PharmaLab

Analytics ▪ Bioanalytics ▪ Microbiology

Part of 12th PharmaLab Conference

- 5th International Mycoplasma qPCR Testing User Day - PharmaLab Pre-Conference Event
- Endotoxin and Pyrogen Testing
- Alternative and Rapid Microbiological Methods

Düsseldorf/Neuss, Germany
25 - 27 November 2024

Highlights

- Pharmacopoeial News in Microbiology
- Modern Alternative Systems and Methods – Rapid, Online, Real Time
- Regulatory Expectations
- Automation in Microbiology
- Recombinant Testing – Current Developments
- Modern Pharmacopoeial and Alternative Endotoxin / Pyrogen Testing from MAT to rFC to Lobster
- Mycoplasma – State of the Art Detection

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Objectives PharmaLab

2022 and 2023, the first two years after the pandemic, PharmaLab has attracted more participants to Düsseldorf/Neuss than ever before. With this success as a template, the 12th PharmaLab Congress will again be held on site in Düsseldorf/Neuss from 25-27 November 2024. The congress, which is aimed at employees and managers in all laboratory areas of the pharmaceutical industry, is composed of a pre-conference workshop, 7 international conferences from the fields of analytics, bioanalytics, microbiology and CGT/ATMP, as well as the accompanying exhibition. It will provide information on the latest developments in laboratory methods, systems, materials and the current status of regulatory requirements of pharmacopoeias and guidelines. In addition, experts from authorities, industrial quality control and contract laboratories will present their experiences with the use and qualification of analytical systems as well as with the validation of analytical methods and microbiological tests. Take advantage of this unique opportunity to learn about the state of the art in pharmaceutical laboratories and discuss current developments with speakers and colleagues.

Key Notes: 26/27 November

Congress Key Note

The Promise and Challenges of In Vitro and In Silico Models in Drug Development
Dr Julia Schüler, Charles River Laboratories
The presentation will highlight important developments in the drug development technology landscape influenced by the concept of 3R and the evolving legal landscape. General characteristics of the different applications, their translational relevance as well as adoption drivers will be discussed. Case studies from oncology drug development will help to elucidate these trends and their impact on future processes.

Trends & Challenges for the Development & Testing of Biotech Drug Products
Prof Dr Hanns-Christian Mahler, Chief Enablement Officer (CEO), ten23 health

The Organiser

CONCEPT HEIDELBERG – On behalf of the ECA Academy
P.O. Box 10 17 64, D-69007 Heidelberg
Phone +49 (0) 62 21/84 44-0 | Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.com

The Contacts:

For questions regarding content of this programme:
Axel H. Schroeder (Operations Director)
Phone: +49 (0) 6221/84 44 10,
E-Mail: schroeder@concept-heidelberg.de

For questions regarding reservation, hotel, organisation, exhibition etc.:
Ronny Strohwald (Organisation Manager)
Phone: +49 (0) 6221/84 44-51
E-mail: strohwald@concept-heidelberg.de

PharmaLab Exhibition

Parallel to the conferences, participants will have the opportunity to visit the accompanying trade exhibition. It offers comprehensive information about available products, services and the latest developments around the laboratory.

All details at: **www.pharmalab-congress.com/exhibitors-plan.html**

5th International Mycoplasma qPCR Testing User Day - PharmaLab Pre-Conference Event | 25 November 2024

Background & Objectives

Mycoplasma contamination of biopharmaceutical products (also known as biologics or large molecules) resulting from cell culture contamination in the manufacturing process poses a potential health risk to patients. Mycoplasmas can affect virtually every cell culture parameter with often only minor visible effects, creating an uncontrollable environment that is undesirable in the biopharmaceutical industry. Therefore, regulatory agencies require manufacturers to test their biopharmaceutical products and to ensure the absence of mycoplasmas in released products. Most regulatory agencies have issued guidelines that provide protocols for mycoplasma testing, and some give recommendations for the validation of rapid NAT (nucleic acid amplification techniques) testing methods. This satellite symposium will give you a scientifically sound introduction into the field of Rapid Mycoplasma testing with a specific focus on NAT and more specifically on qPCR methods. It includes talks, case studies as well as interactive round table discussions from users to users.

Target Audience

The Pre-Conference Workshop is directed to responsible personnel involved in Quality Control testing of biopharmaceuticals and biologics, e.g.:

- QC Managers
- Microbiologists, and Process Microbiologists
- Analytical Experts
- Biosafety and Pathogen Safety SME's
- Bioassay Developers
- Responsible Authority Employers

It is also useful for service providers, such as contract research organisations and contract manufacturers.

