11th PharmaLab Congress

Analytics ▪ Bioanalytics ▪ Microbiology

20 November: Pre-Conference Event

4th International Mycoplasma qPCR Testing User Day

21/22 November 2023: Congress & Exhibition

With 5 Parallel Conference Tracks

Düsseldorf, Germany

Highlights

- Method Validation and Life Cycle Management
- Laboratory Optimisation and Automation
- Modern and Alternative Microbiological Methods
- Cell and Gene Therapies/ATMPs - Quality and Safety
- Endotoxin and Pyrogen Testing
- Mycoplasma Detection
- Outsourcing in Pharmaceutical Laboratories

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All information can be found at: www.pharmalab-congress.com

The Congress Objectives

2022, the first year after the pandemic, the 10 PharmaLab has attracted more participants to Neuss/Düsseldorf than ever before. With this success as a template, the 11th PharmaLab Congress will again be held on site in Düsseldorf/Neuss from 21-22 November 2023. The congress, which is aimed at employees and managers in all laboratory areas of the pharmaceutical industry, is composed of a pre-conference workshop, 6 international conferences from the fields of analytics, bioanalytics, microbiology and CGT/ATMP, as well as the accompanying exhibition. It will provide information on the latest developments in laboratory methods, systems, materials and the current status of regulatory requirements of pharmacopoeias and guidelines. In addition, experts from authorities, industrial quality control and contract laboratories will present their experiences with the use and qualification of analytical systems as well as with the validation of analytical methods and microbiological tests. Take advantage of this unique opportunity to learn about the state of the art in pharmaceutical laboratories and discuss current developments with speakers and colleagues.

Background

Laboratory work is an important part of pharmaceutical research, development and quality control. Especially for modern products, e.g. cell and gene therapy, modern vaccines and the like, it is becoming increasingly important to select analytical methods, bioassays or microbiological controls at an early stage so that they can later be used under GMP requirements. During inspections, regulatory authorities have also increasingly focused their attention on the quality management and performance of laboratories and their quality standards. These inspections by regulators require laboratories to implement GLP- and GMP-compliant systems and methods. They expect:

- General GLP or cGMP understanding and especially with respect to compliance with written procedures.
- Validation, implementation and transfer of analytical methods and microbial tests, especially for alternative test methods, like MAT, rFC etc.
- Validation of analytical methods according to the new USP life cycle model, especially with the update of ICH Q2 (R1) and ICH Q14
- Computer validation (including interpretation of EU GMP Annex 11 and 21 CFR Part 11 and actual laboratory data integrity requirements)
- User training

Target Audience

Especially for pharmaceutical products and active substances of biological origin, classical analytical and testing methods are not suitable. Newly developed methods like MAT for pyrogen tests, rapid methods for sterility tests or necessary bioassays for cell based and gene therapy products require a permanent knowledge update and training of the laboratory personnel and the involved staff.

This conference is of interest to:

- Laboratory managers, supervisors and analysts in pharmaceutical quality control departments
- Laboratory personnel in research and development
- Responsible authorities
- Laboratory suppliers
- Staff of contract laboratories
- QC responsible staff

Conferences Overview

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4th International Mycoplasma qPCR Testing User Day
PharmaLab Pre-Conference Event | 20 November 2023

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.

Programme

- **Current Revision of Ph. Eur. chapter 2.6.7 Mycoplasmas and its Impact on other Ph. Eur. Texts**
  Dr Thuy Bourgeois, EDQM Strasbourg, France

- **NAT-based Methods for Mycoplasma Testing – Validation Strategy in the View of the Revision of the European Pharmacopoeia Chapter 2.6.7**
  Yasmin Heynen, Labor LS

- **Next Generation PCR Closed System Allowing for 1-Hour Mycoplasma Release Test of CGT Products**
  Dr Caroline Kassim, bioMérieux

- **Development of a Digital PCR-based Mycoplasma Detection Kit**
  Dr Nicole Paland, Minerva Biolabs

- **Mycoplasma Real-Time PCR: Generic Method Validation of T-cell Culture**
  Alexander Bartes, Roche

- **Change of Mycoplasma NAT-based Method: Management of a Kit Discontinuation**
  Marine Marius, Sanofi

- **Mycoplasma Testing & Evaluation for ATMPs – lessons learned!**
  Olga Müller, Tetec

- **Mycoplasma Testing – Experiences and Thoughts**
  Jan-Oliver Karo, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines

Congress Key Note

Key Notes:

21 November 2023:

The Impact on the Revised Annex 1 for Rapid Microbiological Methods Implementation

