Image: Charles River Laboratories

The conferences are part of 2022 PharmaLab
Congress & Exhibition
Analytics•Bioanalytics•Microbiology
Düsseldorf, 21-23 November 2022

10 Years of Microbiology at PharmaLab

Modern and Alternative Microbiological Methods

Microbiological Quality of ATMPs

Endotoxin and Pyrogen Testing

Mycoplasma Detection

21-23 November 2022 | Düsseldorf/Neuss, Germany

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3rd International Mycoplasma qPCR Testing User Day
PharmaLab Pre-Conference Event | 21 November 2022

Background & Objectives

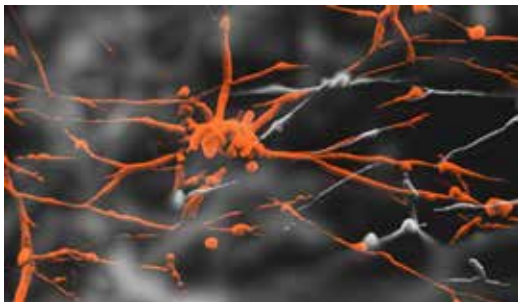
Mycoplasma contamination of biopharmaceutical products (also known as biologics or large molecules) resulting from cell culture contamination in the manufacturing process poses a potential health risk to patients. Mycoplasmas can affect virtually every cell culture parameter with often only minor visible effects, creating an uncontrollable environment that is undesirable in the 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 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
- Responsible Authority Employers

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



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).

Programme

Pitfalls and Issues on Mycoplasma Testing According to Pharmacopoeial Requirements - A Regulator´s View on
Jan Oliver Karo, Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines

dPCR Quantified Mycoplasma Standards – a New Level of Confidence

- Why do we need new methods in DNA standard production?
- Production process of Mycoplasma DNA standards
- Quality control of Mycoplasma DNA standards
- Application data using these standards

Dr Miriam Dormeyer, Sartorius

Challenges During the Validation of an Alternative Mycoplasma Detection Method

- Validation as a release assay
- Mycoplasma reference stocks
- Potential options for extended applications

Christiana Schnitzler, Boehringer Ingelheim

Mycoplasma Testing for ATMPs: Rapid Methods and Validation Strategies

- Rapid DNA-based methods in general
- Product specific method selection
- Validation examples on ATMPs

Dr Stefanie Bayer, Labor LS

Mycoplasma Testing – An Update of RtR at Janssen Biologics BV
Orm Nieuwenhuizen, Janssen Biologics

Validation of DNA Extraction Robots - The Balance between GMP Annex 11 v. Actual Best Performance
Jo Milne, Mycoplasma Experience

Recent Revision Proposal of Ph. Eur.-Chapter 2.6.7 "Mycoplasmas": What is proposed to be changed and why?

- Introduction
- Note on the General Chapter
- Stakeholder Feedback via Public Consultation Process of PharmEuropa

Dr Sven M. Deutschmann, Roche, Member of the EP Expert Group

Alternative Adventitious Agents Detection Methods in Biopharmaceuticals: A Proposal for a Structured Best Practice Approach for their Evaluation, Validation and Implementation

- Introduction
- Framework Paper – A 9-Step-Approach

Dr Sven M. Deutschmann, Roche, Chair of Phamaceutical Microbiology Working Group

Moderation

Haidy Wafy, Roche

Endotoxin and Pyrogen Testing
22/23 November 2022

Background & 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.
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.

Target Audience

This conference is addressed to all persons from pharmaceutical manufacturers, biopharmaceutical companies, contract laboratories, tissue establishments and authorities who are involved in Endotoxin- and Pyrogen Testing.

