10th PharmaLab Congress

21 and 22/23 November 2022 | Congress & Exhibition | Düsseldorf, Germany

With 4 Parallel Conference Tracks and a Pre-Conference Workshop on 21 November

Early Bird Rebate until 31 August 2022 on the congress ticket

Highlights

- Analytical Method Validation and Life Cycle Management
- Laboratory Optimization and Automation
- Modern and Alternative Microbiological Methods
- Quality of ATMP
- Endotoxin and Pyrogen Testing
- Mycoplasma Detection

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

The Congress Objective

After two years in online mode, from 21-23 November 2022, the 10th PharmaLab Congress will again take place on-site in Düsseldorf/ Neuss. The congress, which is aimed at employees and managers in all laboratory areas of the pharmaceutical industry, is composed of a pre-conference workshop, 5 international conferences and a German-language conference as well as the accompanying exhibition. It will provide information on the latest developments in laboratory methods, 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. During inspections, regulatory authorities have increasingly focused their attention on the quality management and performance of laboratories and their quality standards. This scrutiny by regulatory agencies requires laboratories to establish GLP and GMP compliant systems and methods, specifically:

- General GLP or cGMP understanding and especially with respect to compliance with written procedures.
- Validation, implementation and transfer of analytical methods and microbial tests
- 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

	TRACK 1 - QC Analytics	TRACK 2 - QC Endotoxin & Pyrogen Testing	TRACK 3 - QC Microbiology	TRACK 4 - QC Bionanalytics /Biotech
22 November	Analytical Procedure Life Cycle Management (ICH Q14/ICH Q2(R2)	Endotoxin & Pyrogen Testing	Alternative and Rapid Microbiological Methods*	Cells, Tissues and ATMP – Quality Control*
23 November	Laboratory Optimization, Automation and Digitalization	Endotoxin & Pyrogen Testing	Cells, Tissues and ATMP and Alternative Microbiological Methods	
Exhibition (22 and 23 November 2022)				

* Please note that the second day (23 November) will be held as conference **Cells, Tissues and ATMP and Alternative Microbiological Methods**.

Pre-Conference Workshop on 21 November 2022: The day before the congress the pre-conference event **"3rd International Mycoplasma qPCR Testing User Day"** will take place. Ticket 590,- EUR

Organisational Details, Sponsors and Media Partners

The Fees

A one day ticket/two days ticket will enable you to visit the congress (22 November/23 November 2022) 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 21 November 2022 for € 590,- can be combined with the congress (see registrations options on the last page).
Charges are payable after receipt of invoice.

Particularities of PharmaLab 2022

- 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.

The Social Event

On the evening of the first congress day, on 22 November 2022, 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
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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.

Programme

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

- **dPCR Quantified Mycoplasma Standards – a New Level of Confidence**
  Dr Miriam Dormeyer, Sartorius

- **Challenges During the Validation of an Alternative Mycoplasma Detection Method**
  Christiana Schnitzler, Boehringer Ingelheim

- **Mycoplasma Testing for ATMPs: Rapid Methods and Validation Strategies**
  Dr Stefanie Bayer, Labor LS

- **Mycoplasma Detection in Complex ATMP Matrices**
  Dr Jonathan Hanley, Nissui Pharma Solutions

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

Moderation

Haidy Wafy, Roche

Analytical Procedure Life Cycle Management – ICH Q14/ICH Q2(R2) | 22 November 2022

TRACK 1

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.

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. On 14 November 2018, a Final Concept Paper "ICH Q14: Analytical Procedure Development and Revision of Q2(R1) Analytical Validation was published. It was proposed to develop a new quality guideline on Analytical Procedure Development and to revise the ICH Q2(R1) Guideline on Validation of Analytical Procedures: Text and Methodology.

After an extended processing time, the two documents on ICH Q14 and ICH Q2(R2) were published on the 24 March for consultation by the ICH regulatory members. The goal is to finalize by Step 4 by May 2023. 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).

In summary, ICH Q14 and ICH Q2(R2) represent the harmonised scientific and technical principles for analytical methods throughout the lifecycle of analytical methods. ICH Q14, through the principles described, is intended to improve communication between industry and regulatory authorities and achieve more efficient, science-based and risk-based approval, as well as to facilitate post-approval change management of analytical methods. The revised form of ICH Q2(R2) continues to provide the general framework for validation of analytical methods, now expanded to include new technologies (e.g., for biological products or multivariate analytical methods).