Moderation

Haidy Wafy, Roche

Programme

Update on the Revision of Ph. Eur. Texts Related to the Mycoplasma Project
Thuy Bourgeois, EDQM Strasbourg, France

Rapid Mycoplasma Testing
Dr Rudolf Zirwes, independent

- Methodology
- Pitfalls
- Experiences

Real-Time PCR-Based Mycoplasma Testing – Verification for the Intended Use: Data from a User
Dr Robert Hertel, Sartorius

- Matrix suitability testing – Protocol optimization to handle high cell backgrounds
- Validation data from User

RT-qPCR based Mycoplasma Detection from a Developer's Perspective
Caroline Paeschke, Minerva

- Opportunities and challenges of the updated revision of EP and USP from a developer´s perspective
- What needs to be considered with the new RT-PCR system with regard to additional RNA detection
- Comparison of the new RT-qPCR system with existing one
- CFU vs. GC Standards
- Exemplary validation data

Mycoplasma Testing of ATMPs: Current Regulations, Challenges and Trends
Rashid Idd Kihwelo, Shelys Pharmaceuticals

- Mycoplasma in Cell Cultures and ATMP Manufacturing
- Mycoplasma Testing Methods Overview
- Current Regulatory Requirements
- Validation and Implementation of qPCR for Mycoplasma Detection of ATMP

Sensitive and Rapid Testing for Mycoplasma Contamination Using Digital PCR
Dr Francesca Di Pasquale, QIAGEN

- Fast and easy mycoplasma detection workflow using dPCR
- Significantly enhanced sensitivity using RT-dPCR compared with dPCR mycoplasma testing
- The QIAcuity Mycoplasma Quant Kit workflow is validated to meet pharmacopeia requirements and is compatible with a variety of sample matrices
- Validation of dPCR-based mycoplasma testing using mycoplasma standards

Replacement of a DNA extraction system in a validated Rapid Mycoplasma Method
Susan Hoefs, MSD

5th International Mycoplasma qPCR Testing User Day - PharmaLab Pre-Conference Event | 25 November 2024

Ultra-rapid NAT-based Method for Mycoplasma Testing – Implementation, Validation and Transfer Strategy
Yasmin Heynen, Labor LS

- Application of an ultra-rapid NAT-based Method for Mycoplasma Testing: BIOFIRE® FILMARRAY® System
- Application of the method in compliance with regulatory chapters (e.g. Ph. Eur. 2.6.7 + Draft)
- Process steps for implementation, validation and transfer → also as a 3-party-process
- Case-Study: verification at Labor LS, matrix suitability tests

Mycoplasma Testing – Authorities Experiences and New Developments
Jan-Oliver Karo, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines

Scanning electron micrograph showing in graphical orange colorization liquid-culture grown typical pleomorphic and biofilm-forming cells of Mycoplasma pneumoniae type strain FHT (NCTC 10119, ATCC 15531, NBRC 14401).
© 2022 Prof Renate Rosengarten

Speakers

Thuy Bourgeois
EDQM Strasbourg, France
Scientific Programme Manager

Yasmin Heynen
Labor LS
Project Leader Molecular Biology

Jan-Oliver Karo
Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines
Quality Assessor. National expert advisor for the microbial safety of advanced therapy medicinal products (ATMPs). Member of the "Cell Therapy Products" Working Party of the German Pharmacopoeia Commission.

Dr Rudolf Zirwes
Selfemployed
Senior Scientist. GMP and molecular technologies freelancer.

Caroline Paeschke
Minerva Biolabs
Product Management

Dr Francesca Di Pasquale
QIAGEN
Director R&D

Rashid Idd Kihwelo
Shelys Pharmaceuticals
Executive QC Microbiologist

Dr Robert Hertel
Sartorius
Senior Scientist

Susan Hoefs
MSD
Specialist and Project leader in the Center of Expertise - Adventitious Viral Agents group

Alternative and Rapid Microbiological Methods
26/27 November 2024

Background & Objectives

Scientific progress in the field of cell and molecular biotechnology has led to the rapid development of biopharmaceuticals, tissue engineered applications and advanced therapy medicinal products. Against this background, the safety of these new technologies, products and applications is becoming increasingly important. An important issue in the context of risk assessment and safety is contamination with microorganisms and mycoplasmas and their detection, prevention and control using rapid and appropriate methods.

In the context of this conference, current developments in the relevant regulations and scientific methods will be presented and, in addition, experiences in the implementation and validation of alternative and rapid methods will be reported. It will cover applications for in-process control as well as those used in the context of product release. Examples of real-time or online monitoring will also be regularly covered.

This conference will provide an opportunity to discuss the latest advances in technology as well as practical aspects and concerns for meeting regulatory requirements. State-of-the-art presentations by competent speakers from the authorities as well as industrial and academic experts in the field of microbiological detection and identification will provide a comprehensive overview.

