Image: Labor LS

2018 PharmaLab
Congress & Exhibition
Analytics•Bioanalytics•Microbiology
Düsseldorf, 20/21 November 2018

Microbiology Endotoxin Pest Control

1st International Mycoplasma qPCR Testing User Day

Rapid Microbiological Methods and Mycoplasma Testing

Pest Control - from classic trap to digital control

Endotoxin and Pyrogen Testing

19-21 November 2018 | Düsseldorf/Neuss, Germany

ECA Academy
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1st International Mycoplasma qPCR Testing User Day

19 November 2018, 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, Germany*

Speakers

DR ALEXANDER BARTES, *Roche Diagnostics, Germany*
Senior QC Manager. From 2009 to 2014 he was Manager R&D. He was responsible for the development of qPCR/NAT based assays and Kits for Roche Applied Science Custom Biotech.

DAMIAN DERINCOVSKY, *Novartis,* QMS&T Facilitator BioProduction Operations Huningue, France.

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.

AURORE DE LAVAREILLE, *Celyad, Belgium*. QC Lab Supervisor.

DR MICHA NÜBLING, *Paul-Ehrlich-Institut (PEI), German Agency for Vaccines and Biomedicines*
Section Head Molecular Virology.

PROF DR RENATE ROSENGARTEN, *University of Veterinary Medicine Vienna.*
Professor and Chair of Bacterioloy and Hygiene.

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

Programme

Rapid Mycoplasma Testing - A revolution for Quality Control?
Prof. Dr. Renate Rosengarten, University of Veterinary Medicine Vienna

qPCR Mycoplasma Testing at Roche Pharma - method development, validation, and global roll out
Dr Alexander Bartes, Roche Diagnostics

External quality assessment of Mycoplasma NATs: regulatory implications
Dr Micha Nübling, Paul-Ehrlich-Institut

Case Study - Implementation of MycoTOOL as a Release Test
Damian Derincovsky, Novartis

Case Study - Approval of MycoTool Roche qPCR assay by FDA, FAMHP and MHRA, accelerating QC release of an autologous cell therapeutic product
Aurore de Lavareille, Celyad

Parallele Round Table Discussions

Table 1 - MycoTOOL Q&A Session and experience exchange with the developer of the method (Roche Pharma)
Dr Sven Deutschmann and Dr Alexander Bartes, Roche Pharma Biotech

Table 2 - Rapid Mycoplasma Testing for ATMPs
Jessica Wynendale & Kim Baert, Anacura
Aurore de Lavareille, Celyad

Table 3 - Implement MycoTOOL on non-validated instrumentation (e.g. other PCR cycler)
Dr Manuela Natoli, Cancer Research UK
Dr Giusy Canino, Roche Diagnostics

Rapid Microbiological Methods & Mycoplasma Testing

20 November 2018, 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 importance. 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 in Quality, Microbiology and Validation from

- Biotechnological & Biopharmaceutical Companies
- Contract Service Laboratories
- Government Agencies
- 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 20 November 2018, 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 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.

Speakers

MARIO FUSI, *Steriline, Italy*
Technical Director.

DR SUNHEE HONG, *Charles River Laboratories, USA*
Microbial Solutions R&D Senior Staff Scientist.

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 FRANK PANOFEN, *Particle Measuring Systems, Germany*
Product Line Manager Sterility Assurance & Microbiology.

DR JÖRG PEPLIES, *Ribicon, Germany*
Microbial quality control, computer validation.

DR LUCILE PLOURDE OWOBI, *Sanofi Pasteur, France*
Senior Scientist, Microbiology Global Analytical Science.

CHRISTOPHE RIEDEL, *Claranor, France*
Business Management.

SAMUEL ZÜRCHER, *Certus Molecular Diagnostics, Switzerland*
CEO und Co-Founder.