Target Audience

The ECA Academy wish to actively involve analytical chemists, QC analysts, quality assurance associates & managers, R&D scientists, statisticians & managers as well as manufacturing scientists and managers, regulatory affairs specialists and contract laboratories in this critical area for analytical science.

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

Programme

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

- **ICH Q2(R2)/Q14: Mission accomplished?**
  Dr Joachim Ermer, Ermer Quality Consulting
- **USP <1220> and the Proposed Revision of <1058>**
  Dr Chris Burgess, ECA Analytical Quality Control Interest Group
- **Next Steps of Practical Life Cycle Management in Laboratories**
  Ulla Bondegaard, NovoNordisk
- **Insights into ICH Q14: Analytical Procedure Development**
  Dr Mario Ramos, Valicare
- **Impact of New ICH Q14 and Q2(R2) Draft Guidelines on Potency Assays – Focus on SPR**
  Simon Gaderer, VelaLabs
- **Method Validation for Anti-Drug Antibodies (ADA) and Neutralizing Antibdies (NAbs)**
  Dr Ralf Hess, Entourage
- **From Vision to Validation: The Method Live Cycle explained by the Example of a HPLC Method**
  Sarah Herzog, Reference Analytics
- **Development and Validation of a Customized Amplex UltraRed Assay for Sensitive Hydrogen Peroxide Detection in Pharmaceutical Water**
  Dr Alexandra Heussner, Vetter
- **A Full Spin on Analytical Lifecycle Management: Proof of Concept**
  Fábio Brito, Infosaúde - LEF

Moderation

Dr Joachim Ermer, Ermer Consulting

Laboratory Optimization, Automation and Digitalization
23 November 2022

TRACK 1

Background & Objectives

The aim of this conference is to show possibilities to optimize the organization of a laboratory and to reduce costs. The topics LEAN, both for the laboratory and laboratory management and 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 through reduced testing and reduced sampling 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. Many modern tools such as LEAN, Six Sigma, CIP, etc. are increasingly used to increase the efficiency (also) of analytical laboratories. The correct recording and evaluation of the "Key Performance Indicators" (KPIs) plays a decisive role in this. Which of these factors are really "key", which ones can be dispensed with?

With this conference, managers and employees in the laboratory learn tools for more effective and efficient control of laboratory activities.

Topics are:

- LEAN in QC
- Key Performance Indicators (KPIs)
- Optimization of laboratory processes - practical examples
- Cost-efficient design of a laboratory
- Case Studies for Laboratory Automation
- New analysis methods for the optimization of processes in the laboratory
- Reduced sampling and reduced scope of testing in the incoming goods inspection of active and auxiliary materials

Target Audience

This conference is aimed at laboratory managers and laboratory staff in the pharmaceutical industry who work in the areas of incoming goods inspection, finished goods inspection and analytical development. Also addressed are laboratory managers in the field of pharmaceutical active ingredient and excipient production and contract laboratories. The contents will also be of great interest to competent persons according to §14 AMG and to heads of quality control as well as to employees from the QA department.

Programme

- **Operation of PCs & Networks in GMP-Labs**
  Dr Karl-Heinz Bauer, Boehringer Ingelheim
- **Laboratory Control from the Cloud, SaaS and Data Integrity – an Excurse**
  Dr Timo Kretzschmar, Insolve
- **Qualification of Automated Laboratory Systems including Required Computer System Validation**
  Dr Carsten Börger, Valicare
- **MACSQuant Analyzer - a Flow Cytometry Instrument for the GMP Use Case**
  Dr Dmitry Fridman, Miltenyi
- **Implementation of a LIMS integrated with the ERP**
  Flavio Kawakami, Doctorbit/ISPE
- **How do I find the best LIMS for my lab?**
  Joachim Post, wega Informatik
- **Optimization and Real-Time Documentation during the Test for Sterility in Cleanrooms**
  Olivia Halamoda, Labor LS
- **How to transfer your innovation from Lab Scale to Manufacturing?**
  Dr Dana Quaden, Medace
- **Annex 1 in The Age of Digitization: Reimagining Contamination Control**
  Parsa Famili, Novatek
- **The Lab of the Future – Today**
  Sinead Cowman, Lonza

Moderation

Dr Karl-Heinz Bauer, Boehringer Ingelheim

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
- Authorities

who are involved in Endotoxin- and Pyrogen Testing.