Target Audience

This conference is of interest to professionals from

- Biotechnological & Biopharmaceutical Companies
- Contract Service Laboratories
- Academic Research Institutions and Organizations
- Government Agencies
- Cell Culture Collections
- Supplier Detection Systems

with responsibilities in

- Manufacturing
- Quality Assurance
- Quality Control
- Regulatory Affairs
- Research & Development
- Process Development
- Validation

Moderation

Dr Michael Miller, Microbiology Consultants
Dr Ulrich Herber, Charles River Laboratories, Board Member of the ECA Pharmaceutical Microbiology Group

Programme

European Pharmacopeia Perspective
Dr Solène Le Maux, EDQM

- Exploring a certification system for the validation of alternative rapid microbiological methods
- Review of the general chapter 5.1.6. Alternative methods for control of microbiological quality currently under revision
- Updates on the revision of general chapter 5.1.9 Guidelines for using the test for sterility

Evaluation of the New Generation of Solid Phase Cytometry as a Very Rapid Microbial Test of Cell and Gene Therapy Products
Dr Kirsten Høstgaard-Jensen, Novo Nordisk

- Introduction to the necessity of a rapid microbial test of Cell and Gene Therapy Products
- Evaluation of the new generation solid phase cytometry platform
- Data and procedure for sample preparation for Cell and Gene Therapy products
- Current validation/development data of a new generation solid phase cytometry as a rapid microbial test of Cell and Therapy Products
- Evaluation of the new generation solid phase cytometry platform as a rapid microbial test for Cell and Gene Therapy products
- Conclusions

Rapid Sterility Testing by NAT Method Targeting RNA Instead of DNA
Yotaro Yamamoto, FUJIFILM Wako Pure Chemical

- Rapid sterility testing using RT-qPCR
- Multi-assay to detect RNA from bacteria and fungi
- Complete assay within approximately 5 hours
- Extraction and purification of RNA using magnetic particle method
- Includes a pretreatment step to remove and inactivate nucleic acids derived from dead organisms, reagents, and the environment

Proposal of the New Rapid Sterility Test for Regenerative Medicine Using qPCR
Akari Teramoto, Shimadzu Diagnostics

- Regenerative medicine products are characterized by short shelf life, so rapid testing is required
- We developed the PCR reagent to detect microbial nucleic acids with substantially reduced microbial background
- This PCR reagent provides highly sensitive, target-specific detection of a wide range of microorganisms, even in the presence of cells
- At this conference, we will present the results of our evaluation of test systems using PCR reagents we have developed

Alternative and Rapid Microbiological Methods
26/27 November 2024

Rapid Non-Destructive Growth-Based Microbial Testing for In-Process Bioburden of Continuous Manufacturing Lines
Philip Junker Andersen, Intubio and Dr Cedric Joossen, Janssen

- What is growth-based rapid microbial testing
- Why does it matter for continuous manufacturing of pharmaceuticals
- Why is it important for pharmaceutical microbiology to identify the contaminants
- What is the current status of rapid growth-based methods for GMP use

High Throughput Sequencing, a Rapid Method for Safety Analysis in Pharmaceutical Manufacturing
Dr Thomas Bovbjerg Rasmussen, Novo Nordisk

- We have developed an automated HTS method to test for presence of contaminating virus, bacteria and fungi in unprocessed bulk samples as well as Cell based ATMPs
- The method handles both cell free sample types as well as sample types with a high titer of e.g. mammalian cells
- Both the wet lab process and bioinformatic analysis pipeline are automated running in a hands-off fashion
- Data from development, robustness and validation will be presented as well as the bioinformatic pipeline

Assessing the Use of Solid-Phase Cytometry for Rapid Bioburden Testing
Sophie Drinkwater, AstraZeneca

- Introduction to Solid-Phase Cytometry and applications in pharmaceutical microbiology
- Summary of feasibility assessment and outcomes
- Application and suitability assessment of technology to current processes
- Outline of further work and challenges faced

How to Validate Non-CFU RMMs and Guidance on Setting New Acceptance Levels
Dr Michael Miller, Microbiology Consultants

- Discuss what a non-CFU signal is and why it may not be directly compared with the traditional CFU
- Guidance on how to validate non-CFU RMMs and show comparability with existing methods
- What statistical methods are appropriate
- How would you set new alert and action limits

Strategy for Accelerated Implementation of New Technologies (SAINT): Roche's Post-Approval Change Program for Control System-Updates of Biologics
Dr Christina Heinlein & Dr Sven Deutschmann, Roche