Programme

20 November 2018

Alternative Microbiological Methods: AstraZeneca's, Johnson&Johnson's, MSD's and Roche's Global Implementation Roadmap

MIRIAM GUEST, *AstraZeneca*
PHILIP BREUGELMANN, *JnJ*
MARJA CLAASEN, *MSD*
DR SVEN M. DEUTSCHMANN, *Roche*

Microbial test automation to support plate incubation and enumeration

- Why to implement an automated colony count technology?
- The Growth Promotion Test (GPT) as a possible automated method
- Validation strategy for an automated compendial method

DR LUCILE PLOURDE OWOBI, *Sanofi Pasteur*

Present and Future of Molecular Microbial Identification – Bridging of Scientific Progress and Practical Application in Regulated Environments

- The 16S rRNA gene as the gold standard for DNA-based bacterial (and fungal) identification, in both the academic and the industrial field
- Dependency of regulated environments on academic resources in microbial systematics
- Challenge of preparing high-grade and up-to-date reference data sets in terms of DNA sequence quality, taxonomy, and nomenclature
- Progress in DNA sequencing technology and impact on productive use in microbial quality control
- Potential of better resolving alternative marker genes (such as gyrb) and increasing relevance of whole genome sequencing in microbial identification

DR JÖRG PEPLIES, *Ribocon*

Bringing Innovation into quality control: How a novel Isothermal mycoplasma assay changes the race

- Isothermal amplification and real-time detection Potential uses of this technology in varied e.g. viral contaminations or rapid sterility testing

SAMUEL ZÜRCHER, *Certus Molecular Diagnostics*

Rapid detection of bacteria in ATMP prior treatment - validation of a qPCR-based test

- Importance of a microbial release test for mPatiens safety
- qPCR zo detect total bacterial contamination
- Validation approach according to EP 5.1.6 and USP <1223>

KAI NESEMANN, *Sartorius Lab Instruments*

Understanding the Revised Ph. Eur. Chapter 5.1.6 and how it compares with USP 1223, PDA Technical Report 33 and Industry Best Practices

- A holistic review of the revised chapter 5.1.6
- How it compares with USP 1223 and PDA Technical Report 33
- Understanding of the similarities and differences between each of the guidance documents

DR MICHAEL MILLER, *Microbiology Consultants*

Strategies for Rapid Sterility Testing of Gene and Cell Therapy Products

- The issue of small batch sizes and short shelf life
- Possible ew strategies for sample preparation and release testing
- How helpful are Ph. Eur. 2.6.27, Ph.Eur 5.1.6 USP 1223, and PDA TR 33
- Considerations from the harmonized compendial sterility test and the U.S. Code of Federal Regulations

DR MICHAEL MILLER, *Microbiology Consultants*

Modern alternative viable air monitoring in light of the new Annex 1 draft

- Annex 1 draft - new concepts of environmental monitoring
- The potential to revolutionize the viable testing approaches
- New aspects of viable air testing to the concepts of risk management, scientific data generation and data integrity including RMM

DR FRANK PANOFEN, *PMS*

Using an alternative gene sequence for species-level identification for members of the Burkholderia cepacia complex (Bcc).

- History of the Burkholderia cepacia complex.
- Burkholderia capacia complex in pharmaceutical industries.
- The importance of species-level identification for members of the Bcc.
- Phylogenetic relationships between Bcc species based on 16S rRNA gene sequencing.
- Evaluation of recA gene sequences for species-level resolution in the Bcc.

DR SUNHEE HONG, *Charles River Laboratories*

Pulse Light Decontamination - Robotic Tub Decontaminating System

- Background and history
- technical inbformations
- Denaturation of macromolecules (DNA, prozeins and enzymes) and the increase by effects of UV light

CHRISTOPHE RIEDEL, *Clearanor*
MARIO FUSI, *Steriline*

Pest Control - from classic trap to digital control

20 November 2018, Düsseldorf/Neuss, Germany

Objectives

This session will show you the regulatory background and authorities expectations on a suitable pest control programme in the field of GMP manufacturing. Additionally experts from manufacturing, laboratory and pest control companies present their experiences in developing and implementing a suitable pest control strategy. The presentations will cover the requirements for different areas and cleanroom classes and laboratories. Amongst the classic traps for rodents and insects, the course provides you information about modern online controlled pest control systems.

