2019 PharmaLab
Congress & Exhibition
Analytics•Bioanalytics•Microbiology
Düsseldorf, 12/13 November 2019

Rapid and Real Time Methods Mycoplasma qPCR Endotoxin and Pyrogens

2nd International Mycoplasma qPCR Testing User Day

Rapid Microbiological Methods

Microbiological Real Time Counting and Testing

Endotoxin and Pyrogen Testing

11-13 November 2019 | Düsseldorf/Neuss, Germany

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2nd International Mycoplasma qPCR Testing User Day

11 November 2019, Düsseldorf/Neuss, Germany

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 pharmaceutical 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 satellite symposium is directed to responsible personnel involved in Quality Control testing of biopharmaceuticals and biologics, e.g.:

- QC Director, Manager, Scientists, Microbiologists, and Process Microbiologists
- Analytical Experts
- Biosafety and Pathogen Safety departments
- Bioassay Developer
- Regulatory departments

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

Moderation

DR PETER STEINHARDT, Roche Diagnostics

Speakers

DR CHRISTIE ENGLISH, Mycoplasma Experience. Scientist - Molecular Biology.

JAN-OLIVER KARO, Paul-Ehrlich Institut (PEI), German Federal Agency for Vaccines and Biomedicines
Division Microbial Safety. Quality assessor and national expert advisor for the microbial safety of ATMPs. Member of the "Cell Therapy Products" Working Party of the German Pharmacopoeia Commission.

DR FÉLIX A. MONTERO JULIAN, bioMerieux, France. Scientific Director.

DR ALEXANDRA MÜLLER-SCHOLZ, Sartorius Stedim Biotech, Germany.
Scientist - Applications for Molecular Biology.

CHRISTIANA SCHNITZLER, Boehringer Ingelheim, Germany. Head Mycoplasma Laboratory.

DR PETER STEINHARDT, Roche Diagnostics, Germany. International Alliance Manager, Business Development Pharma & Biotech, EMEA LATAM.

ANDREJ STEYER, University of Ljubljana, Slovenia. Institute of Microbiology and Immunology Faculty of Medicine

Programme

Pitfalls and Issues on Mycoplasma Testing according to Pharmacopoeial Requirements - A Regulator´s View on ATMPs

- Challenges and Current Regulatory Basis
- Mycoplasma Safety Concepts for ATMPs - Requirements and Expectations
- Considerations on Ph. Eur. 2.6.7 Revision
- Case Studies from Microbiological Assessment

Jan-Oliver Karo, Paul-Ehrlich Institut (PEI)

MycoTOOL – Method Development and Generic Validation Strategy

- Scope of Method (cell bank release testing, raw materials release testing, unprocessed bulk release testing, and facility protection)'
- Strategy and results of method development
- Generic validation strategy and results

Christiana Schnitzler, Boehringer Ingelheim

Comparative Evaluation of 2 real-time PCR-based Mycoplasma Kits

- Evaluation of the Minerva Biolabs 'VenorGem qEP Mycoplasma Detection Kit for qPCR'
- Evaluation of the Roche 'Myco Tool Mycoplasma Real-Time PCR Kit'
- Applications of the Kits in our mycoplasma laboratory

Dr Christie English, Mycoplasma Experience

Automatization of Mycoplasma detection using a new fast and easy to use molecular method

- Architecture of the system with broad detection of Mollicutes with less than five minutes of hands-on time
- Sensitivity
- Application - screening at various stages of the manufacturing process for low level mycoplasma contamination in a wide range of possible sample types

Dr Félix A. Montero Julian, bioMerieux

Detection of Mycoplasma contaminations in High Cell Density Cell Cultures

- During this presentation Real-time PCR data will be shown for different Mycoplasma species.
- A Challenging experimental setup has been selected: Mycoplasma spike levels of 10 CFU/ml have been detected in the presence of different cell types with a concentration of up to 20 million cells per ml.

Dr Alexandra Müller-Scholz, Sartorius Stedim Biotech

Mycoplasma detection system and its verification

- Two commercial mycoplasma detection systems were compared, testing cell culture media with mycoplasma strains spiked at different concentrations
- The preferred system showed high reproducibility and sensitivity, with potential to reach the acceptability criteria to replace the culture method

Andrej Steyer, University of Ljubljana (co-author: Dr. Marjanca Blas, Sandoz, Slovenia)

Summary

Dr Peter Steinhardt, Roche Diagnostics

Rapid Microbiological Methods

12 November 2019, Düsseldorf/Neuss, Germany

Objectives

This conference will review the current knowledge about developments in modern microbiological methods and mycoplasma detection strategies for quality control in biopharmaceutical manufacturing.