- Introduction - Technologies and Methods
- Description of Post Approval Change Program
- Challenges for Implementation

Digitalization of Environmental Monitoring in a New Facility
Alexandra Wagner and Martin Brandl, Daiichi Sankyo
Susan Cleary, Novatek

- System /Hardware installation and validation
  - Process mapping and process definition
  - Digitalized Facility PQ
  - System and hardware use
  - Trending and state of control / Handling of Out Of Specification Results

Microorganism Verification Testing of an Alternative Rapid Microbial Method
Meg Provenzano, Veolia

- Outline of testing according to USP <1223> and EP 2.6.12 and EP 2.6.13
- Data showing correlation to traditional plate counts with an alternative method
- 11 typical microorganisms (bacteria, yeast, and mold) were tested in conjunction with a mixed culture
- Demonstrate how to determine the LOD and LOQ when performing alternative method testing

Applications of Whole Genome Sequencing for Microbial Quality and Contamination Control
Dr Prasanna Khot, Charles River

- Overview of wet lab and bioinformatics workflows for microbial Whole Genome Sequencing
- Considerations to operationalize wet lab and bioinformatics workflows under a Quality System
- Examples of how Whole Genome Sequencing is used for microbial quality control (Strain Identity), contamination control (Strain Typing) and product risk assessment (Gene Detection)
- Potential and challenges of using Whole Genome Sequencing for detecting low bioburden microbial

Lessons Learned from Feasibility of MOLDS on Maldi-TOF, what to Consider for Validation and Implementation in Routine
Marie-Laurence Baille, MSD

- Feasibility on panel of 10 molds included impact on Maldi results by using different parameters
- Use of IDFP and TSA media
- Culture incubation time on maldi results
- Method EDT vs EX with and without MBT FAST Shuttle
- Impact of use of additional database like MSI
- Comparison against Microseq , ITS sequencing and Westerdijk identification

What are the Benefits of the Real Time Colony Counting in Microbial Analysis?
Dr Thomas Alexandre, Interscience

- ScanStation: a smart incubator
- 21 CFR PART 11 compliant software
- Application fields
- Data from the lab
  - Pharmacopeia pure strains analysis
  - Environmental monitoring
- Conclusion

Feasibility Study of the 3P Station, an Automated Environmental Monitoring System
Annalena Tegethoff, Novartis

- Functionality of the 3P Station
- Feasibility Study
  - Used Microorganism
  - Accuracy, Precision, Linearity
  - Hold Time
  - TTR
  - Results
- Potential use

Strategy to Handle Low Viable Particle Count in grade A Environment with an Advanced BFPC
Dr Svetlana Kiseleva, Plair

- The presentation will cover a study with newly released bio-fluorescent particle counter, which combines real-time detection with advanced laser technology and traditional active air sampling method
- This study covers a parallel phase study in controlled environment close to ISO5/Grade A, where real-time viable particle counts (AFU) and colony-forming units (CFU) are compared
- The objective of this presentation is to provide more understanding between the relationship of AFU generated by BFPC and CFU, in order to define the actions to be taken in response to alarms

Speakers

Meg Provenzano
Veolia
Global Product Manager - Biodetection

Sophie Drinkwater
AstraZeneca
Senior Scientist Pharmaceutical Microbiology

Philip Junker Andersen
IntuBio
Senior Technical Service Manager

Dr Solène Le Maux
EDQM, Strasbourg, France
Scientific Programme Manager

Dr Thomas Bovbjerg Rasmussen
NovoNordisk
Principal Scientist

Marie-Laurence Baille
MSD
Senior Microbiology Specialist

Dr Svetlana Kiseleva
Plair
Chief Product Officer

Dr Prasanna Khot
Charles River Laboratories
Director Biosciences R&D

Dr Thomas Alexandre
Interscience
Field Application Scientist

Annalena Tegethoff
Novartis
Senior AS&T Specialist

Dr Sven M. Deutschmann
Roche
"Analytical Science"-Chapter, Quality and Compliance for Roche Pharma Technical Operations

Dr Michael Miller
Microbiology Consultants
President

Dr Christina Heinlein
Roche
Pharma Technical Regulatory, Portfolio Lead for New Technologies & Innovation

Alexandra Wagner
Daiichi Sankyo
Director/Head of Microbiology and Monitoring

Martin Brandl
Daiichi Sankyo
Quality Control

Susan Cleary
Novatek
Director of Product Development

Yotaro Yamamoto
FUJIFILM Wako Pure Chemical
Researcher

Akari Teramoto
Shimadzu Diagnostics
Business Planning Department; Reagents development