Background

Many national and international regulatory guidelines ask for a conclusive concept of pest control for pharmaceutical and biopharmaceutical manufacturers. But details what and how to do that can't be found in these documents. It seems that this effects that the complexity and importance is underestimated. Mostly the small organisms of microbiology get more attention than the "big animals" that can be seen with the human eyes.
For an integrated and effective system to avoid pest infestation, a risked based approach for buildings, rooms and manufacturing conditions must be evaluated. Additionally the monitoring of the preventive actions, the traps and the corrective actions in case of pest infestation must be conceived.
Therefore, the exchange of information and a structured cooperation of the responsible persons of the manufacturer and maybe of the contact pest control supplier is essential.

Moderator

Dr Marcel Goverde, *MGP, Switzerland, Member of EP Microbiology Expert Group*

Target Group

This conference is of interest to professionals from

- Manfacturing, construction and maintenance
- Storage and Logisticss
- Procurement and Purchase
- Outsourcing
- Contract Pest Control Companies

Social Event

On the evening of the first congress day, on 20 November 2018, 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 JÜRGEN BALLES, *Labor LS, Germany*
He joined Labor LS in 1997. After several years in different positions with responibilities in microbiologica, chemical and physical release testing, quality assurance as well as internal training, he became head of operation management. Finally, since 2018 he is one of the three managing directors of Labor LS.

DR CORNELIA BODINET, *Schaper & Brümmer, Germany*
Since 1986, Cornelia is at Schaper & Brümmer and today she is head of Division "Pharmaceutical Laboratories" and a member of the management board.

PETRA BARTH, *Former Abbvie*
Petra was until 2016 Head of the Quality Department QA Systems at Abbvie (former Abbott) in Ludwigshafen, Germany. Amongst Pest Control issues, she was responsible for inspection management, supplier qualification, risk management, internal audits and documentation. 2016 she started her own business as consultant and trainer.

DR RAINER GNIBL, *Local Government of Upper Bavaria*
Dr Rainer Gnibl is EU-GMP inspector in Germany and performs GMP inspections worldwide also on behalf of the European Medicines Agency (EMA).

TINA GRAUWET, *SGS, Belgium*
Business Unit Manager Pest Management Benelux. Focussed on the prevention of biorisks, Tina Grauwet had several responsibilities within the department "Agriculture Food Life", from commercial to technical expert and business unit manager. Moreover, the Benelux division is the innovation and excellence center worldwide for pest management

GERHARD KARG, *B.U.G.S, Germany*
Managing Director. Gerhard Karg is officially appointed expert for Pest Control and auditor for ISO 16636. He is lecturer at LFA Stuttgart and University Geisenheim.

MARTIN TABAK, *Xendo, The Netherlands*
Martin Tabak is a consultant with over 20 years of broad working experience in the pharmaceutical industry and life sciences organisations. He works at the independent consultancy and project management organization Xendo with offices in Germany, Sweden and The Netherlands

Programme

20 November 2018, Düsseldorf/Neuss, Germany

Alternative Microbiological Methods: AstraZeneca's, Johnson&Johnson's, MSD's and Roche's Global Implementation Roadmap

MIRIAM GUEST, *AstraZeneca*
PHILIP BREUGELMANN, *JnJ*
MARJA CLAASEN, *MSD*
DR SVEN M. DEUTSCHMANN, *Roche*

Authorities´ Expectations

- Quality Risk Management - QRM
- Outsourcing - External Service Provider
- Technical Agreement
- Pest Control Manual Japan Affiliate - ISPE (Industry Guidance)

DR RAINER GNIBL, *Government of Upper Bavaria*

Pest Elimination – Outside to inside

- Implementation of a system – the core of consideration
- Zoning Concept against Bugs
- Risked Based Approach – postions, Frequence and Limits
- Acceptable Limits – an Approach of Evaluation
- „Monitoring with a Logbook Concept - Chain of Reporting and Actions
- Life Cycle of a Pest Control System