Dr Michael Miller

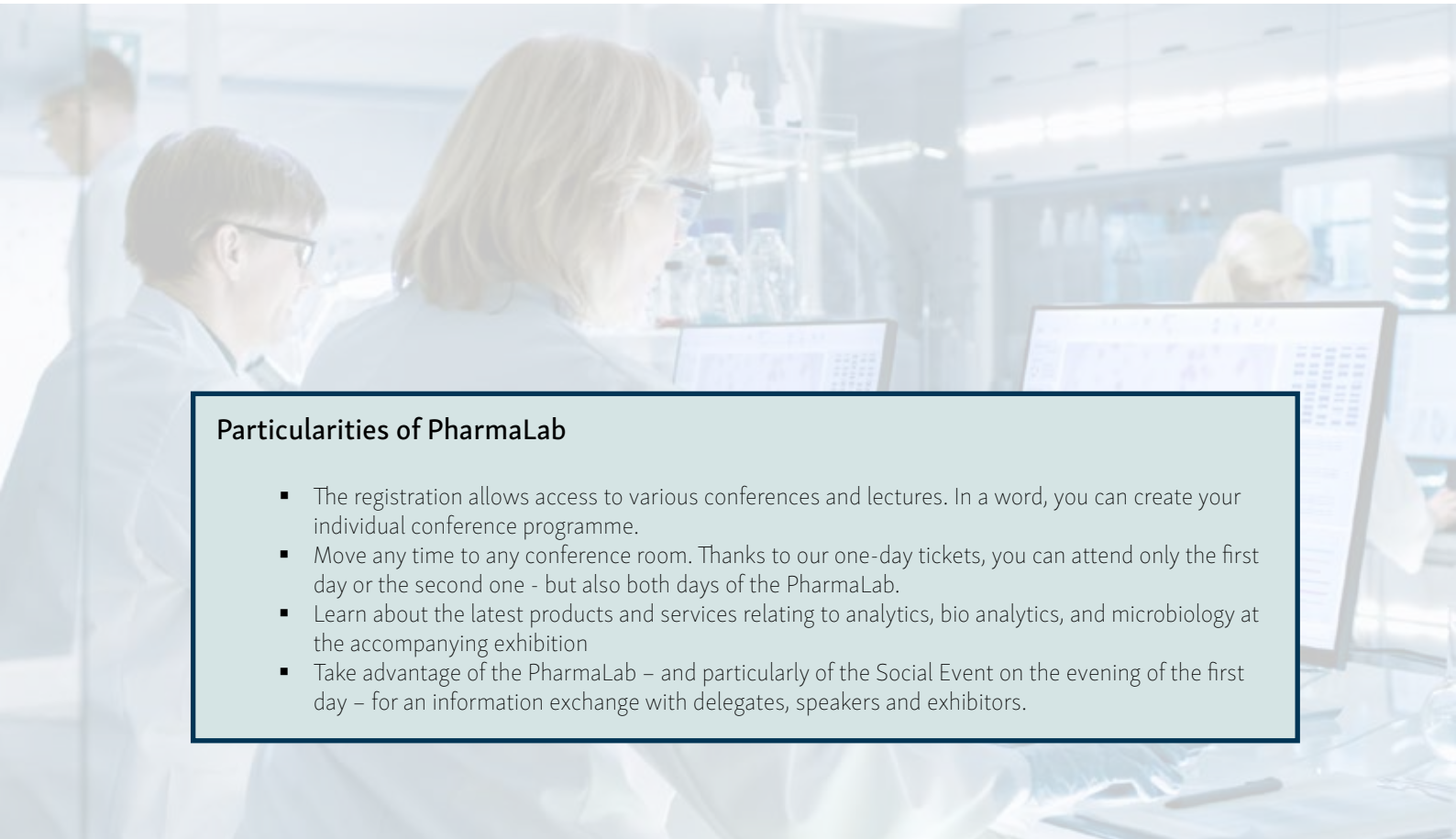
The revised EU Annex 1 now highlights the quality benefits of employing rapid methods in place of slower, conventional methods for the detection of contaminants and to reduce the risk to product. This presentation will highlight the most relevant changes as they apply to the validation and implementation of rapid methods. Of note, attendees will learn encouraging changes that allow for action levels to be determined based on rapid method signals, rather than the conventional colony forming unit (CFU). Examples of how real-time rapid methods for environmental monitoring can be utilized to meet the guidance specified in the revised Annex 1 document.

1. Understand the changes to Annex 1 as they relate to rapid methods for environmental monitoring and product safety.
2. Learn how to establish new action levels based on new rapid method signals, rather than the CFU.
3. Explore technologies/scientific principles aligned with Annex 1's commitment to advancing the detection of microorganisms during sterile drug manufacturing.
4.Discuss how rapid methods may be validated as alternatives to conventional EM test methods.

22 November 2023:

Preparedness in pandemic vaccine manufacturing and deployment

Prof Dr Isabelle Bekeredjian-Ding



Particularities of PharmaLab

- The registration allows access to various conferences and lectures. In a word, you can create your individual conference programme.
- Move any time to any conference room. Thanks to our one-day tickets, you can attend only the first day or the second one - but also both days of the PharmaLab.
- Learn about the latest products and services relating to analytics, bio analytics, and microbiology at the accompanying exhibition
- Take advantage of the PharmaLab – and particularly of the Social Event on the evening of the first day – for an information exchange with delegates, speakers and exhibitors.

GMP Compliance Trends in Analytical Laboratories/Out-sourcing in Pharmaceutical Laboratories | 21 November 2023

TRACK 1

Background & Objectives

It is the aim of this course to address GMP compliance issues that are currently discussed as hot topics in analytical quality control laboratories and during GMP-/FDA-Inspections.

Furthermore, this conference will highlight the wide range of regulatory requirements and practical aspects that need to be considered when testing on a contract basis. The conference in particular addresses topics that are relevant from a GMP point of view.