This one-day meeting provides the opportunity to discuss the recent advances in the area of the newest technological developments as well as practical aspects and concerns of meeting the regulatory requirements. State-of-the-art presentations from authority speakers, as well as industrial and academic experts in the field of microbiological detection and identification and mycoplasmology with particular focus on the current methodologies their implementation and validation will provide an in-depth overview.

Background

The scientific progress in the field of cellular and molecular biotechnology led to a fast development of biopharmaceuticals, tissue engineered applications and advanced therapy medicinal products (ATMPs). Against this background, the safety of such new technologies, products and applications becomes more important. One important topic in the focus of risk assessment and safety is the contamination with microorganisms and mycoplasmas and their detection, prevention and control.

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

Social Event

On the evening of the first congress day, on 12 November 2019, 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.

Moderation

DR MICHAEL J. MILLER, Microbiology Consultants

Speakers

DR ALEXANDER BARTES, Roche Diagnostics, Germany
Senior Quality Control Manager.

DR SVEN M. DEUTSCHMANN, Roche Diagnostics, Germany
Head of Global ASAT "Adventitious Agents Testing and Alternative Microbiologica. Chairman of the Advisory Board of the ECA "Pharmaceutical Microbiology Interest Group", Member of PDA Task Forces.

STEFAN GÄRTNER, Labor LS, Germany
Head of Department Sterility Testing, Member ECA Mat Task Force.

BARBARA GERTEN, Merck, Germany
Chairwoman DIN Working Group Microbiological Food Testing incl. Rapid Methods.

DR PRASANNA KHOT, Charles River Laboratories, USA
Senior Research Scientist Microbial Solutions.

DR MICHAEL J. MILLER, Microbiology Consultants, USA
Global expert in rapid methods, validation and pharmaceutical microbiology.

KAI NESEMANN, Sartorius Lab Instruments Germany
Global Product Manager DNA-based rapid QC-testing.

DR GEROLD SCHWARZ, Bruker Daltronics, Germany
Manager Application Support.

JONAS VAN DEN BERG, Roche Diagnostics, Germany
Validation of the Celsis-based Alternative Sterility Test.

Programme

12 November 2019

New ICH Q14 and ICH Q2 Revision – an industry view

DR JOACHIM ERMER, Sanofi-Aventis Deutschland
Head of QC Lifecycle Management Frankfurt Chemistry

RMM Validation - ECA PMWG / PEI Activities

DR SVEN M. DEUTSCHMANN, ECA Pharmaceutical Microbiology Interest Group

RMM Validation Guide Food – A Look to the Neighbourhood

- The Validation Guidance in Food Microbiology
- Validation of a standardized reference method
- Validation and certification of alternative methods
- Verification of validated methods in the user's lab

BARBARA GERTEN, Merck

Evaluation and Optimization of MALDI-TOF for Identification of Filamentous Fungi

- Background of identifying filamentous fungi by MALDI-TOF
- Cultivation and sample processing methods
- Adopting MALDI-TOF for identifying filamentous fungi found during Environmental Monitoring
- Workflow optimization, ID rate and accuracy, Impact of targeted library development

DR GEROLD SCHWARZ, Bruker Daltronics
DR PRASANNA KHOT, CRL

Validation of the Celsis-based Alternative Sterility Test

- Method validation approach
- Celsis validation results
- Lessons learned during implementation of the alternative sterility test

JONAS VAN DEN BERG, Roche Diagnostics

Different Products require different Methods - Overview of three rapid Sterility Test Methods

- Compendial vs. Alternative Methods
- GMP aspects
- EP 5.1.6, USP <1223>, USP <1071>, PDA TR 33
- Overview – 3 Alternative Methods for Rapid Sterility Testing
- Conclusion / Summary

STEFAN GÄRTNER, Labor LS

Picture: Labor LS

A Practical Guide on how to demonstrate a significant return of investement when implementing Real-Time RMMs

