LAL-Testing. Chair EDQM Working Party "Bacterial Endotoxin Test.

Dr Sandra Stoppelkamp, University Tübingen, Germany
Currently working in the field of haemocompatibility and pyrogen testing of medical devices at the University Hospital Tübingen and at the University of Applied Sciences Iserlohn. She has especially gained experience in using the MAT with diverse variants in clinical settings and on medical devices.

David Wadsworth, Suez Water Technologies & Solutions, Analytical Instruments, USA
Product Management. Focusing exclusively on endotoxin and bioburden technology to address customer needs and problems.

Veronika Wills, Associates of Cape Cod, USA
SME on Endotoxin. Focus on Endotoxin Testing.

Easy Registration

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Date of the Live Online Conference

Thursday, 25 November 2021, 09.00 – 17.30 h CET
Friday, 26 November 2021, 09.00 – 13.30 h CET

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- ❑ 22 November: Optimisation and Automation
- ❑ 23 November: Validation of Analytical Methods and Life Cycle Management of Analytical Procedure
- ❑ 24 November: Alternative- and Rapid Microbiological Methods
- ❑ 25 November: Endotoxin and Pyrogen Testing (Day 1)
- ❑ 26 November: Endotoxin and Pyrogen Testing (Day 2)

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