Due to changing regulatory requirements, pharmaceutical quality control units are continuously facing new challenges. There are many regulatory requirements relevant for the pharmaceutical quality control, both in EU and in the US. Laboratory Managers and Analytical Scientists must be familiar with the different GMP-related topics and must be aware of the latest updates and the current interpretation.

Outsourcing is one of the critical process in the pharmaceutical industry. According to the EU GMP Guidelines (Chapter 7 – Outsourced Activities) *"any activity covered by the GMP Guide that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party. The Quality Management System of the Contract Giver must clearly state the way that the Qualified Person certifying each batch of product for release exercises his full responsibility."*

There are various reasons for outsourcing analytic testing. Tests are sometimes outsourced only for specific projects. However, the analyses are sometimes conducted externally for each batch of a product in routine quality control, for example if the manufacturer does not have the necessary know how or the required capacity.

This conference therefore deals with the following topics:

- Data Integrity
- Regulatory and legal requirements
- Business Continuity
- Selection and management of partners
- Practical aspects to consider when establishing contracts
- Auditing contract laboratories

Target Audience

This conference will be of significant value to

- Laboratory managers, supervisors and analysts
- Quality control managers
- Heads of quality control
- Qualified Persons (QPs)
- Analytical scientists
- Senior laboratory staff
- Responsible authorities

This conference is also intended for employees in Quality Assurance and from contract laboratories. Furthermore, it is useful for service providers, such as contract research organisations and contract manufacturers.

Programme

- **Data Integrity and Cloud Computing in GMP Compliant Laboratories – Presence, Future or a Contradiction? A Perspective from the Eyes of a GxP Auditor**
  Dr Timo Kretzschmar, Inosolve
- **Business Continuity in cGMP**
  Alexander Pfülb, Labor LS
- **Shelf Life of Reagents in a Chemical-pharmaceutical Laboratory**
  Dr Jochen Kolb, BioChem
- **Understanding & preventing Human Errors**
  Dr Karl-Heinz Bauer, Boehringer
- **Microbiology Testing in Contract Labs**
  Dr Radhakrishna Tirumalai, MSD, formerly at USP
- **Transfer to External Partners - Overcoming Pitfalls in Analytical Method Transfers**
  Dr Holger Bauer, Merck
- **Case Study: Technologies that make Lab of the Future and drive Collaborative Innovation**
  Lukasz Paciorkowski, A4BEE

Background & Objectives

The aim of this conference is to show possibilities to optimize the organization of an analytical laboratory. The optimization of structures and processes in the laboratory are addressed. Furthermore, the possibilities of automation are presented and the benefits that can result from the optimization of the method portfolio. Equally, modern approaches to cost savings while maintaining GMP compliance will be presented.

The pressure that the pharmaceutical industry is under today to reduce costs and increase efficiency and effectiveness applies equally to analytical laboratories. Often waiting for the results of quality control is still a speed-limiting step in the entire production process.

With this conference, participants will get to know tools for more effective and efficient control of laboratory activities.

You become informed about:

- Optimization of laboratory processes - practical examples
- Cost-efficient design of a laboratory
- Case studies for laboratory automation/digitalization
- New analysis methods for the optimization of processes in the laboratory

Target Audience

This conference will be of significant value to

- Laboratory managers, supervisors and analysts
- Quality control managers
- Heads of quality control
- Qualified Persons (QPs)
- Analytical scientists
- Senior laboratory staff
- Responsible authorities

This conference is also intended for employees in Quality Assurance and from contract laboratories. Furthermore, it is useful for service providers, such as contract research organisations and contract manufacturers.

Programme

- **Annex 1: Data Analysis and Trending for Contamination Control**
  Dr Christina Müller, Boehringer Ingelheim Pharma
  Susan Cleary, Novatek International
- **Future QC Testing using Automation and Robotics – a Digitalized Foundation of Sterility Testing**
  Anke Hossfeld, Merck
- **Agile Validation**
  Mathias Fuchs, Wega
- **Challenges and Solution for the Performance Validation of EM Automation**
  Laura Bailac, bioMérieux
- **From Theory to Practice: Current Requirements for Microbiological Monitoring – Establishing Efficient Strategies for Microbiological Monitoring based on Integrated, Proprietary Software Tools**
  Melissa Schülein, Labor LS
- **Considerations when introducing Automated EM Systems in a Large Biopharmaceutical Company**
  Niels Visschers, MSD
- **Key to Digitalisation: Understanding and redesigning your Laboratory Processes**
  Dr Bob McDowall, R.D. McDowall Limited
- **Is my Contract Laboratory big enough for becoming Paper-Less? A Case Study**
  Alexander Doppelreiter, Reference Analytics
- **Key Performance Indicators (KPIs) in Pharmaceutical Quality Control Laboratories – Tools to measure and monitor Optimizations**
  Dr Karl-Heinz Bauer, Boehringer

Analytical Method Validation and Life Cycle Management - ICH Q14/Q2 (R2) | 21/22 November 2023

TRACK 2

Background & Objectives

The conference will present and highlight the current developments in the field of method validation and life cycle management. Experts from industry and laboratories will present the current status of the revision and the contents of the guidelines on the one hand, and their own experiences in the establishment and validation of methods and procedures on the other hand.