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**
  Dr Ingo Spreitzer, Paul-Ehrlich Institut
- **Advantages of the Monocyte Activation Test in Quality Control Testing of Lifecycle Products**
  Dr Liliana Alleri, GSK
- **Optimization of the Monocyte Activation Test to assess Reactogenicity of Outer Membrane Vesicle Vaccines**
  Dr Marijke Molenaar-de Backer, Sanquin
- **Generic Method and Specific Product Validation of the Monocyte Activation Test**
  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**
  Dr Koen Marijt, MAT Research
- **Monocyte Activation Test as the Sole Tool to identify Synergistic Effects when Parenteral Drugs are contaminated with Multiple Pyrogens**
  Shabnam Solati, CTL-MAT
- **Monocyte Activation Test: A Pyrogen Detection Solution for Gene Therapy Products?**
  Anne Claire Erba, Merck
- **Alternative Pyrogen Methods: FDA Case Studies**
  Dr Reyes Candau-Chacon, FDA, USA
- **Alternative Approaches to Medical Device Testing with the MAT**
  Dr Sandra Stoppelkamp, University Tübingen
- **Interleukin Interference during MAT Testing**
  René Ørving, Novo Nordisk
- **Validation of the Monocyte Activation Test with three Therapeutic Monoclonal Antibodies**
  Dr Ruth Daniels, Janssen

Programme Day 2

- **LER Challenges and Their Solutions – A Case Study**
  Harald Meißner, Morphosys
- **Validation of a Dedicated Sample Preparation Method**
  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**
  Hayden Skalski, SUEZ
- **T Custom Made iPSC-Derived Macrophages as an Efficient Tool for Next Generation Pyrogen 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 Substrates**
  Maria Luisa Bernuzzi, Fedegari
  Alessandro Pauletto, Charles River Laboratories
- **How to increase Sustainability in QC Testing? Future Proofing Pyrogen Detection**
  Allen Burgenson, Lonza
- **Implementing Annex 1 Revisions: Improving Biofilm Detection in WFI Systems Using Rapid LAL Methods**
  Jordi Iglesias, Charles River Laboratories
- **Recombinant Reagents for BET – Regulatory Landscape, Comparability Studies and Their Future Routine Use including Automation**
  David Guy, ACC
- **The rFC Journey: Validation for Water Testing Completed – What's Next?**
  Carmen Marín Delgado de Robles, F. Hoffmann-La Roche
- **Endotoxin Testing: LAL, rFC and Semi-Automation**
  Marine Marius, Sanofi
- **Diversity, Complexity, and Originality of Lipopolysaccharides Structures**
  Dr Martine Caroff, LPS Biosciences

Moderation

Dr Johannes Reich, Microcoat

Alternative and Rapid Microbiological Methods
22/23 November 2022

TRACK 3

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**
  Dr Philipp Kucera, VelaLabs
- **Next Generation Sequencing: Current Trends and Perspectives for Pharma and Biotech**
  Dr Inanc Deger Erserim, Thermo Fisher
- **MS for ID - Regulatory Changes and their Influence of ID in Laboratory**
  Dr Gerold Schwarz, Bruker
- **New Solid Phase Cytometry Method**
  Dr François Baglinière, Microbs
- **Case Studies on Burkholderia Cepacia Complex (BCC) Investigations, QC Lab Testing and Remediation**
  Dr Michael Miller, Microbiology Consultants
- **ATP Bioluminescence for Non-sterile Product Testing: Roadmap to Implementation**
  Inge van der Schoot, J&J
- **Novel Automated Rapid Sterility Test**
  Dr David Jones, RMB
- **Non-inferiority Testing for Qualitative Microbiological Methods: Assessing and improving the Approach in USP <1223>**
  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 ATMP*.

Cells, Tissues and ATMP – Quality Control
22/23 November 2022

TRACK 4

Background & Objectives

This conference is for cells, tissues, cell- and tissue-based products and ATMPs and deals with microbiological and analytical quality requirements, appropriate methods and test systems and their implementation. Representatives of authorities and colleagues from the small-scale and industrial manufacturing sectors will explain the current requirements and report on their experiences during inspections and implementation in the company.

Modern systems of regenerative medicines, such as cells and tissues or ATMPs (gene therapeutics, somatic cell-based products and tissue-based products) represent an innovative group of drugs that is becoming increasingly important. With the entry into force several regulatory guidelines e.g. of the European Directive EC 1394/2007 for ATMPs, such products were classified as medicinal products and must therefore comply as such with the EU requirements for medicinal products. Although the biopharmaceutical industry has considerably intensified its activities in this field, 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 fulfilling the compliance requirements for quality, safety and GMP aspects and approval. This is also forced by frequently given manufacturing conditions, e.g. the open manipulation of cells and tissues, which are necessary for obtaining such products on a medical/surgical level or by the short shelf life of the obtained final product. Rapid testing and analysis is a challenge for such short shelf life products.