Picture: Charles River Laboratories

Programme Day 1

KEYNOTE Presentation at the Plenum
Biological Manufacturing – Demanding Quality and Compliance Requirements
Dr Tilman Rock, SVP, Site Head Vienna (Austria), Boehringer Ingelheim Biopharma

Pyrogenicity: The transition from RPT to MAT
- Highlights of the new 2.6.30 draft
- The strategy of the EDQM
- How to convert product specific RPT-Limits to the MAT
- Issues with spike recovery

Dr Ingo Spreitzer, Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines

Advantages of the Monocyte Activation Test in Quality Control Testing of Lifecycle Products
- Development roadmap of semi-quantitative and quantitative Monocyte Activation Test (MAT) tests based on product features (product responses and matrix interference aspects will be analyzed)
- Case studies of semi-quantitative and quantitative MAT methods (a not intrinsically pyrogenic product and product derived from Lipopolysaccharides will be presented as case studies for the two methods, respectively)
- Effective assessment of pyrogens detectability by applying the final methods format
- Advantages of MAT implementation for routinary control of products' pyrogenicity

Dr Liliana Alleri, GSK

Optimization of the Monocyte Activation Test to assess Reactogenicity of Outer Membrane Vesicle Vaccines
- Determining reactogenicity of a concept pertussis Outer Membrane Vesicle (OMV) vaccine from Intravacc with Bexsero as a reference using a cryopreserved pooled PBMC-based MAT
- Comparison of a fetal bovine serum- versus a human AB serum-based MAT: investigating the potential interfering effect of serum antibodies in human AB serum
- Utilization of the optimal MAT assay to test concept OMV vaccines from different bacterial species
- Comparison of the MAT assay results with the results of an adjusted rabbit pyrogen test

Dr Marijke Molenaar-de Backer, Sanquin

Generic Method and Specific Product Validation of the Monocyte Activation Test
- Replacement of RPT with MAT
- Generic Method Validation
- Product specific verifications in combination with one generic method validation

Dr Jonas van den Berg, Roche; Maria Gajewi, Microcoat

Development and Validation of the Monocyte Activation Test (MAT) for Parenteral Preparations that still require RPT Testing for Regulatory Compliance

- The development and validation of five parenteral preparations (e.g., Glucose, Deferoxamine, Cloxacillin, Amikacin, and Ceftriaxone) still requiring RPT testing, using the MAT pyrogen-assay
- Replacing the Rabbit Pyrogen Test (RPT) with the Monocyte Activation Test (MAT)
- A single donor product-specific validation strategy to validate the Monocyte Activation Test (MAT)
- Product-specific validation of Glucose, Deferoxamine, Cloxacillin, Amikacin, and Ceftriaxone using the Monocyte Activation Test (MAT)

Dr Koen Marijt, MAT Research

Monocyte Activation Test as the Sole Tool to identify Synergistic Effects when Parenteral Drugs are contaminated with Multiple Pyrogens

- The unique efficacy of MAT to detect the synergistic effects of mixed pyrogen and its impact on drug safety
- Studying the synergetic effect of mixed pyrogens in different drug categories
- MAT as the ultimate solution to ensure pyrogen-free medical devices
- Studying Material Mediated Pyrogenicity in testing medical devices

Shabnam Solati, CTL-MAT

Monocyte Activation Test: A Pyrogen Detection Solution for Gene Therapy Products?

- Why pyrogen testing should be considered for gene therapy products?
- Evaluation of the potential interfering elements for the MAT
- Development of solution to reduce or eliminate interferences
- How to manage inherent pyrogenicity of the gene therapy products components?

Anne Claire Erba, Merck

Alternative Pyrogen Methods: FDA Case Studies

- Update to the FDA position on alternative pyrogen methods
- FDA Case studies:
  - Case-Study 1: Recombinant Factor C
  - Case-Study 2: Monocyte Activation Test
  - Case-Study 3: Rabbit Pyrogen Test

Dr Reyes Candau-Chacon, FDA, USA

Alternative Approaches to Medical Device Testing with the MAT

- Ph. Eur. Chapter 2.6.30-based testing of medical devices
- Differences in testing to parenteral drugs
- Importance of additional controls and alternative pyrogen limits

Dr Sandra Stoppelkamp, University Tübingen

Interleukin Interference During MAT Testing

- The challenge
- Mitigation strategy
- Dedicated case study

Rene B. Ørving, Novo Nordisk

Validation of the Monocyte Activation Test with Three Therapeutic Monoclonal Antibodies

- MAT
- GMP validation
- European Pharmacopoeia method
- Cryo-preserved PBMC
- Regulatory approval