In March 2022 the European Medicines Agency (EMA) published the ICH guidelines Q2(R2) on validation of analytical procedures and the ICH Q14 on analytical procedure development for public consultation (Step 2b).

The previous harmonised guideline Q2(R1) has been in force in its current form since 2005. At that time, it combined the two guidelines Q2A, which contained analytical methods for required validation parameters, and Q2B, the methodology guideline. In 2018, it was decided to develop a new ICH quality guideline on analytical method development (ICH Q14) and to revise the ICH Q2(R1) guideline on analytical method validation to potentially combine both documents into one document for simplification and clarity. In parallel, the USP also developed the <1220> Analytical Procedure Life Cycle chapter, which was published in October 2021

Together, ICH Q14 and ICH Q2(R2) describe the development and validation activities proposed during the life cycle of an analytical method to assess the quality of medicinal products and medical devices:

- ICH Q14 addresses the scientific basis for the development, change management, and submission requirements of analytical methods for a minimal as well as an extended approach.
- ICH Q2(R2) provides information and specifications for establishing, submitting, and maintaining evidence that an analytical method is fit for purpose (assuring drug product quality).

Target Audience

This conference will be of significant value to

- Laboratory managers, supervisors and analysts
- Quality control managers
- Heads of quality control
- Qualified Persons (QPs)
- Analytical scientists
- Senior laboratory staff
- Responsible authorities

Programme

- **Update on USP <1220> and <1058>**
  Dr Christopher Burgess
- **Introduction to the new ECA Analytical Quality Control Group (AQCG) Guide on Analytical Instrument Qualification and Software Validation (AIQ&SV)**
  Dr Christopher Burgess, Burgess Analytical Consultancy
  Dr Bob McDowall, R.D. McDowall Limited
- **Product Life Cycle Concept from the Perspective of the Authorities - Enhanced Approach in Process Validation & Production Routine**
  Dr Rainer Gnibl, Government of Upper Bavaria
- **Iterative Validation Approach for Precision: Stage 1 or Stage 2?**
  Dr Joachim Ermer, Ermer Quality Consulting
- **The Impact of the new ICH Q14 on the Practical Approach to Transfer of Analytical Procedures**
  Ulla Bondegaard, Novo Nordisk
- **Case study: Standard and Extended Use of a Validated, Customized Amplex UltraRed Assay for Sensitive Hydrogen Peroxide Detection in Pharmaceutical Water**
  Dr Alexandra Heussner, Vetter Pharma
- **Opportunities and Challenges from ICH Q2 (R2) and Q14 for the Analytical Lifecycle**
  Jean-Francois Dierick, GSK
- **Analytical Target Profile (ATP) for Large Molecules**
  Annick Gervais, UCB
- **Validation for MAA/NDA**
  Dr Xaver Schratt, GBA Pharma
- **Implementation of Quality by Design Principles for Analytical Assay Development and Validation**
  Dr Mohamad Toutounji, Molgenium
- **HPLC Stability-indicating Procedure Design using Analytical Procedure Lifecycle Approach and AQbD Principles**
  Dr Amanda Guiraldelli, USP
- **The use of Design of Experiment to ensure appropriate Understanding throughout a Method's Lifecycle**
  Patrick Jackson, GSK
- **Strategies of Overcoming Risks of changing Analytical Methods**
  Dr Stephan Kirsch, Novartis
- **Validation of Specific Methods for Inhalation Drug Products**
  Dr Manfred Fischer, Fischer Consulting

Background & Objectives

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

You become informed about

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

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

Enough reasons to attend this Endotoxin and Pyrogen Session at PharmaLab 2023.

Target Audience

This conference is addressed to all persons from

- Pharmaceutical manufacturers
- Biopharmaceutical companies
- Contract laboratories
- Tissue establishments
- Authorities

who are involved in Endotoxin- and Pyrogen Testing.

Programme

- **Towards Animal Free Pyrogen Tests in the Ph. Eur: Latest Progress**
  Dr Gwenaël Ciréfice, EDQM
- **If it's not broken, why fix it?**
  Jelena Novakovic Jovanovic, Galenika
- **Suitability of rFC-based Endotoxin Tests: a Comparison Study including Different Pharmaceutically Relevant Grades of Water and Product**
  Dr Ana Gonzalez Hernandez, GSK
- **Establishment of a rFC Assay for the Detection of Bacterial Endotoxins**
  Dr Holger Kühn, BioChem
- **Novel Recombinant Cascade Reagent (rCR) as Equivalent of LAL for Sustainable BET**
  Dr Hiroki Fukuchi, Fujifilm
- **A Validation Approach for Implementing a Sustainable, Scientifically Sound Recombinant Cascade Reagent**
  Jordi Igelsias, Charles River Laboratories
- **Seamless Software Integration Allows for Complete Automation of the entire Endotoxin Testing Workflow**
  Sinéad Cowman, Lonza
- **Transformative Developments in Endotoxin Testing**
  Dr Veronika Wills, Associates of Cape Cod
- **A Trimeric coiled-coil Motif Binds Bacterial Lipopolysaccharides with Picomolar Affinity**
  Prof Dirk Linke, University Oslo
- **All endotoxins are Lipopolysaccharides, but all Lipopolysaccharides are not Endotoxins!**
  Dr Martine Caroff, LPS -Biosciences
- **Endotoxin Masking – Dependency on LPS Mutant and Matrix Formulation**
  Luisa Burgmaier, Microcoat
- **Preselection of NEP-reference Materials in different MAT-setups**
  Dr Josephine Hubloher, Paul Ehrlich Institut, German Federal Institiute for Vaccines and Biomedicines
- **Implementing New Type of Monocyte Activation Test Method to detect and quantify Pyrogens**
  Dr Kasia Marciniak-Darmochwal, Charles River Laboratories
- **Advancing Pyrogen Testing with Automated MAT**
  Ruben Huis in 't Veld, MAT Research
- **Development of a Novel MAT Test Product (MylcMAT) using Immortalized Monocyte Cells (aMylc cell) derived from Peripheral Blood Mononuclear Cells**
  Kazuo Miyazaki, MiCAN Technologies Inc
- **MAT Investigation on two Non-endotoxin Pyrogens**
  Dr Peter Brügger, Lonza/MAT Research