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

Target Audience

This conference is aimed at all persons who

- are involved in the extraction and manufacture of Cells, Tissues and ATMPs
- Responsible persons from quality assurance and control of Cells, Tissues and ATMPs
- Are responsible for microbiological or analytical testing
- Perform inspections or audits of ATMPs facilities
- Deal with the authorisation

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

- **Welcome /Analytical Toolbox AAV Virus**
  Dr Sabine Hauck, Leucocare
- **Analysis Strategies for Cell and Gene Therapy Products**
  Dr Mohamad Toutounji, Sanofi
- **Personal Experience of Biological Raw Material Sourcing for an Early Stage ATMP and Considerations for later Clinical Stage Development**
  Sidonie Karlsson, Amniotics
- **Cells of Quality: ICH in the Lab - ICH S6, Q5A-D in the Context of Cell Banking Cell Substrates for the Production of ATMPs**
  Assoc. Prof Dr Simon Schulz, Entourage
- **Batch Release and Stability Studies, especially for ATMPs – a Challenge?**
  Dr Markus Fido, MFI Bio-Consulting
- **Bioactivity Testing for Cell and Gene Therapy Products**
  Dr Ulrike Herbrand, Charles River Laboratories
- **Analytical Quality by Design Approach: a Challenge for Viral Vector Testing in Gene Therapy**
  Dr Isabelle Moineau, AKTEHOM
  Dr Anne Sophie Cottard, Yposkesi
- **Automation of Hematopoietic Progenitor Cell (HPC) Processing: a Platform for ATMP Manufacturing**
  Dr Bechara Mfarrej, Institut Paoli-Calmettes
- **Development of a Cell-based Potency Bioassay for mRNA Medicine**
  Sabrina Rottal, VelaLabs

Moderation

Dr Sabine Hauck, Leucocare

Programme Day 2: Please note that the second day (23 November) will be held together with the conference on *Alternative and Rapid Microbiological Methods*.

Programme Day 2

- **Microbiological Control of ATMP**
  Chiemezie Nwakire, Neuroplast BV
- **Implementation of a Comprehensive Rapid Microbial Contamination Control Platform for Testing of Sterile Pharmaceuticals and Cell-Based Therapies using ATP Bioluminescence**
  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**
  Corinne de la Foata, bioMerieux
- **Viral Safety – Evaluation of Eukaryotic Cell Bank Purity with a Special Focus on Adventitious Agents and Replication Competent Viruses**
  Larissa Nkenmei-Pietsch, Tentamus
- **Short Shelf Life and Sterility Testing - Challenges of Cell Based ATMP Market Supply**
  Debora D`Amico, Tetec
- **Rapid Sterility by qPCR for ATMPs**
  Dr Anja Fritsch, Confarma
- **ScanRDI System - Validation and Implementation of an Alternative Sterility Test (Solid Phase Cytometry) for a Cell and Gene Therapy Product**
  Mahsa Mohammadi, Novartis
- **Implementation of a Real Time PCR-based Method for Release Testing the Sterility of ATMPs, a Practical Approach**
  Yasmin Heynen, Labor LS

Moderation

Dr Michael Miller, Microbiology Consultants

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.

Dr François Baglinière | *Microbs, France.* Ingénieur microbiologiste et validation de méthodes.

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

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

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

Ulla Bondegaard | *NovoNordisk, Denmark.* Specialist.

Dr Carsten Börger | *Valicare, Germany.* Senior Project Manager.

Fábio Brito | *Infosaúde - LEF, Portugal.* Analytical Development & Validation Technician.

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

Dr Chris Burgess | *Chairman of the ECA Analyticals Quality Control Interest Group and Member of the USP Expert Panel on Validation and Verification.*

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

Dr Anne Sophie Cottard | *Yposkesi, France.* Responsible of method validation and Analytical Life Cycle Management.

Sinead Cowman | *Lonza, Ireland.* Associate Director Strategy & Marketing - Informatics.

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

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.

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

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

Dr Miriam Dormeyer | *Sartorius, Germany.* Application Scientist.

Debora D`Amico | *Tetec, Germany.* Team Leader Quality Control Microbiology & Hygiene Monitoring.

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

Dr Joachim Ermer | *Ermer Quality Consulting, Germany.*

Parsa Famili | *Novatek International, Canada.* President & CEO.