Dr Kirsten Høstgaard-Jensen
Novo Nordisk
Senior Principal Scientist

Dr Cedric Joossenn
Janssen
Principal scientist – Microbiology expert

Endotoxin and Pyrogen Testing
26/27 November 2024

Background & Objectives

Testing for endotoxins and pyrogens is a critical in-process and final release test for parenteral products. Over the past decades, various approaches have been developed to provide solutions for the wide range of products tested for endotoxins and pyrogens: RPT, LAL, MAT. With the LAL test method as an established, compendial methodology for bacterial endotoxins, including the harmonisation of EP, USP and JP, there is a solid basis for such testing. But the range of products to be tested is becoming broader and more complex as biotechnological and molecular biological techniques advance. Because of the importance of these tests, they are therefore under constant scrutiny by industry and regulators to ensure the effectiveness of the tests and the safe manufacture and release of products onto the market. Novel medicines such as cell and gene therapies and combinations with medical devices, as well as complex biopharmaceutical formulations, pose challenges for testing and require in-depth knowledge and expertise in the field of endotoxins and pyrogens. Furthermore, as the range of solutions offered by endotoxin testing vendors increases (e.g. recombinant factor C, ELISA-based test kits, automated LAL cartridge technology), it is important to gain a data-driven understanding of the benefits and limitations of each approach. Therefore, it is not only the discussions on low endotoxin recovery and endotoxin masking that are important. We should also focus on the need for future innovations within BET that provide solutions to current challenges with modern pharmaceutical and biopharmaceutical products for daily testing. In addition, automated solutions will play an important role, making issues of computer validation and data integrity important.

This conference will inform you about current developments in Endotoxin and Pyrogen testing, implementation of new methods as well as the practical use of established test methods like LAL for Endotoxin testing.

You become informed about

- 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, RFC and more

Target Audience

- Representatives of the regulatory and authorisation authorities
- Specialists in laboratories for Endotoxin and Pyrogen Testing
- QA/QC personnel in the biopharmaceutical environment
- Scientist in research and development of testing systems
- Project managers and outsourcing personnel
- Biologists, analytical chemists and biochemists interested in Endotoxins and Pyrogens products

Moderation

Dr Johannes Reich, Member of the ECA Pharmaceutical Microbiology Group, GM at Microcoat Biotechnologie
Dr Sven M. Deutschmann, Roche, Chair of the ECA Pharmaceutical Microbiology Group

Current Regulatory Developments in the Field of Endotoxin and Pyrogen Detection
Dr Ingo Spreitzer, Paul-Ehrlich Institute, German Federal Agency for Vaccines and Biomedicines

Approval of a Monocyte Activation Test as a Replacement of the Rabbit Pyrogen Test
Dr Sven M. Deutschmann, Roche

- Introduction and Problem Statement
- Additional MAT-RPT Equivalency Study

A Comparison of Recombinant Factor C and LAL Based Methods for Bacterial Endotoxin Testing
Hiram Huzeyfe Yakut, Turkish Medicines and Medical Devices Agency

- Four different bacterial endotoxin testing methods were compared
- Six different parenteral products were studied in each method
- Enhancement/inhibiton effects were examined
- The advantages and weaknesses of the methods over each other have been revealed

Good Practice in LER Hold Time Study: the Choice of the Endotoxin
Alessandro Pauletto, bioMérieux

- Look Back on Hold Time Studies- Naturally occurring endotoxin (NOE) or standard endotoxin (CSE/RSE)?
- PDA TR82 and CSE and RSE in low endotoxin recovery (LER) hold time studies
- Possible impact that CSE and RSE may have on the results of a LER hold time study

Addressing Low Endotoxin Recovery During Biological Development - from Early Stage to Submission
Melanie Jänsch und Jessica Stolzenberger, Boehringer Ingelheim

- A strategy to address the issue of low endotoxin recovery (LER) during biological product development
- To avoid underestimation of endotoxins, Boehringer Ingelheim considers individual approaches for early and late stage development in studies for endotoxin recoveries:
  - Exploratory LER
  - Sample hold time
  - Endotoxin removal studies
- A case study will demonstrate proof of concept

Endotoxin and Pyrogen Testing
26/27 November 2024

The Mitigation Concept - Understanding the Masking Impact on Drug Product Manufacturing of Biologicals
Martina Wespel, Boehringer Ingelheim und Dr Anthea Darius, Microcoat Biotechnologie

- The challenge in ensuring accurate in-process control (IPC) testing.
- Sample hold time (SHT) is an integral part of Boehringer Ingelheim's low endotoxin recovery (LER) concept
- Effects of downstream process steps such as capture, virus inactivation, filtration, polishing, and ultra-filtration diafiltration on masking, including buffer composition, pH, and conductivity
- Potential impact on the control and removal of endotoxins during the downstream process, leading to masking effects
- Mitigated Masking using multiple approaches, to overcome the masking to guarantee, that no underestimation of endotoxins during IPC measurements occurred - shown by a case study
- Evaluation of SHT data and the findings contribute to enhancing the reliability and accuracy of IPC testing by identifying and mitigating endotoxin masking