Background & Objectives

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

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

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

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

- **Future Revision of Ph. Eur. Chapters 5.1.6 Alternative methods for control of microbiological quality and 5.1.9 Guidelines for using the test for sterility**
  Dr Solène Le Maux, EDQM
- **New Generation of Solid Phase Cytometry for Rapid Sterility Testing of Pharmaceutical Products (under Ph. Eur chapter 2.6.1)**
  Dr Joseph Pierquin/Dr Silvia Scotti, Redberry/Eurofins Biopharma Product Testing
- **The Route to faster Bioburden and Sterility Testing with the Milliflex Rapid System 2.0**
  Dr Anne-Grit Klees, Merck
- **Rapid Micro QC Test- Ensuring Product Safety When It Really COUNTS**
  Johannes Oberdörfer, RMB
- **Physical and biological sampling efficiency for active microbial air samplers**
  Dr Miriam Schönenberger, MBV
- **Automated Environmental Monitoring Plate Reading Powered by AI**
  Andrew Gravett, AstraZeneca
- **Building the House of Rapid Sterility - A Successful Platform Approach to introducing Rapid Methods**
  Sophie Drinkwater, Astra Zeneca
- **A unique instrument combining real-time viable particle counting and traditional growth-based sampling. Validation approach and results.**
  Dr Svetlana Kiseleva, Plair
- **Alternatives and Rapid Microbiological methods and Pharmacopeias Regulation (Europe, US, Japan and China)**
  Dr Thierry Bonnevay, Sanofi
- **A Review of the Next Revision to PDA Technical Report #33**
  Dr Michael Miller, Microbiology Consultants LLC
- **Primary Validation of Flow Cytometry as an Alternative Plate Count Method**
  Dr Jürgen Illerhaus, BWT Aqua
- **Next generation Pyrogen Testing Method Developed for Rapid, ELISA Free and Variety of Pyrogen Detection**
  Dr Tomohisa Nanao, Fujifilm
- **Validation of Methods for the Detection of DNase and RNase Contaminations in Pharmaceuticals and Single Use Devices**
  Annemarie Jordan, Labor LS
- **NGS Methods in Microbiology**
  Dr Oleg Krut, Paul Ehrlich Institute, German Federal Institut for Vaccines and Biomedicines
- **NGS Strategies from Sample to Report for Microbial Identification and Viral Contamination Detection in Pharma**
  Dr Inanc Erserim, Thermo Fisher Scientific

Background & Objectives

This meeting is aimed at manufacturers and developers of cells, tissues, cell- and tissue-based products or ATMPs and deals with microbiological and analytical quality requirements, suitable methods and test systems and their implementation and validation. Representatives from authorities and colleagues from small-scale and industrial manufacturing and academic institutions will explain the current regulatory requirements and report on their experiences during inspections and implementation in the company.

Modern regenerative medicine systems such as cells and tissues or ATMPs (gene therapeutics, somatic cell-based products and tissue-based products) represent an innovative group of medicinal products that is becoming increasingly important. With the entry into force of several regulatory directives, e.g. the European Directive EC 1394/2007 for ATMPs, such products have been classified as medicinal products and as such must comply with EU requirements for medicinal products. Although the biopharmaceutical industry has significantly intensified its activities in this area, many of these products are developed and manufactured at universities, hospitals and in small and medium-sized enterprises. These university or medical roots lead to special challenges for the respective institutions as well as for the regulatory authorities in meeting compliance requirements for quality, safety and GMP aspects and approval. The frequently given manufacturing conditions also contribute to this, e.g. the open manipulation of cells and tissues necessary for obtaining such products on a medical-surgical level, or the short shelf life of the obtained end product. And potentially there are always conflicts when it comes to the relevance of different guidelines, e.g. when an Annex 1, or an Annex 2 or a WHO Guideline does not harmonise with the ATMP Guideline.