Dr Ruth Daniels, Janssen

Programme Day 2

KEYNOTE Presentation at the Plenum
Impurities - USP Draft Chapter <477>
User-Determined Reporting Thresholds (UDRT), and Other Relevant Chapters

Dr Christian Zeine, Senior Manager Scientific Affairs EMEA, USP

LER Challenges and their Solutions – A Case Study

- Identification of LER and its consequences
- Strategies to mitigate a LER effect
- Dedicated case study

Harald Meißner, Morphosys

Validation of a Dedicated Sample Preparation Method

- Demasking as sample treatment to overcome LER effect
- Validation of a rFC based method
- Combination of demasking and rFC as release test for DP

Dr Gertrud Lallinger-Kube, Boehringer Ingelheim
Dr Michael Kracklauer, Microcoat

Reducing the Environmental Impact on LAL Testing and Improving Employee Sustainability Utilizing Microfluidic Technology for BET

- Reduction in LAL reagent (90% less for 21 samples)
- Maintain data integrity adherence/ 21 CFR Part 11 and ACLOA + -Improve system implementation and cGMP release for products
- Define how centripetal microfluidics work with less reagent and easier set up
- Reduce cold room storage and minimize cost

Hayden Skalski, Veolia Water Technologies and Solutions

Custom Made iPSC-Derived Macrophages as an Efficient Tool for Next Generation Pyrogen Testing

- Fully defined iPSC-derived macrophages(iMonoMac) present a novel cell type for MAT testing given their high sensitivity to a variety of pyrogens, with broad dynamic range
- Standardized iMonoMac from fully defined donors reflect the donor dependent sensitivity to pyrogens in direct comparison to in vivo counterparts
- iMonoMac display superior sensitivity to pyrogen stimulation compared to approved monocytic cell standards in MAT testing
- Reporter-based iMonoMac pave the path for an automated/high throughput next generation MAT based parenteral testing

Shifaa Abdin, Hannover Medical School

Depyrogenation by Moist Heat: How Removing Endotoxins in an Autoclave; Time/Temperature Results on different Endotoxins located in/on Different Substratesng MAT Testing

- Depyrogenation by moist heat treatment: a comparison between CSE and NOE
- Moist heat depyrogenation, a case study (Hyaluronic acid)

Maria Luisa Bernuzzi, Fedegari; Alessandro Pauletto, CRL

How to increase Sustainability in QC Testing? Future Proofing Pyrogen Detection

- Increase sustainability – from the rabbit test to LAL and now, MAT and recombinant endotoxin detection methods
- Challenges and opportunities when switching from traditional animal-based to cell based or recombinant methods
- Comparison of traditional and recombinant reagents in detecting endotoxin in "naturally" contaminated, representative pharma products
- Automation to reduce retesting rates due to human errors
- Putting it all together: "Error-proofing" and "Future proofing" pyrogen testing

Allen Burgenson, Lonza

Implementing Annex 1 Revisions: Improving Biofilm Detection in WFI Systems Using Rapid LAL Methods
- Enhanced requirements within the Annex 1 revision related to WFI
- Routine monitoring of water systems for Gram-negative endotoxin as an early warning of adverse drift
- How rapid LAL technologies can be utilized early on to detect the presence of biofilm in a WFI system

Jordi Iglesias, Charles River Laboratories

Recombinant Reagents for BET – Regulatory Landscape, Comparability Studies and Their Future Routine Use including Automation
- Overview of the types of recombinant technologies and key differences
- Regulatory landscape around the use of recombinant reagents as alternatives to LAL reagents
- Comparability studies
- Product specific method validation approach
- The future applications of recombinant reagents
- Automation of the use of recombinant reagents and their use for water samples

David Guy, ACC

The rFC Journey: Validation for Water Testing Completed – What's Next?
- Change strategy for method implementation
- Regulatory assessments
- Feedback from Health Authorities
- Method transfer to other sites
- Not an animal-free method, but still a sustainable and 3R-compliant method

Carmen Marín Delgado de Robles, F. Hoffmann-La Roche

Endotoxin Testing: LAL, rFC and Semi-Automation
- Implementation of new technologies for endotoxin testing
- New solutions in LAL testing
- How to increase the throughput - a simple way through rFC
- Semi-automation of the assays

Marine Marius, Sanofi

Diversity, Complexity, and Originality of Lipopolysaccharides Structures
- General LPS structure
- Natural LPS diversity
- Adaptation of structures according to growth conditions
- Challenges in Endotoxin detection

Dr Martine Caroff, LPS Biosciences

Moderation

Dr Johannes Reich, Microcoat

Speakers

Shifaa Abdin | *Hannover Medical School, Germany.*
PhD Candidate Applied Stem Cell and Translational Macrophages Research.