- Understand the need for performing a financial assessment
- Learn about relevant economic models such as return-on-investment (ROI) and net present value
- Compare operating costs, capital expenses and cost savings for a rapid and conventional method
- Conduct an actual ROI calculation and discuss the results

DR MICHAEL MILLER, Microbiology Consultants

PCR - Rodent Parvo Virus Testing

DR ALEXANDER BARTES, Roche Diagnostics

Rapid detection of bacteria and fungi in ATMP prior treatment - Validation of a Real-time PCR-based test

- Validation data according to international guidelines for the implementation of alternative methods
- Results about sensitivity, specificity, robustness and equivalency of a qPCR detection kit for total bacteria and fungi

KAI NESEMANN, Sartorius Labs Instruments

Microbiological Real Time Counting and Testing

13 November 2019, Düsseldorf/Neuss, Germany

Objectives

In this course we give an overview of the current requirements, available systems and methods and their areas of application. Speakers from industry, laboratories and manufacturers will report on their experiences and the challenges involved in introducing, establishing and validating real-time test systems.

Background

Microbiological control, whether for environmental monitoring, in-process control or release testing, is mandatory in many cases. In order to be able to react quickly to deviations or to achieve the greatest possible safety for products with a short shelf life, be it ATMP or radiopharmaceuticals, methods for real-time measurement would be desirable. Some of these methods are already available on the market, but they present us with a number of challenges during implementation, e.g:.

- Comparability with Compendial Methods
- Greater sensitivity than previous methods (limit conflict with current requirements)
- Possibility of further cultivation
- Differentiation live/dead

Moderator

DR SVEN M. DEUTSCHMANN, Roche Diagnostics

Target Group

All employees who have to deal with real-time systems, i.e.

- in the laboratory
- in quality control
- during validation
- in the context of inspections or audits
- at a regulatory level

Social Event

On the evening of the first congress day, on 12 November 2019, 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.

Speakers

DR MARJA CLAASSEN–WILLEMSE, MSD, The Netherlands
Senior microbiological specialist, Microbiology Center of Excellence.

DR SVEN DEUTSCHMANN, Roche Diagnostics, Germany. Head of Global ASAT "Adventitious Agents Testing and Alternative Microbiologica. Chairman of the Advisory Board of the ECA "Pharmaceutical Microbiology Interest Group", Member of PDA Task Forces.

ANNETTE KUNZ, CSL Behring, Switzerland.
Manager Monitoring.

DR MICHAEL J. MILLER, Microbiology Consultants, USA
Global expert in rapid methods, validation and pharmaceutical microbiology.

DIARMAID O'RIORDAN, Pfizer, Ireland.
QC Microbiologist.

JOSEPH PIERQUIN, Redberry, France
Chief Technical Officer.

DR DAVID ROESTI, Novartis Pharma Stein, Switzerland
Technical Steward Microbiology, Manufacturing Science & Technology.

NATASCHA STAUB, Mibelle, Switzerland
Microbiological QC.

Programme

13 November 2019, Düsseldorf/Neuss, Germany

Laboratory Services - from Outsourcing to a strategic partnership

DR JÜRGEN BALLES, DR THOMAS MEINDL AND INGO GRIMM, Labor LS

Different Measurement Methods/Systems - Pros and Cons

- Different online measurement systems available
- Why measuring bioburden online
- Where to place in the system
- Not only costs but savings

ANNETTE KUNZ, CSL

Implementation of a Microbial Detection Analyzer For Real-Time Monitoring of Microbial Contamination for Purified Water

- Implementation of the Mettler 7000RMS Bioburden Analyzer for Purified Water
- How do you implement a new technology and set limits for which there are no official regulations?
- Find out how Mibelle Group Buchs faced this challenge

NATASCHA STAUB, Mibelle

Biofluorescent Particle Counting (BFPC) for continuous monitoring in aseptic manufacturing

- Auto Fluorescent Units and traditional CFU's are difficult to correlate
- For setting environmental monitoring limits a correlation is not relevant
- BFPC has great value for process understanding and investigations
- Data shows a clear correlation with cleanliness of rooms and activities

DR MARJA CLAASSEN–WILLEMSE, MSD

Evaluation of the Scanstation 100 system for the automated incubation and analysis of pharmaceutical environmental monitoring samples using standard Petri plates

DIARMAID O'RIORDAN, Pfizer

Picture: Labor LS

Case Study: Using continuous Real-Time intrinsic Fluorescence Techniques for EM in Isolators