Supramolecular Assembly of Micellar Aggregates is the Basis of Low Endotoxin Recovery (LER) in a Drug Formulation that Can be Resolved by a Whole Blood Assay
Prof Klaus Brandenburg, Brandenburg Antiinfektiva c/o Forschungszentrum Borstel

- Sepsis
- Endotoxin supramolecular conformation
- Anti-LPS peptides
- Structural polymorphism

Developing Endotoxin Assays Based on a Novel LPS-Binding Peptide
Prof Dirk Linke, University of Oslo

- Preliminary data on our LPS-binding peptide last year
- Updated data on how to build an "ELISA-like" assay using our peptide
- Possible detection limits and industrial-scale feasibility

On the Detection and Quantification of the Endotoxic, or Not Endotoxic, Lipopolysaccharides
Dr Flavien Dardelle, LPS-Bioscience

- Lipopolysaccharides are highly diverse at the molecular level
- Comparison of detection and quantification methods (LAL, HEK-blue TLR-4, LC-MS2, and MALDI-MS)
- Structure-activity relationship of lipopolysaccharides
- Not all lipopolysaccharides are toxic

Update on the Status of the USP proposed General Chapter <86> Endotoxin Testing using Recombinant Reagents
Dr Mark Schweitzer, USP

- Overview of the status of the chapter
- Discussion of the rationale for the introduction as a new general chapter
- Next steps in the evolution of the chapter

Validation of a Complex Drug Product Using Recombinant Cascade Reagent
Veronika Wills, Associates of Cape Cod

- Specifics of USP <86>
- Ramifications that European manufacturers will likely face in the pursuit of implementation
- Compiled information on the validation of complex drug products using recombinant cascade reagent PyroSmart NextGen®
- This presentation serves as a crucial compass for European entities as they prepare to traverse the terrain of modern regulatory compliance, emphasizing recombinant technology's role in fostering a more ethical and sustainably-sourced framework for endotoxin testing

Endotoxin Testing of mRNA Vaccines: Ensuring Product Safety and Effectiveness
Dr Mohamad Toutounji, Lonza

- Challenges in ensuring the safety of RNA-based products with LNP
- Why the complexity of LNPs with different lipids that encapsulate nucleic acids makes it difficult to detect endotoxins using conventional test methods
- Solubilisation and destruction of the LNP lipids with detergents to reduce the masking effects.
- Proof-of-concept results to develop a versatile platform method that can be customised to the properties of RNA-LNP products using this approach

The Lobster Hemocyte Lysate (LHL) Method for the Detection of Lipopolysaccharides (LPS), Peptidoglycans and (1,3)- β-D-Glucans
Rolando Perdomo Morales, Center for Pharmaceuticals Research and Development, Cuba

- Towards the development of the LHL reagent
- Principle of the LHL method
- Future planning

Evaluating Synthetic Reagents for Endotoxin Testing
Poppy Cliffe, AstraZeneca

- Introduction and background
- Why AZ are exploring synthetic endotoxin testing reagents
- Our evaluation of synthetic reagents for endotoxin testing
- Future plans and next steps

Recombinant Cascade Reagent and Limulus Amebocyte Lysate: A Detailed Analysis of Endotoxin Testing Methods
Dr Shady Kamal, Galderma

- Comparison of inhibition/enhancement profile in different variety of samples
  - Phosphate, acetate and tris/HCl based buffers
  - Sample containing β-Glucan
- Comparison of natural environmental endotoxin present in process water and water going through different purification processes

Out of the Endotoxin Box: Rethinking Pyrogens and Pyrogenicity
Dr Djikolngar Maouyo, PyroDex

- Pharmacological heterogeneity of lipopolysaccharides (LPS)
- Non-linearity of biological responses uncovered by the MAT
- New concepts for pyrogen testing: Iterative exhaustive serial dilutions, definitive product pyrogenicity profiles, optimal valid dilution factor and equivocal pyrogen concentrations
- Beyond the pyrogenic LPS. The larger world of pyrogens: PAMPs and DAMPs and the necessary MAT

Automation of the Monocyte Activation Test Method 2 with the Opentron OT-2 Robot
Delphine Trélat, Sanofi