PETRA BARTH, *formerly AbbVie*

Possibilities and Limits of Monitoring Systems

- Monitoring for Rodent Control
- Monitoring of different Insects
- Possibilities of visual Control
- Evaluation and interpretation of the Monitoring Data
- How to start such systems

GERHARD KARG, *B.U.G.S*

The Pest Management Standard in Pharma - Non-Toxic, zero tolerance and IoT Solutions

- Challenges of pest Management without biocides
- The strength of direct and interactive web-based reporting
- Permanent remote monitoring
- IoT and other non-tox solutions
- Success by partnership

TINA GRAUWET, *SGS*

GxP compliant Pest Control in Pharmaceutical Laboratories

- Relating GxP Rules
- Survey about Pest Control Challenges in Pharmaceutical Laboratories
- Results and Outcome
- Take Home Message

MARTIN TABAK, *Xendo*

Case Study: Pest Control Strategy for a New Laboratory Building

- Overview about potential Pests in Lab and Laboratory Animal Husbandry
- Possibilities of Identification and Monitoring
- Riskevaluation relating to Preventive and Corrective Actions
- Implementation in a new Lab Building

DR JÜRGEN BALLES, *Labor LS*

Pest Control Strategies for Phytopharmaceutical Manufacturing

- Fundamental Requirements and Measurements
- "High Risk Area" Herbal Drugs Storage
- Pest Control in the context of GACP
- Case Studies
- Inspection Experiences

DR CORNELIA BODINET, *Schaper & Brümmer*

Picture: Labor LS

Endotoxin and Pyrogen Testing

20/21 November 2018, 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 2018

Moderator

Dr Friedrich von Wintzingerode, *Roche Diagnostics, Germany*
Senior Manager QC Microbiology. Lead of Endotoxin Expert Group Roche/Genentech.

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

On the evening of the first congress day, on 20 November 2018 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

MATHILDE ARNAULT, *Merck*. Research Scientist - BioMonitoring R&D.
DR BARBARA CAPECCHI, *GSK.* Senior Manager in Analytical Research and Development.
MARTINE CAROFF, *LPS Bioscience.*
WILMAR CORREA, *Research Center Borstel.* Chief Scientific Officer.
JOHN DUBCZAK, *Charles River Laboratories*. General Manager Microbioal Solutions Division.
DR ANJA FRITSCH, *Confarma.* Responsible for cell based bioassays (development and routine).
DR EELO GITZ, *Sanquin Reagents*. Project manager product development.
JESSICA HANKINS, *U.S. Food and Drug Administration*
YUTAKA KIKUCHI, *National Institute of Health Sciences (NIHS Japan)*
MARINE MARIUS, *Sanofi Pasteur.* Scientist in Analytical R&D Microbiology.
HANS NOORDERGRAAF, *Abbott Biologicals.* Global Microbiological Expert.
DR RUTH RÖDER, *Microcoat Biotechnologie.* Project Manager Endotoxin Services.
DR JAN ERIK RAU, *Lonza AG.* Head of QC Microbiology.
DR INGO SPREITZER, *Paul-Ehrlich-Institut (PEI) - German Federal Agency for Vaccines and Biomedicines*
Deputy Head of Section 1/3, "Microbial Safety and Parasitology".
SHABNAM SOLATI, *MAT BioTech.* Co-founder and Lead scientist.
KEVIN WILLIAMS, *BioMerieux.*
VERONIKA WILLS, *Associates of Cape Cod.* Assistant Manager of Technical Services.
DR FRIEDRICH VON WINTZINGERODE, *Roche Diagnostics.* Senior Manager Microbiology, Head of Roche/Genentech global Endotoxin Expert Group and Roche/Genentech global SME on microbial product contaminations.