But also rapid tests and analyses are a challenge for such products with a short shelf life in terms of

- Comparability with Compendial Methods
- Sensitivity and Robustness
- Suitability Testing and Validation
- Variability

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

- Analytical Challenges in Development of Cell and Gene Therapies
  Alicja Fiedorowicz, Dark Horse Consulting
- Challenges of a Point-of-Care Model for Cell Therapy from an Analytical Perspective
  Matthias Heemskerk, CellPoint, a Galapagos company
- Potency Testing for ATMPs
  Dr Sascha Karassek, Charles River Laboratories
- Analytical Methods to support mRNA-LNP Formulation Development
  Dr Sabine Hauck, Leukocare
- Achieve Lower LLOQs for siRNA Quantification in Plasma using Microflow LC
  Dr Ferran Sanchez, Sciex
- Low Energy Electron Irradiation (LEEI)
  Dr Sebastian Ulbert, Fraunhofer-Institut für Zelltherapie und Immunologie
- Different Analytical Tools to characterize ATMPs - from Assay Development to Release Testing
  Dr Markus Fido, MFI Consulting
- Selection of Appropriate Methods for Detection of Microbiological Contaminations in ATMPs
  Dr Stefanie Bayer, Labor LS
- Innovations in Quality Control for Cell and Gene Therapy using Digital PCR
  Dr Mahdieh Rahmatollahi, Thermo Fisher Scientific
- Development of a Digital PCR-based system for the Detection of Residual DNA in Pharmaceutical Products
  Dr Nicole Paland, Minerva Biolabs
- Transfer of Complex Analytical Methods for ATMPs
  Dr Cornelia Rosner, Minaris
- Mycoplasma Testing & Evaluation for ATMPs – lessons learned!
  Olga Müller, Tetec
- Challenges of Endotoxin Detection During Development of a Novel product
  Dr Ruth Röder, Microcoat
- Automating the Future of Cell and Gene Therapy: Streamlining Endotoxin Detection, Data Integrity and Compliance Solutions with recombinant Factor C
  Dr Christian Faderl, bioMerieux

Speakers

The following speakers will lecture at PharmaLab 2023:

Dr Laura Bailac, *bioMérieux*.
Senior Scientist.

Dr Alexander Bartes, *Roche*.
Senior Manager Global Analytical Science and Technology (gASAT).

Dr Karl-Heinz Bauer, *Boehringer*.
Head of Strategic Quality Management & Culture.

Dr Holger Bauer, *Merck*.
Global Analytical Technology Expert.

Dr Stefanie Bayer, *Labor LS*.
Director Molecular Development.

Prof Dr Isabelle Bekeredjian-Ding, *Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines*
Acting Director of ZEPAI (Center for Pandemic Vaccines and Therapeutics) and Head of Microbiology.

Ulla Bondegaard, *Novo Nordisk*.
Specialist.

Dr Thierry Bonnevay, *Sanofi*.
Global Microbiology Analytical Expert.

Dr Thuy Bourgeois, *EDQM Strasbourg, France*.
Scientific Programme Manager, European Pharmacopoeia Department.

Dr Peter Brügger, *Lonza/MAT Research*.
Senior scientific advisor.

Dr Christopher Burgess, *Burgess Analytical Consultancy*.
Managing Director.

Luisa Burgmaier, *Microcoat*.
Doctoral Student.

Dr Martine Caroff, *LPS-Biosciences*.
Chairwoman and CSO.

Dr Gwenaël Ciréfice, *EDQM*.
Scientific Officer, European Pharmacopoeia Department.

Susan Cleary, *Novatek International*.
Director of Product Development.

Sinéad Cowman, *Lonza*. Director, Strategy & Market Intelligence.

Jean-Francois Dierick, *GSK*.
Strategic Analytical Validation and Lifecycle Lead - Analytical R&D.

Alexander Doppelreiter, *Reference Analytics GmbH.*
CEO/Head of Quality Control.

Sophie Drinkwater, *Astra Zeneca*.
Senior Scientist, New Modalities and Parenterals Development, Pharmaceutical Technology & Development.
Dr Joachim Ermer, *Ermer Quality Consulting.*

Dr Inanc Erserim, *Thermo Fisher Scientific*.
Senior NGS Sales Specialist.

Dr Christian Faderl, *bioMérieux*.
Project Leader.

Dr Markus Fido, *MFI Consulting*. CEO.

Alicja Fiedorowicz, *Dark Horse Consulting*.
Senior Consultant.

Dr Manfred Fischer, *Fischer Consulting*.
General Manager.

Mathias Fuchs, *Wega*.
Scrum Master, Agile Coach, Enabler for Agilized Validation Setups.

Dr Hiroki Fukuchi, *Fujifilm*.
Researcher/Assistant Manager.

Andrew Gravett, *AstraZeneca.*

Annick Gervais, *UCB*.
Head of Analytical Development Sciences.

Matthias Heemskerk, *CellPoint, a Galapagos company.*
Head of Analytical Development.

Dr Ana Gonzalez Hernandez, *GSK*.
Projekt Manager Global QC.

Dr Rainer Gnibl, *Government of Upper Bavaria.*

Dr Amanda Guiraldelli, *USP*.
Scientific Affairs Manager.

Dr Sabine Hauck, *Leukocare*.
EVP Corporate Development.

Dr Alexandra Heussner, *Vetter Pharma*.
Lab Manager.

Yasmin Heynen, *Labor LS*.
Molecular Development.

Anke Hossfeld, *Merck*.
Global PM Pharma Development.

Dr Josephine Hubloher, *Paul Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines.*
Postdoctoral researcher and member of the group "Microbiological Safety". Specialized on pyrogen testing.