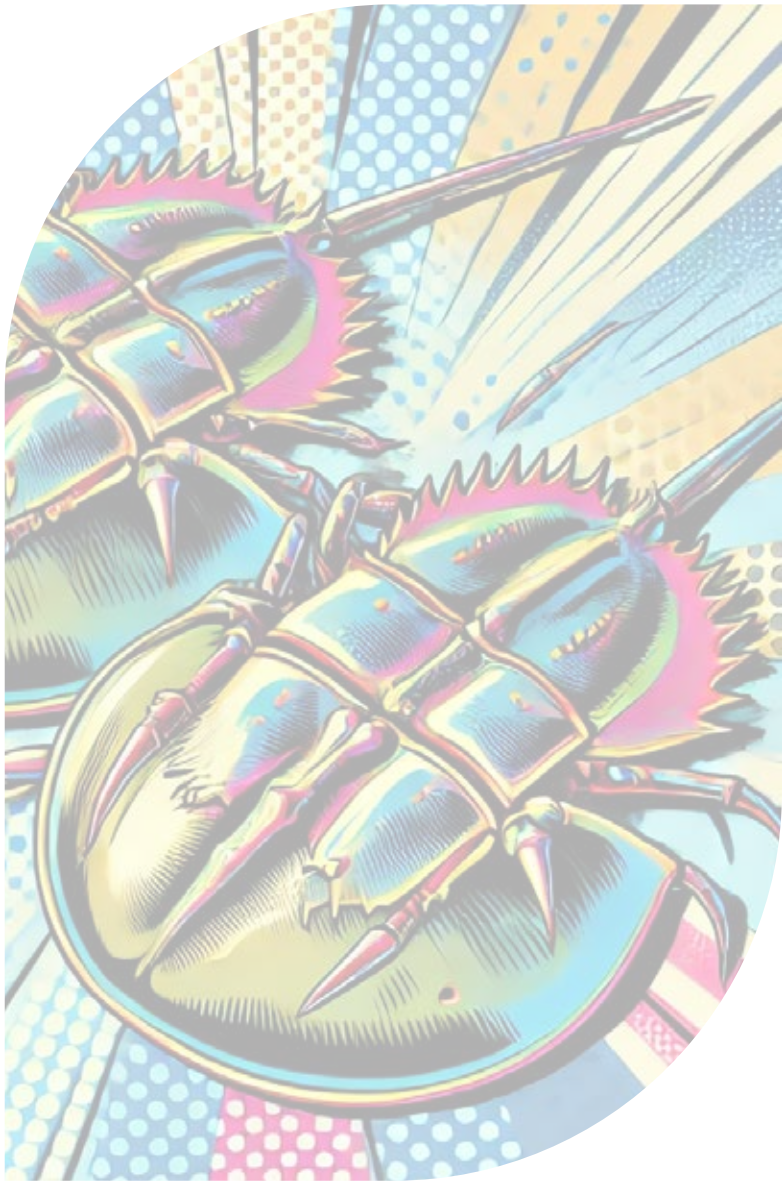
- MAT according to EP 2.6.30 for pyrogen testing of bacterial vaccines containing inherent pyrogens and to evaluate batch-to-batch consistency in comparison with a validated reference batch of this product
- Automation of the routine test after the assay has been developed in terms of cell count, sample volume, incubation time and assay detection, the automation of the routine tests was the final step in the development of the MAT method to save time and money
- Opentron OT-2-Automat as a possibility for automation
  - Adaptation of the assay sequence and comparison of the manual and the automated MAT method in terms of their performance and time savings
  - Further development of an automated MAT process and investment in a MAT machine

LumiMAT™ : Rapid and easy MAT Using the Luciferase Reporter Assay
Tomohisa Nanao, FUJIFILM Wako Pure Chemical

- Current pyrogen testing method RPT (Rabbit pyrogen test) is going to be replaced by MAT (Monocyte activation test). However, MAT using PBMC (Peripheral Blood Mononuclear Cells) ELISA (Enzyme-Linked Immunosorbent Assay) assay raises concerns about data variability, PBMC availability, and required assay time (2 days)
- Producing NF-kB reporter gene transfected cell lines for MAT and the cells the reactivity for LPS (Lipopolysaccharide) and variety of NEP (non-endotoxin pyrogen)
- Validation data was obtained for the practical use
- The use of reporter gene stable expressed cell line allows for highly reproducible tests and a stable supply of products
- The advantage of NF-kB reporter gene assay is ELISA free, easy handling and significantly short reaction time as this system does not need to wait for IL-6 release. This pyrogen testing method can finish the whole assay within 5~6 hours and can be expected as a replacement of RPT

Development of a Rapid MAT Test Using Immortalized Monocyte Cells (aMylc)
Kazuo Miyazaki, Mican Technologies