Dr Liliana Alleri | *GSK, Italy.*
Analytical Science and Technology.

Maria Luisa Bernuzzi | *Fedegari Group, Italy.*
R&D Manager.

Allen Burgenson | *Lonza, USA.*
Associate Director, Global SME Testing.

Dr Reyes Candau-Chacon | *FDA, USA.*
Microbiologist in Branch 2 of the Division of Biotechnology Manufactruing (DBM), Office of Pharmaceutical Quality (CDER).

Dr Martine Caroff | *LPS Biosciences, France.*
Chairwoman and CSO.

Dr Ruth Daniels | *Janssen, Belgium.*
Senior Scientist Microbiology CoE.

Carmen Marín Delgado de Robles | *F. Hoffmann-La Roche, Switzerland.* QC Scientist Microbiology.

Anne Claire Erba | *Merck, France.*
Senior Scientist.

Maria Gajewi | *Microcoat, Germany.*
Project Leader.

David Guy | *ACC, UK.*
European Sales Manager.

Jordi Iglesias | *Charles River Laboratories, Spain.*
Technology and Market Development Manager.

Dr Koen Marijt | *MAT Research, The Netherlands.*
Co-founder & Lead scientist.

Dr Michael Kracklauer | Microcoat, Germany.
Manager Endotoxin Services.

Dr Gertrud Lallinger-Kube | *Boehringer Ingelheim, Germany.*
Bio Process Analytics.

Marine Marius | *Sanofi, France.* Senior Scientist.

Harald Meißner | *Morphosys, Germany.*
Senior Director, Head of Quality Control.

Dr Marijke Molenaar-de Backer | *Sanquin, The Netherlands.*
Manager MAT Service Testing.

René Ørving | *Novo Nordisk, Denmark.* Research Scientist.

Alessandro Pauletto | *Charles River Laboratories, Italy.*
Senior Technical Service Coordinator.

Dr Johannes Reich | *Microcoat, Germany.* General Manager

Hayden Skalski | *Veolia Water Technologies and Solutions, USA.*
Lead Global Applications Specialist, Product Management.

Shabnam Solati | *CTL-MAT, USA.* CEO.

Dr Ingo Spreitzer | *Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines.* Deputy Head at PEI and Chair EDQM Working Party "Bacterial Endotoxin Test.

Dr Sandra Stoppelkamp | *University Tübingen, Germany.*
Expert MAT Medical Devices.

Dr Jonas van den Berg | *Roche, Germany.*
Global Quality Manager.

Alternative and Rapid Microbiological Methods
22/23 November 2022

Background & 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 conference 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.

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 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

Programme Day 1

KEYNOTE Presentation at the Plenum
Biological Manufacturing – Demanding Quality and Compliance Requirements
Dr Tilman Rock, SVP, Site Head Vienna (Austria), Boehringer Ingelheim Biopharma

Game Changer? Use of Rapid Microbiological Methods (RMM) in the GMP - Quality Control Lab

- Comparison between established EP and new rapid methods
- Advantages of RMM for batch release
- Validation of RMM for the use in GMP labs
- Some case studies and examples

Dr Philipp Kucera, VelaLabs

Next Generation Sequencing: Current Trends and Perspectives for Pharma and Biotech

- Introduction to NGS and Ion Torrent Technology
- Overview of Thermo Fisher Scientific Ion Torrent NGS instruments and sequencing strategies
- NGS Applications for Pharma and Biotech Laboratories
- Demonstration of GMP compliance strategies for NGS

Dr Inanc Deger Erserim, Thermo Fisher

MS for ID - Regulatory Changes and their Influence of ID in Laboratory

- The trend towards the rapid and reliable identification of microorganisms
- Revision of Annex 1 is mandating microbial testing in more cases?
- MALDI-TOF MS - current developments of platform, database etc.
- Case Studies: Laboratory testing such as environmental, water and production operator monitoring and management of microbial suspensions and strains