Programme

20 November 2018, Düsseldorf/Neuss, Germany

Alternative Microbiological Methods: AstraZeneca's, Johnson&Johnson's, MSD's and Roche's Global Implementation Roadmap

MIRIAM GUEST, *AstraZeneca*
PHILIP BREUGELMANN, *JnJ*
MARJA CLAASEN, *MSD*
DR SVEN M. DEUTSCHMANN, *Roche*

Current US Regulation and FDAs Thinking

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

PDA LER Technical Report Scope, Overview, Impact on Industry

DR FRIEDRICH VON WINTZINGERODE, *Roche*

The Evolution of Endotoxin Test

- Advent of biologics
- Fever and biologics
- A modern biologics microbiological context
- Advent of recombinant Factor C
- Future considerations

KEVIN WILLIAMS, *bioMerieux*

LER – An alternative Explanation

JOHN DUBCZAK, *Charles River Laboratories*

Pyrogenicity of Food Supplements - Comperative Study of MAT, BET and rFC

- The issue of orally taken LPS-containing food supplements and immune-stimulants
- Testing of Pyrogenocity using MAT, BET and rFC
- Conclusions

STEFAN GÄRTNER, *Labor LS*

From First Evaluation to a Representative Endotoxin Test: a Story about Masking

- Relevant definitions
- Expectations (internal and external)
- Case study: step by step to a representative test
- Lessons Learned

DR JAN ERIK RAU, *Lonza*

An approach to LER (Low Endotoxin Recovery) & Update of EP chapter 5.1.10

- LER Phenomenon and implications for Influenza vaccine
- Study to execute with NOE or RSE?
- Results RSE LER study
- Proposal 5.1.10 change : comments to EP proposal
- New chapter requires Risk Assessment to conclude BET or MAT as reference method
- Risk Assessment detailed execution for Influenza vaccine process form Egg to Syringe
- Issues to implement MAT for a viral vaccine
- Conclusion

HANS NOORDERGRAAF, *Abbott Biologicals*

Evaluation of new solutions for endotoxin testing for water samples

- Comparison of LAL-based and new rFC assays
- Assay Duration
- Results in IU/mL
- PPC recovery
- Assay variability and invalidity rates

MARINE MARIUS, *Sanofi Pasteur*

(1->3)-ß-D-Glucan: A biological response modifier found as a contaminant in pharmaceuticals

- Description and sources of glucans
- Biological effects of glucans
- Glucan quantification
- Case studies documenting glucan contamination
- Biologics manufacturing approaches

VERONIKA WILLS, *Associates of Cape Cod*

Programme

21 November 2018, Düsseldorf/Neuss, Germany

ECA Analytical Quality Control Group: Aims, Achievements and Activities

GUIDELINES DEVELOPED BY THE ECA QC GROUP

- OOS
- OOE/OOT
- Data Governance (with the IT Group)
- Analytical Procedures Lifecycle Management (QbD for Analytical Procedures)

DR CHRISTOPHER BURGESS, *Chairman of the ECA QC Group*

Requirements of JP

YUTAKA KIKUCHI, *National Institute of Health Sciences (NIHS) Japan*

LPS Structure

MARTINE CAROFF, *LPS Bioscience*

Biophysical interpretation of a systematic comparison of MAT and BET for LER understanding

WILMAR CORREA, *Research Center Borstel*

Pyrogen and Endotoxin Testing – Where do we go?

- Testing for Pyrogens or for Endotoxin?
- Pyrogens: MAT in its variations
- Intrinsic pyrogenicity; new chapter under development
- Endotoxins: relevance of standard vs. NOE-preparations; regulation vs. science
- Current issues in detecting endotoxin and Non Endotoxin pyrogens
- rFC: current situation
- Will I see the day that it becomes compendial (I´m 51 years old ...), ?