Dr Markus Fido | *MFI Bio-Consulting, Austria.* CEO.

Dr Dmitry Fridman | *Miltenyi, Germany.* Global Product Manager.

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

Simon Gaderer | *VelaLabs, Austria.* Head of Ligand Binding Assay Group.

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

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

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

Olivia Halamoda | *Labor LS, Germany.*

Dr Jonathan Hanley | *Nissui Pharma Solutions, France.* General Manager.

Dr Sabine Hauck | *Leucocare, Germany.* Vice President Research & Development.

Dr Ulrike Herbrand | *Charles River Laboratories, Germany.* Scientific Director Global in vitro Bioassays.

Sarah Herzog | *Reference Analytics, Germany.* Deputy Lab Supervisor.

Dr Ralf Hess | *Entourage, Germany.* Principal Project Consultant.

Dr Alexandra Heussner | *Vetter, Germany.* Head of Laboratory.

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

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

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

Dr David Jones | *RMB, USA.* Director Industry Affairs.

Sidonie Karlsson | *Amniotics, Sweden.* Production Manager.

Jan Oliver Karo | *Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines.*

Flavio Kawakami | *Doctorbit/ISPE, Portugal.* GAMP CoP Chair (vol.).

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

Dr Timo Kretzschmar | *Insolve, Austria.* Senior Consultant / Projektmanagement.

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

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

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

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

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

Dr Bechara Mfarrej | *Institut Paoli-Calmettes, France.* Research and Development engineer, Responsible Person in interim.

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

Jo Milne | *Mycoplasma Experience, UK.*

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

Dr Isabelle Moineau | *AKTEHOM, France.* Analytical Leader.

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

Larissa Nkenmei-Pietsch | *Tentamus, Germany.* Head of Cell and Immune Analytics.

Chiemezie Nwakire | *Neuroplast BV, The Netherlands.* QA Manager/Trainee QP.

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

Alessandro Pauletto | *Charles River Laboratories, Italy.* Sales and Tech Support in Pharma Industry.

Joachim Post | *wega Informatik, Germany.* Senior LIMS Consultant.

Dr Dana Quaden | *Medace, The Netherlands.* Quality Associate GMP.

Dr Mario Ramos | *Valicare, Germany.* GMP Consultant.

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

Dr Tilman Rock | *Boehringer Ingelheim Biopharma, Austria.* Site Head Biopharma Vienna - SVP at Boehringer Ingelheim.

Sabrina Rottal | *VelaLabs, Austria.* Application Specialist - R&D and Analytical Development.

Christiana Schnitzler | *Boehringer Ingelheim, Germany.* Senior Associate Director/Head of Laboratory Mycoplasma.

Assoc. Prof Dr Simon Schulz | *Entourage, Germany.* Senior Management Consultant.

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

Hayden Skalski | *SUEZ, 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 Mohamad Toutounji | *Sanofi, The Netherlands.* ADQC Scientist.

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

Inge van der Schoot | *J&J, The Netherlands.* SME Microbiology.

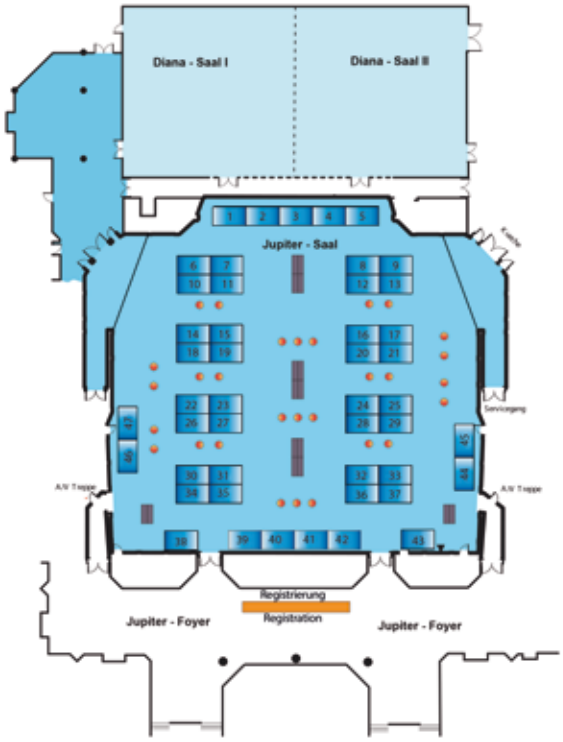
Haidy Wafy | *Roche, Germany.* Product and Marketing Manager.