Dr Gerold Schwarz, Bruker

New Solid Phase Cytometry Method

- Solid Phase Cytometry and Artifical Intelligence
- 5 Key automated steps
- Possible Applications

Dr Wilfried Ablain, Microbs

Case Studies on Burkholderia Cepacia Complex (BCC) Investigations, QC Lab Testing and Remediation

- Understand the sources of BCC contamination in manufacturing unit operations, facilities and water systems
- Learn the appropriate sampling and test methods for detecting BCC by the QC micro laboratory
- Review recent regulatory deficiencies associated with BCC contamination and the impact on industry
- Introduce methods to remediate BCC contamination and prevents its reoccurrence
- Review case studies on where BCC has been recovered and how the micro lab took the right samples to detect its presence

Dr Michael Miller, Microbiology Consultants

ATP Bioluminescence for Non-sterile Product Testing: Roadmap to Implementation

- Importance of method screening and feasibility studies for the selection of an RMM
- Worldwide introduction of the ATP bioluminescence system for testing non-sterile materials
- Validation approach according to USP <1223>, Ph. Eur. 5.1.6 and PDA TR33

Inge van der Schoot, J&J

Alternative and Rapid Microbiological Methods
22/23 November 2022

Next Level Environmental Monitoring - Automated Filamentous Fungi Detection

- Regulatory requirements on species detection
- The past and the future of filamentous fungi detection in Environmental monitoring testing
- Application validation and detection performance

Johannes Oberdörfer, Rapid Micro Biosystems

Non-inferiority Testing for Qualitative Microbiological Methods: Assessing and improving the Approach in USP <1223>

- Explain in which situations the statistical approaches suggested in USP<1223> are or are not suitable, and in which situations they may incorrectly claim non-inferiority
- Present a more general statistical approach that:
  - is independent of the exact spike levels used
  - purely measures the microbiological method performance
  - has higher power than the MPN-based USP approach

Dr Pieta IJzerman-Boon, MSD

Moderation

Dr Sven M. Deutschmann, Roche

Programme Day 2: Please note that the second day (23 November) will be held together with the conference on *Cells, Tissues and ATMPs*.

Speakers

Dr Wilfried Ablain | *Microbs, France.*
CEO.

Dr Inanc Deger Erserim | *Thermo Fisher, Germany.*
Senior Product Specialist NGS.

Dr Sven M. Deutschmann | *Roche, Germany.*
Member of the EP Expert Group & Chair of the Phamaceutical Microbiology Working Group.

Dr Pieta IJzerman-Boon | *MSD, The Netherlands.*
Principal Statistician.

Dr Philipp Kucera | *VelaLabs, Austria.*
Quality Assurance Officer.

Dr Michael Miller | *Microbiology Consultants, USA.*
President.

Johannes Oberdörfer | Rapid Micro Biosystems, USA.
Field Application Scientist.

Inge van der Schoot | *J&J, Belgium.*
Senior Scientist Microbiology CoE.

Dr Gerold Schwarz | *Bruker, Germany*.
Manager Application Support.

Programme Day 2

KEYNOTE Presentation at the Plenum
Impurities - USP Draft Chapter <477> User-Determined Reporting Thresholds (UDRT), and Other Relevant Chapters

Dr Christian Zeine, Senior Manager Scientific Affairs EMEA, USP

Regulatory Expectations for Rapid Sterility Testing of ATMPs

- Understand the regulatory enablers, policies and expectations for rapid sterility testing of ATMPs
- Discuss validation strategies, including the use of stressed and slow-growing organisms
- Review expectations for demonstrating limit of detection (LOD), specificity, method suitability and equivalence to the compendial sterility test

Dr Michael Miller, Microbiology Consultants

Implementation of a Comprehensive Rapid Microbial Contamination Control Platform for Testing of Sterile Pharmaceuticals and Cell-Based Therapies using ATP Bioluminescence