- Discuss the need for real-time environmental monitoring
- Introduce relevant technologies
- Review a case study on using a real-time method in a manufacturing isolator
- Share real-time EM data during a sterile fill, transfer of components and interventions
- Determine how real-time monitoring can detect the presence of pinholes in isolator gloves
- Learn how to address potential EM hits in ISO 5 environments

DR MICHAEL MILLER, Microbiology Consultants

IMD-W "In-line system for purified water systems" and other devices for rapid water bioburden analyses

- Feasibility studies as offline device in the lab
- Feasibility study as online device at a purified water loop
- Challenges and possible solutions for online WFI bioburden analysis

DR SVEN DEUTSCHMANN, Roche Diagnostics

Calculating alert levels and trending of microbiological data

- Challenges with microbiological data
- Parametric percentile ranking method
- Defining and investigating adverse trends

DR DAVID ROESTI, Novartis Stein Pharma

New Generation of Solid Phase Cytometry for Rapid Detection of Microbiological Contaminants in Water Samples

- Principle of staining kinetics in solid-phase cytometry
- Application to water samples testing: real-time and post-enrichment detection
- Discussion on limits of detection, recovery rate and linearity of the method

JOSEPH PIERQUIN, Redberry

Endotoxin and Pyrogen Testing

12/13 November 2019, Düsseldorf/Neuss, Germany

Objectives

This 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.

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 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 2019.

Moderator

DR JOHANNES REICH, Microcoat Biotechnologie

Target Audience

This Conference is addressed to all persons of
- pharmaceutical manufacturers
- biopharmaceutical companies
- contract laboratories
- tissue establishments
- authorities

who are involved in Endotoxin and Pyrogen Testing.

Social Event

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Speakers

CHIARA CELLI, Merck, Italy. Scientist Microbiological ID.
DR ANJA FRITSCH, Confarma, France. Responsible for cell based bioassays (development and routine).
STEFAN GÄRTNER, Labor LS, Germany. Head of Department Sterility Testing, Member ECA Mat Task Force.
DR EELO GITZ, Sanquin Reagents, The Netherlands. Project manager product development.
DR JESSICA HANKINS, U.S. Food and Drug Administration
DR QING HE, Chinese National Institutes for Food and Drug Control. Pharmacology Division.
PETER KITSCHMANN, Bausch & Stroebel, Germany. Lead Pharma Compliance und Aseptic Packaging
DR MICHAEL KRACKLAUER, Microcoat, Germany.
DR OLEG KRUT, Paul-Ehrlich-Institut (PEI) - German Federal Agency for Vaccines and Biomedicines Unit Microbiological Safety.
MARINE MARIUS, Sanofi Pasteur, France. Scientist in Analytical R&D Microbiology.
DR HIKARU MIZUMURA, Seikagaku Corporation, Japan.
ALEXANDER NEGWER, Paul-Ehrlich-Institut (PEI) - German Federal Agency for Vaccines and Biomedicines Scientist Section 1/3, "Microbial Safety and Parasitology".
DR JELENA NOVAKOVIC, Galenika, Serbia. Senior Expert Associate.
KATRIN PAULS, Lonza, Germany. Market Development and Scientific Affairs Manager.
DR JOHANNES REICH, Microcoat Biotechnologie, Germany. General Manager.
NICOLE REID, Charles River Laboratories, UK. Senior Product Manager.
DR RUTH RÖDER, Microcoat Biotechnologie, Germany. Project Manager Endotoxin Services.
STÉPHANIE RICHARD, Sanofi Pasteur, France. Scientist-Analytical Sciences Department-Immunology platform.
DR MILANKA SETINA, National Control Laboratory Medicines and Medical Devices Agency of Serbia. Scientist.
DR INGO SPREITZER, Paul-Ehrlich-Institut (PEI) - German Federal Agency for Vaccines and Biomedicines Deputy Head of Section 1/3, "Microbial Safety and Parasitology".
ANDERS THORN, NovoNordisk, Denmark. Quality Control Specialist.
VERONIKA WILLS, Associates of Cape Cod., USA. Assistant Manager of Technical Services.
KEVIN WILLIAMS, bioMérieux, USA. Endotoxin Expert.