- Immortalized Monocyte Cell using stem cell technology from PBMC of healthy donor (aMylc) shows cytokine production after LPS / NEP stimulation
- MylcMAT using aMylc was validated in EU / JP will release as MAT evaluation kit from Jan/2025
- About development MylcMAT rapid kit (2nd generation) within 3 hrs for cultivation time, and easy detection for inflammatory cytokine (TNF-α)
- Evaluation protocol of MylcMAT rapid kit is quite similar original one (just change evaluation time and detection system)
- Because of ¡monocyte cell, customer can check not only TNF-α but IL-1β, IL-6 as cytokine production
- Comparison with the current MylcMAT (1st generation product, 20 hrs, hIL-6 ELISA system)



Speakers

Prof Dr Klaus Brandenburg
Brandenburg Antiinfektiva c/o
Forschungszentrum Borstel
CSO

Alessandro Pauletto
bioMérieux
Global LER BDM

Kazuo Miyazaki
Mican Technologies
Founder & CEO

Tomohisa Nanao
FUJIFILM Wako Pure Chemical
Reasearcher/Assistant Manager

Prof Dr Dirk Linke
University of Oslo
Professor in Molecular Microbiology

Dr Anthea Darius
Microcoat Biotechnologie
Project Leader Endotoxin Services.

Veronika Wills
Associates of Cape Cod
Associate Director Global Technical Services

Martina Wespel
Boehringer Ingelheim
Process Expert

Melanie Jänsch
Boehringer Ingelheim
Senior Scientist in Analytical Development
Biologicals

Jessica Stolzenberger
Boehringer Ingelheim
Lead Lage Stage Downstream Laboratory

Dr Flavien Dardelle
LPS-Biosciences
Laboratory Manager

Hiram Huzeyfe Yakut
Turkish Medicines and Medical Devices Agency
Pharmacist

Rolando Perdomo-Morales
Centro de Investigación y Desarrollo de Medicamentos (CIDEM)/Center for Pharmaceuticals Research and Development, Cuba
Senior Researcher

Dr Mark Schweitzer
USP/Consultant
Chair of the USP General Chapters Microbiology Expert Committee

Stéphanie Richard
Sanofi
Analytical Sciences

Dr Shady Kamal
Galderma
Senior Microbiologist

Dr Djikolngar Maouyo
PyroDex
Managing Director and President

Dr Sven M. Deutschmann
Roche
"Analytical Science"-Chapter, Quality and Compliance for Roche Pharma Technical Operations

Dr Ingo Spreitzer
Paul-Ehrlich Institute, German Federal Agency for Vaccines and Biomedicines
Deputy Head of Department Microbiological Safety at Paul-Ehrlich-Institut Chair of the EDQM Working Party "Bacterial Endotoxin Test"

Poppy Cliffe
AstraZeneca
Pharmaceutical Technology and Development

Dr Mohamad Toutounji
Lonza
Molecular Biologist and CMC Scientist

Media Partners 2024:

European Biotechnology – Life Sciences and Industry Magazine
LABORWELT
transkript
BioPharma Asia
rapid microbiology
GIT LABOR-FACHZEITSCHRIFT

The Social Event

On the evening of the first congress day, on 26 November 2024, all congress delegates and speakers are invited to a „Get together" in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

BOOK ONLINE NOW !

At www.pharmalab-congress.com/registration-congress.html or use the QR code on the right.

To avoid incorrect information, please give us the exact address and full name of the participant.

- **25 November 2024: Pre-Conference - 590 € plus VAT**
- **26+27 November 2024: PharmaLab Congress & Exhibition (day 1 + 2) - 1.380 € plus VAT**
- **26 November 2024: PharmaLab Congress & Exhibition (day 1 only) - 690 € plus VAT**
- **27 November 2024: PharmaLab Congress & Exhibition (day 2 only) - 690 € plus VAT**

Conference Language: The official conference language will be English.

Particularities of the PharmaLab Congress:

With a one-day ticket/two-day ticket for the PharmaLab Conferences (26/27 November 2024) you can attend any conference offered that day/both days. It includes participation in any conference on that day/on both days and the visit of the exhibition. In addition, it comprises lunch and beverages during the conferences and in breaks (on one or both days) as well as the social event on the evening of the first congress day.

Please mark if you would like to attend the Social Event.

To be able to prepare the conference rooms, please choose the conference you are most interested in during the online registration process.

Content last updated:
The status of the content is as of **18.10.2024**.
The latest content can be found on the PharmaLab website at https://www.pharmalab-congress.com.

Please note

There will be no hotel/ room reservations via Concept Heidelberg. Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice. There will not be any print-outs at the Congress. Instead you will receive all presentations prior to the Congress as downloads. presentations of this Course will be available for download and your print-out one week before the conference.

Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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