Exhibitors Information

The Exhibiton

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

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.



The **charges per stand are 3.980,- Euro** plus VAT. The following services are included:

- Booth including exhibition wall with the size of 3,32 x 1,91 m, 1 table, 2 chairs and power
- Participation for the person mentioned on the registration form is free of charge
- Lunch and refreshments during the conferences
- Participation in the Social Event
- 2 free tickets for your clients
- On-site support

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

Registration for the Exhibition – PharmaLab 2022

Registration for a stand at the PharmaLab 2022 on 22/23 November 2022 in Düsseldorf/Neuss.
For the registration of your stand you can also alternatively use the online registration form, which you will find on the website at **www.pharmalab-congress.com**. The charges for a stand are 3.980,- Euro plus VAT.
(Please note that exhibitors will be responsible for all charges for building and taking down of stand as well as for all materials related to the presentation.)

☐ **I want to register a stand with the stand number below.**
(Please note that for cancellation after 31 July 2022 the full registration fee of 3.980,- Euro will be charged. In addition, the General Terms and Conditions for Fairs/Exhibitions as available on the PharmaLab website do apply.)

The exhibitor plan on the website at www. pharmalab-congress.com is updated every day. Please take a look at this plan to see what spaces are still open and to pick your stand number which you then fill in here:

Preferred Stand Number: _____ or alternatively _____

Registration / Reservation – Company Information / Invoice Address:

Company	
Contact	
Department	
Phone / Fax	
E-Mail	

Contact on site – this person is also free to attend all conferences (registration as delegate included):

First & Last Name	
Department	
Street, ZIP & City	
Invoice Address	
Participation in Social Event on 22 November 2022: Yes ☐ No ☐	

Additional Stand Personnel:
For additional stand personnel a flat rate of **€ 300, -** will be charged per person. Please register additional personnel together with your registration as exhibitor. The participation of conferences is not included.

	Stand Personnel – Person 1:	Stand Personnel – Person 2:
Company		
First & Last Name		
Street, ZIP & City		
Phone / E-Mail		
Invoice Address		
Participation in Social Event on 22 November 2022:	Yes ☐ No ☐	Yes ☐ No ☐

Conference Selection for Congress Delegate (not for Stand Personnel):
PharmaLab 2022 delegates are free to attend the conferences they are interested in. To set up the conference rooms, though, we would appreciate it if you let us know what conference you are specifically interested in – **please mark your choice per day below**.

21 November 2022: ☐ ECA – Pre-Conference Workshop "3rd International Mycoplasma qPCR Testing User Day" - € 590,- plus VAT

22 November	☐ ECA – Analytical Procedure Life Cycle Management - ICH Q14/ ICH Q2(R2)	23 November	☐ ECA – Laboratory Optimization, Automation and Digitalization
	☐ ECA – Endotoxin and Pyrogen Testing (Day 1)		☐ ECA – Endotoxin and Pyrogen Testing (Day 2)
	☐ ECA – Alternative and Rapid Microbiological Methods (Day 1)		☐ ECA – Cells, Tissues and ATMP and Alternative Microbiological Methods (Day 2)
	☐ ECA – Cells, Tissues and ATMP – Quality Control (Day 1)		

Room Reservation:
Direct room reservation by reservation form! Reservations/bookings cannot be made through Concept Heidelberg. Receipt with confirmation/invoice.
CONCEPT HEIDELBERG has reserved a limited number of rooms in the Crowne Plaza Düsseldorf/Neuss. You can make your room reservation directly with the reservation form you will receive together with the registration confirmation. We recommend to register early.

Court of jurisdiction is Heidelberg, German law is applicable. In addition, the General Terms and Conditions for Fairs/Exhibitions as available on the PharmaLab website at www.pharmalab-congress.com do apply.

City and Date _____ Signature _____

Please complete the form and return to CONCEPT HEIDELBERG, Fax +49 (0) 6221 84 44 34.

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Telefax:
+49 (0) 6221 84 44 34

E-Mail:
info@concept-heidelberg.de

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

Registration Options PharmaLab 2022

I want to take part in:

Early Bird Rebate on the congress ticket

- ☐ 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 **(until 31 August 2022 only € 590,-)**
- ☐ PharmaLab Conferences on 23 Nov 2022 – € 690,- plus VAT **(until 31 August 2022 only € 590,-)**

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 ATMP – 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 ATMP and Alternative Microbiological Methods (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
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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