Ruben Huis in 't Veld, *MAT Research*.
Scientist Monocyte Activation Test Specialist.

Dr Jürgen Illerhaus, *BWT Aqua*.

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

Patrick Jackson, *GSK*.
Investigator.

Annemarie Jordan, *Labor LS*.

Dr Sascha Karassek, *Charles River Laboratories*.
Scientist R&D Bioassay.

Jan-Oliver Karo, *Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicine*.

Dr Caroline Kassim, *bioMérieux*.
R&D Bioscience Manager.

Dr Stephan Kirsch, *Novartis*.
Director Scientific Office Analytical Development.

Dr Svetlana Kiseleva, *Plair*.
Chief Marketing Officer.

Dr Anne-Grit Klees, *Merck*.
Lead Expert, Product and Portfolio Manager.

Dr Jochen Kolb, *BioChem*. General Manager.

Dr Timo Kretzschmar, *Inosolve*.
Sen. Consultant (extern).

Dr Oleg Krut, *Paul Ehrlich Institute, German Federal Institut for Vaccines and Biomedicines.*

Dr Holger Kühn, *BioChem*.
Laboratory Head Microbiology.

Dr Solène Le Maux, *EDQM*.
Scientific Programme Manager in the European Pharmacopoeia Department.

Prof Dirk Linke, *University Oslo*.
Section for Genetics and Evolutionary Biology.

Dr Kasia Marciniak-Darmochwal, *Charles River Laboratories*.
Head of Analytical Strategies and Scientific Support.

Marine Marius, *Sanofi Vaccines*.
Sr Scientist/New Vaccine CMC Analytical Leader - Microbiology platform Analytical Sciences Europe at Sanofi Vaccine.

Dr Bob McDowall, *R.D. McDowall Limited*.
Director.

Dr Michael Miller, *Microbiology Consultants LLC.*
President.

Dr Christina Müller, *Boehringer Ingelheim Pharma*.
Senior Data Manager.

Olga Müller, *Tetec*.
Head QC.

Kazuo Miyazaki, *MiCAN Technologies Inc*.
Chief Executive Officer.

Dr Tomohisa Nanao, *Fujifilm*.
Assisstant Manager/Researcher.

Dr Jelena Novakovic Jovanovic, *Galenika*.
Microbiology Manager.

Johannes Oberdörfer, *RMB*.
Field Application Scientist.

Lukasz Paciorkowski, *A4BEE*.
Chief Strategy Officer.

Dr Nicole Paland, *Minerva Biolabs*.
Head Product Development.

Dr Joseph Pierquin, *Redberry*.
Chief Technical and Scientific Officer.

Alexander Pfülb, *Labor LS*.
Head of Customer Management.

Dr Mahdieh Rahmatollahi, *Thermo Fisher Scientific.*
Field Application Scientist - Genetic Sciences (qPCR-dPCR).

Dr Ruth Röder, *Microcoat*.
Director Endotoxin Services.

Dr Cornelia Rosner, *Minaris*.
Team Lead Tech Transfer/Clinical Quality Control.

Dr Ferran Sanchez, *Sciex*.
Market Development Manager, Pharma/CRO EMEA.

Dr Miriam Schönenberger, *MBV*.
Product Manager.

Dr Xaver Schratt, *GBA Pharma*.
Team Leader Global Quality Management. Member of Management Team Site Neuried.

Dr Silvia Scotti, *Eurofins Biopharma Product Testing*.
Senior Project Manager.

Melissa Schülein, *Labor LS*.
Microbiology/Central Service.

Dr Radhakrishna Tirumalai, *MSD, formerly at USP.*

Dr Mohamad Toutounji, *Molgenium*.
CEO.

Dr Sebastian Ulbert, *Fraunhofer-Institut für Zelltherapie und Immunologie.*
Deputy Head of Institute Head of Department Vaccines and Infection Models.

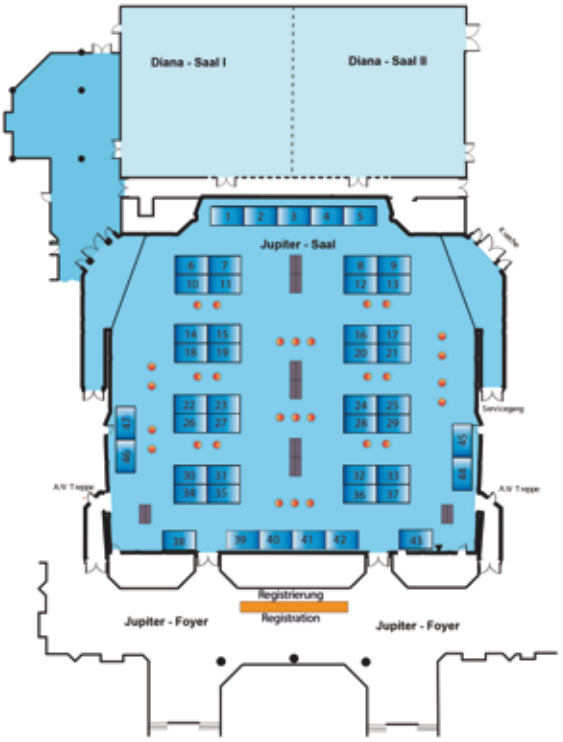
Niels Visschers, *MSD*.
Senior Specialist.