DR INGO SPREITZER, *PEI, German Federal Agency for Vaccines and Biomedicines*

Monocyte Activation Test for predicting pyrogenic content in vaccines without animal models

- Development and validation of the Monocyte Activation Test using human PBMC to reliably quantify endotoxin and non-endotoxin pyrogens in a vaccine with intrinsic pyrogenicity
- Demonstration of a significant correlation between MAT values and LAL and RPT
- Implementation of the MAT as release testing for Bexsero in replacement of the canonical animal-based pyrogen tests (RPT and LAL)
- Additional applications of MAT as limit test to assess the absence of exogenous pyrogens in non-pyrogenic vaccine

DR BARABARA CAPECCHI, *GSK*

Challenges in applying the Monocyte Activation Test for routine testing in the QC environment

- MAT - Current regulatory perspectives
- Non endotoxin pyrogens – Standards for MAT needed
- How to choose the right cells - Sources and their variability
- Read-out of cytokines and their interpretation

DR RUTH RÖDER, *MicroCoat Biotechnologie*

Pyrogen detection with the cryopreserved PBMC-based MAT Cell Set: performance, study examples and challenges

- Characteristics and performance of Sanquin Reagents MAT Cell Set
- Examples of validation and drug release testing of plasma derived products
- Other critical aspects and tips for performing MAT

DR EELO GITZ, *Sanquin Reagents*

Pyrogen detection with the MM6 cell-line: implementation as a routine test

- Pyrogen testing: taking Non Endotoxin Pyrogens into consideration for patient safety
- Pyrogen testing and the 3Rs: replacing animal-based methods by Monocyte Activation Test
- Cell line-based MAT: key benefits and performances
- Validation of the MM6 cell-line based MAT: a robust and sensitive method
- How to implement cell-line based MAT in routine testing: example with different matrices

MATHILDE ARNAULT, *Merck*

DR ANJA FRITSCH, *Confarma*

Healthy human immune cells as pyrogen detection source and advancement of drug release testing

- An end-to-end process: MAT kit generation, test performance and product-specific validation
- Presenting the solution to recent EP criteria: MAT as risk assessment for the endotoxin test and replacement of RPT
- Advancing human health by maximising contamination detection capabilities
- The solution for pyrogenicity tests of medical devices

SHABNAM SOLATI, *MAT Biotech*

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 (0) 6221
84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.pharmalab-congress.com

Dates
Monday, 19 November 2018, 12.30 – 17.45 h
Tuesday, 20 November 2018, 09.00 – 18.00 h
Wednesday, 21 November 2018, 09.00 – 18.00 h
(Registration Monday, 19 November, 11.30 – 12.30 h and
Tuesday, 20 November/Wednesday, 21 November 08.00 – 09.00 h)

Venue
Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
41460 Neuss, Germany
Tel.: +49 (0) 2131 77 - 00
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emailus@cphotelduesseldorfneuss.com

Fees (per delegate plus VAT)
19 November 2018: Pre-Conference ,,1st International Mycoplasma qPCR Testing User Day" € 249,-
20 November 2018 € 690,-
21 November 2018 € 1.380,-

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! Charges are payable after receipt of the invoice.

Organisation & Contact
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For questions regarding reservation, hotel, organisation etc.:
Mr Ronny Strohwald (Organisation Manager) at +49 6221/84 44 51, or per e-mail at strohwald@concept-heidelberg.de

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Part of PharmaLab 2018, Düsseldorf/Neuss, Germany, 20-21 November 2018
☐ Pre-Conference ,,1st International Mycoplasma qPCR Testing User Day" (19.11.2018 incl. Networking Dinner) - € 249,- plus VAT
☐ Conferences on 20.11.2018 – € 690,- plus VAT
☐ Conferences on 21.11.2018 – € 690,- plus VAT
I would like to attend the following conference(s):
☐ **Rapid Microbiological Methods and Mycoplasma Testing** (20 November 2018)
☐ **Pest Control - from classic trap to digital control** (20 November 2018)
☐ **Endotoxin and Pyrogen Testing** (20/21 November 2018)
☐ Yes, I will participate in the Social Event on 20 November.
☐ Mr ☐ Ms

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E-Mail (Please fill in)

PLEASE NOTE: Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice!

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

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.gmp-compliance.org/privacy-policy). 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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