Various applications and possible uses of this ATP bioluminescence technology

- Practical experience with
  - Implementation
  - Validation
  - Verification

Stefan Gärtner, Labor LS

Dr Lucia Ceresa, Charles River Laboratories

Ultra-Rapid Microbial Detection in Cell & Gene Therapy Products: the closest you can be to Real-Time Release

- Development of a specific C&GT ultra-rapid sterility test application
- Comparison to methods currently in use
- Matrix compatibility / method suitability
- Future validation approaches

Corinne de la Foata, bioMerieux

Viral Safety – Evaluation of Eukaryotic Cell Bank Purity with a Special Focus on Adventitious Agents and Replication Competent Viruses

- Evaluation eukaryotic cell banks:
  - Determination of adventitious agents in vitro by sophisticated cell culture technologies (Ph. Eur. 2.6.16 / 5.2.3)
  - Evaluation of defined virus induced effects such as cytopathic effect (CPE), Hemadsorption, Hemagglutination
  - Alternative methods for testing of Adventitious Agents
- Short view on Prokaryotic cell banks à purity and bacteriophage contamination

Marina Jorge Miranda, Tentamus

Short Shelf Life and Sterility Testing - Challenges of Cell-Based ATMP Market Supply

- Sterility: Quality by Design tools applied
- Technical challenges: solutions and questions

Mareike Klingler, Tetec

Rapid Sterility by qPCR for ATMPs

- The compendial methods for sterility testing of cell and gene therapy products (ATMPs) USP <71>, Ph. Eur. 2.6.1 and Ph. Eur. 2.6.27
- USP <1223>, Ph. Eur. 5.1.6. and TR#33 - the Possibility of using alternative test methods
- Current alternative methods their incubation time incubation time and matrix interference
- Important distinction between background contamination (DNA) and viable microorganisms
- Method combining bacterial growth and enrichment with qPCR

Dr Anja Fritsch, Confarma

ScanRDI System - Validation and Implementation of an Alternative Sterility Test (Solid Phase Cytometry) for a Cell and Gene Therapy Product

- Overview of the ScanRDI system - detection principle and workflow
- Why the ScanRDI for cell-based products? - Results of the ScanRDI evaluation study
- Overview of ScanRDI - validation results for cell-based products
- Current status of ScanRDI - evaluation for in-process control (media/buffer)
- Risks and challenges of the ScanRDI method

Mahsa Mohammadi, Novartis

Implementation of a Real Time PCR-based Method for Release Testing the Sterility of ATMPs, a Practical Approach

- Real Time PCR method as sterility test for cellular products and the detection limit according to Pharm. Eur. 2.6.27
- Special requirements of a molecular biological method (multi-room concept)
- Practical implementation taking into account possible risk factors

Yasmin Heynen, Labor LS

Moderation

Dr Michael Miller, Microbiology Consultants

Speakers

Dr Lucia Ceresa | *Charles River Laboratories, Italy.*
Senior Technology and Market Development Manager.

Corinne de la Foata | *bioMerieux, France.* R&D Senior Manager.

Dr Anja Fritsch | *Confarma, France.*
Scientific Officer.

Stefan Gärtner | *Labor LS, Germany.*
Head of Department - Sterile Products Rapid and Alternative Methods.

Yasmin Heynen | *Labor LS, Germany.*
Biological Laboratory Technician.

Marina Jorge Miranda | *Tentamus Pharma & Med, Germany.*
Deputy Head of Cell- and Immune Analytics.

Mareike Klingler | *Tetec, Germany.*
Technician Quality Control Microbiology / Sterility testing.

Dr Michael Miller | *Microbiology Consultants, USA.*
President.

Mahsa Mohammadi | *Novartis, Switzerland.*
Senior AS&T Specialist/ Analytics, Launch and Transfer-Large Molecules.