Dr Veronika Wills, *Associates of Cape Cod*.
Associate Director, Global Technical Services.

The Exhibiton

Is your company specialised in products and services for pharma laboratories?

Take advantage of the unique opportunity to exhibit and get in touch with users and decision makers from the fields of analytics, bio analytics, microbiological lab, QA and QC. Moreover, the Social Event will give you the chance to make new contacts with congress delegates and speakers in a more relaxed atmosphere.



There are different stand packages available for booking:

Standard – Package
6sqm Stand
Costs: € 4,580.00 plus VAT

Standard – Package
12sqm Stand
additionally a second person for attending the conferences
Costs: € 7,960.00 plus VAT

PREMIUM – Package
12sqm Stand
(only available once)
Like Standard - Package 12sqm, additionally:

- Named as a premium sponsor and logo in all congress-specific print and online media
- Your logo on all name badges and the exhibition plan
- Ice cream station for lunch break at your stand
- Cocktail bar at the social event (incl. 100 cocktails)

Costs: € 13,960.00 plus VAT

All details at: www.pharmalab-congress.com/exhibitor-infos.html

Materials for your Marketing

As an exhibitor you can take advantage of various marketing materials for promoting your presence. These include

- **online exhibition banner** – for your website and as signature in your e-mails.
- **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.

Sponsoring

Moreover, take advantage of the sponsoring opportunities to make Congress delegates aware of your company. In addition to sponsoring coffee breaks or lunches on the 1st and 2nd Congress day there are plenty of other sponsor possibilities. You will find the details on the website.

Do you have any questions with regard to the exhibition? Then please contact:
Ronny Strohwald, (Organisation), phone. +49 (0) 6221/84 44-51,
E-mail: strohwald@concept-heidelberg.de

The Fees

A one-day ticket/two-day ticket will enable you to visit the congress (21 November/22 November 2023) either only on day 1 or only on day 2 or on both days. The charges for the one day tickets are € 690,- plus VAT, for the two days ticket € 1.380,- plus VAT. They include lunch and beverages during the conferences and in breaks as well as the social event on the evening of the first congress day (Due to the special fees for the congress, ECA membership discounts are not applicable).
The visit of the pre-conference on 20 November 2023 for € 590,- can be combined with the congress (see registrations options on the last page). Charges are payable after receipt of invoice.

The Social Event

On the evening of the first congress day, on 21 November 2023, 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.

Location

Crowne Plaza Düsseldorf / Neuss
Rheinallee 1, 41460 Neuss
Phone: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
E-mail: emailus@cphotelduesseldorfneuss.com
www.crowneplaza.com/neuss

The Organiser

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For questions regarding content (Track 1 and 2):
Dr Markus Funk (Operations Director)
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For questions regarding reservation, hotel, organisation, exhibition etc.:
Ronny Strohwald (Organisation)
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E-mail: strohwald@concept-heidelberg.de

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Rischerstraße 8
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Fax:
+49 (0) 6221 84 44 34

E-mail:
info@concept-heidelberg.de

Internet:
www.pharmalab-congress.com

Registration Options PharmaLab 2023

I want to take part in:

- ☐ PharmaLab Pre-Conference Workshop "4th International Mycoplasma qPCR Testing User Day" (20 Nov 2023) - € 590,- plus VAT
- ☐ PharmaLab Conferences on 21 Nov 2023 – € 690,- plus VAT
- ☐ PharmaLab Conferences on 22 Nov 2023 – € 690,- plus VAT
- ☐ PharmaLab Conferences on 21 and 22 Nov 2023 – € 1,380,- plus VAT

With a one-day ticket/two-day ticket for the PharmaLab Conferences (21 Nov/22 Nov 2023) you can attend any conference offered that day/both days. It includes 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.

☐ Yes, I would also like to take part in the Social Event on the evening of 21 November. ☐ No

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 (21 November 2023)** and I'm primarily interested in the conference:

- ☐ ECA – GMP Compliance Trends in Analytical Laboratories/Outsourcing in Pharmaceutical Laboratories
- ☐ ECA – Analytical Method Validation and Life Cycle Management - ICH Q14/Q2 (R2) (Day 1)
- ☐ ECA – Endotoxin and Pyrogen Testing (Day 1)
- ☐ ECA – Alternative and Rapid Microbiological Methods (Day 1)
- ☐ ECA – Cell and Gene Therapies/ATMPs - Quality and Safety (Day 1)

☐ I would like to attend on **day 2 (22 November 2023)** and I'm primarily interested in the conference:

- ☐ ECA – Laboratory Optimization, Automation and Digitalization
- ☐ ECA – Analytical Method Validation and Life Cycle Management - ICH Q14/Q2 (R2) (Day 2)
- ☐ ECA – Endotoxin and Pyrogen Testing (Day 2)
- ☐ ECA – Alternative and Rapid Microbiological Methods (Day 2)
- ☐ ECA – Cell and Gene Therapies/ATMPs - Quality and Safety (Day 2)

PLEASE NOTE:

- There will be no reservations via Concept Heidelberg. Please book your **hotel room directly with the reservation form** which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.
- There will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as downloads.

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
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Reservation Form (Please complete in full)

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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.
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- Cancellation until 4 weeks prior to the conference 10 %,
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