Programme

12 November 2019, Düsseldorf/Neuss, Germany

New ICH Q14 and ICH Q2 Revision – an industry view

DR JOACHIM ERMER, Sanofi-Aventis Deutschland
Head of QC Lifecycle Management Frankfurt Chemistry

MAT Task Force

- Kick-off Meeting
- Milestones and Deliverables

DR OLEG KRUT, Paul-Ehrlich-Institut (PEI), German Federal Agency for Vaccines and Biomedicines

Validation of MAT – Regulatory Experiences

- Feedback from users during validations
- MAT Task Force: relation to BET-Working Party
- Putative modifications on Methods A and B
- Which NEP to choose?

DR INGO SPREITZER, Paul-Ehrlich-Institut (PEI), German Federal Agency for Vaccines and Biomedicines

Development of the Monocyte Activation Test on vaccines containing inherently pyrogenic component

- The issue: inherently pyrogenic components
- Embedded TLR agonists such as endotoxin (liposaccharide) and non-endotoxin (lipoprotein)
- Pyrogen test to be used to monitor process consistency
- Evaluation of different Human Peripheral Blood Mononuclear Cells (PBMCs) and read out systems
- PBMC pool (8 donors) and IL6 cytokine quantification by HTRF technology

STÉPHANIE RICHARD, Sanofi Pasteur

Comparison of a Monocyte Activation Test based on fetal bovine serum and on human AB serum

- Performance of a cryopreserved PBMC-based Monocyte Activation Test (MAT) using fetal bovine serum (FBS) or human AB serum as cell culture supplement
- Case studies of analyzing drug products using FBS and human AB serum as supplement for the MAT assay
- Advantages and disadvantages of using FBS and human AB serum as supplement for the MAT assay
- Critical aspects for performing the MAT assay

DR EELO GITZ, Sanquin Reagents

Pyrogenicity associated with heat-inactivated microorganisms isolated in our laboratory from actual samples

- Microorganisms found in bioburdens or environmental monitoring
- Evaluating the pyrogenicity associated with heat-inactivated microorganisms
- Evaluated and compiled data
- Possible approach to risk-based management of pyrogenicity during production

DR ANJA FRITSCH, Confarma

Proficiency Test Program for MAT

- Summary of results of 2019
- Conclusions for applicability of MA
- Need for new concepts?

DR RUTH RÖDER, Microcoat Biotechnologie

MAT implementation: from validation to use in routine in a GMP QC Lab

- Monocyte Activation Test: a pyrogen test to replace animal-based tests for batch release
- Implementing MAT in a GMP QC lab, what should be considered?
- Product Specific Validation: example of hormone-based drugs

CHIARA CELLI, Merck

MAT - Ready for GMP Routine?

- MAT - Advantages and disadvantages of the respective methods from the point of view of a contract laboratory
- Selection of suitable sources for monocytes
- Critical aspects of the test
- Comparison with other test methods

STEFAN GÄRTNER, Labor LS

The Monocyte Activation Test: Validation & Analysis

- Establishing a cryo-preserved, PBMC-based Monocyte Activation Test (MAT) in a new laboratory
- Characterization of MAT response towards Non-Endotoxin Pyrogens (NEP) and Toll-like Receptor (TLR) Ligands
- Comparison of MAT and Bacterial Endotoxin Test (BET, various methods)
- Selected MAT Case Studies with different product types
- Analysis of the MAT – Development of a complete FDA 21 CFR Part 11 MAT analysis software solution

KATRIN PAULS, Lonza

Endotoxin, ten misconceptions around detection and control

- Detection depends upon the definition of endotoxin
- Control versus detection (i.e. detection is confirmation of control)
- Recombinant factor C comparability

KEVIN WILLIAMS, bioMérieux

Programme

13 November 2019, Düsseldorf/Neuss, Germany

Laboratory Services - from Outsourcing to a strategic partnership

DR JÜRGEN BALLES, DR THOMAS MEINDL AND INGO GRIMM, Labor LS

Current development in Endotoxin and Pyrogen Testing – FDA Point of View

DR JESSICA HANKINS, U.S. Food and Drug Administration

Putting Patient Safety First, View from the other side

- Putting patients safety first through ensuring safety production of injectables and medical devices regardless to Bacterial endotoxin testing. Highlight: new general chapter Ph Eur 2.6.32
- What a BET methodology is the most appropriate from the point of view of a manufacturer (regardles the stages of sterile pharma manufacturing, i.e. raw materials, semifinished or final product) VS regulatory body (release testing)
- Role and an advantages of recombinant DNA technology in production of highly purified and well biologically and chemically caractarised protein C zymogen
- Transition from conventional bacterial endotoxin testing to an alternative i.e. rFC (Method standardization and validation)