Exhibitors Information

The Exhibition

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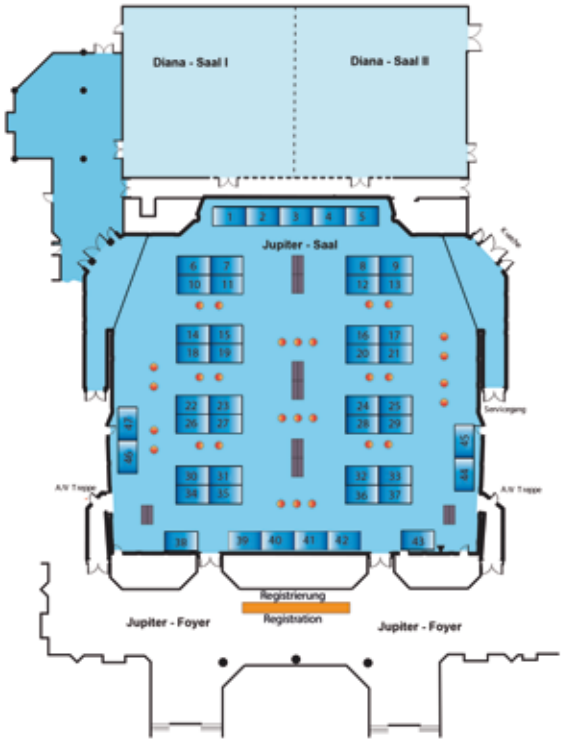
As an exhibitor in the PharmaLab exhibition you can take advantage of the unique opportunity to directly address users and decision makers in the areas analytics, bioanalytics, from microbiological laboratories, Quality Assurance and Quality Control. In addition to high-level discussions during the Congress you can also get in touch with Congress delegates and with speakers during the Social Event.



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- an ad in the GMP Journal (subject to extra charges) – get directly in touch with your target group

You will find more detailed information on these materials on the Congress website at www.pharmalab-congress.com.

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Ronny Strohwald, (Organisation), Tel. +49 (0) 6221/84 44-51,
E-Mail: strohwald@concept-heidelberg.de.

Easy Registration

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Internet:
www.pharmalab-congress.com
www.pharmalab-kongress.de

Dates
Monday, 21 November 2022, 11.30 – 18.00 h
Tuesday, 22 November 2022, 09.00 – 18.00 h
Wednesday, 23 November 2022, 09.00 – 18.00 h
(Registration Monday, 21 November, 11.00 – 11.30 h and
Tuesday, 22 November/Wednesday, 23 November 08.00 – 09.00 h)

Venue
Crowne Plaza Hotel Düsseldorf / Neuss
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41460 Neuss, Germany
Tel.: +49 (0) 2131 77 - 00
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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

Social Event
On 22 November you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Registration Options
I want to take part in:
- ☐ PharmaLab Pre-Conference Workshop "3rd International Mycoplasma qPCR Testing User Day" (21 Nov 2022) - € 590,- plus VAT
- ☐ PharmaLab Conferences on 22 Nov 2022 – € 690,- plus VAT
- ☐ PharmaLab Conferences on 23 Nov 2022 – € 690,- plus VAT

With a one day ticket/two days ticket for the PharmaLab Conferences (22 Nov/23 Nov 2022) 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, we would appreciate it if you marked the conference you are interested in. Please also mark the day you plan on attending the Congress.

Please mark only one conference per day.

- ☐ I would like to attend on **day 1 (22 November 2022)** and I'm primarily interested in the conference:
  - ☐ ECA – Analytical Procedure Life Cycle Management - ICH Q14/ICH Q2(R2)
  - ☐ ECA – Endotoxin and Pyrogen Testing (Day 1)
  - ☐ ECA – Alternative and Rapid Microbiological Methods (Day 1)
  - ☐ ECA – Cells, Tissues and ATMPs – Quality Control (Day 1)

  - ☐ I would also like to take part in the Social Event on the evening of 22 November.

- ☐ I would like to attend on **day 2 (23 November 2022)** and I'm primarily interested in the conference:
  - ☐ ECA – Laboratory Optimization, Automation and Digitalization
  - ☐ ECA – Endotoxin and Pyrogen Testing (Day 2)
  - ☐ ECA – Cells, Tissues and ATMPs and Alternative Microbiological Methods (Day 2)

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

☐ Mr ☐ Ms ☐ Dr

First name, Surname

Company

Department

Important: Please indicate your company's VAT ID Number P.O. Number (if applicable)

Street/P.O. Box

City Zip Code

Country

Phone/Fax

E-Mail (please fill in)

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
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks 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 dedutions- 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)! German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. CONCEPT HEIDELBERG will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. CONCEPT HEIDELBERG will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at 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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