MILANKA SETINA, Medicines and Medical Devices Agency of Serbia

LER Hold-Time studies

- PDA Technical Report on LER: Principles for performing LER hold time studies
- Hold time study design at Novo Nordisk

ANDERS THORN, Novo Nordisk

Endotoxin and Pyrogen detection of LER Samples

- LER in pharmaceuticals
- OMV as model of NOE
- LER and NOEs

ALEXANDER NEGWER, Paul-Ehrlich-Institut (PEI), German Federal Agency for Vaccines and Biomedicines

Endotoxins – Requirements of CP

- Development of pyrogen detection methods in Chinese pharmacopoeia
- Development of a reporter gene assay for pyrogen detection

DR QING HE, Chinese National Institutes for Food and Drug Control

Practical Insights in BET

- Structure and characteristics of endotoxins
- Most common sources of endotoxins
- History of BET testing
- Endotoxin potency vs bacterial numbers
- Calculation of the BET limit

DR JELENA NOVAKOVIC, Galenika

A Global Perspective for Quantifying All Endotoxins within Pharmaceutical Water Systems

- Methods utilized when quantifying endotoxins
- Importance of the methodology
- Review how it combines endotoxin determinations with sessile microbial identification

NICOLA REID, CRL

4 Factors affecting the recovery of endotoxin

- Interference of LAL test reaction
- Inadequate interpretation of raw data
- Masking of endotoxin
- Depletion of endotoxin

PETER KITSCHMANN, Bausch & Stroebel

DR MICHAEL KRACKLAUER, Microcoat

Application of a recombinant three-factor chromogenic reagent, PyroSmart, for bacterial endotoxins test

- PyroSmart as an alternative test for BET
- Assessment of analytical characterization of PyroSmart
- Comparison of PyroSmart to lysate reagents and other recombinant reagents in susceptibility to inhibition and/or enhancement components

DR HIKARU MIZUMURA, Seikagaku Corporation

VERONIKA WILLS, Associates of Cape Cod

Evaluation of rFC for product testing

- Background on rFC - rationale for implementation in Pharma industry
- Implementation of rFC for product testing
- ROE on rFC

MARINE MARIUS, Sanofi Pasteur

Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

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Dates
Monday, 11 November 2019, 12.30 – 17.45 h
Tuesday, 12 November 2019, 09.00 – 18.00 h
Wednesday, 13 November 2019, 09.00 – 18.00 h
(Registration Monday, 11 November, 11.30 – 12.30 h and
Tuesday, 12 November/Wednesday, 13 November 08.00 – 09.00 h)

Venue
Crowne Plaza Düsseldorf / Neuss
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Fees (per delegate plus VAT)
11 November 2019: Pre-Conference „1st International Mycoplasma qPCR Testing User Day" € 490,-
12 November 2019 € 690,-
13 November 2019 € 690,-

The conference fee is payable in advance after receipt of invoice and includes lunch on that day/on both days as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day. VAT is reclaimable.
Your registration also entitles you to participate in all other PharmaLab Congress conferences during the day of your conference/during the two days. For information on all PharmaLab conferences please visit **www.pharmalab-congress.com**.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.pharmalab-congress.com

PLEASE NOTE
Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center. Please further note that there will be no room reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice!

Organisation & Contact
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Part of PharmaLab 2019, Düsseldorf/Neuss, Germany, 12-13 November 2019
☐ Pre-Conference „2nd International Mycoplasma qPCR Testing User Day" (11.11.2019)
☐ Conferences on 12.11.2019
☐ Conferences on 13.11.2019

I would like to attend the following conference(s):
☐ **Rapid Microbiological Methods and Mycoplasma Testing** (12 November 2019)
☐ **Microbiological Real Time Counting and Testing** (13 November 2019)
☐ **Endotoxin and Pyrogen Testing** (12/13 November 2019)

☐ Yes, I will participate in the Social Event on 12 November.
☐ Mr ☐ Ms

Title, first name, surname

Company

Department

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CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. 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)!

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 **https://www.pharmalab-congress.com/privacy-policy.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.

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