

12th PharmaLab Congress

Analytics ■ Bioanalytics ■ Microbiology

Developments in Modern Pharmaceutical and Biopharmaceutical Laboratories

Düsseldorf/Neuss,
Germany
25 - 27 November 2024

Highlights

- **NEW:** Analytical Instrument Qualification and System Validation
- GMP Compliance Trends in Analytical Laboratories
- 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
- **NEW:** Bioassays/Potency Assays

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The Congress Objectives

2022 and 2023, the first two years after the pandemic, PharmaLab has attracted more participants to Düsseldorf/Neuss than ever before. With this success as a template, the 12th PharmaLab Congress will again be held on site in Düsseldorf/Neuss from 25-27 November 2024. The congress, which is aimed at employees and managers in all laboratory areas of the pharmaceutical industry, is composed of a pre-conference workshop, 7 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, etc., 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 new pharmacopoeial or alternative test methods, like MAT, rFC etc.
- Validation of analytical methods according to the new USP life cycle model, especially with the new ICH Q2(R2) and ICH Q14 Guidelines.
- Analytical instrument qualification and system validation and a lifecycle processes for specifying, purchasing, commissioning, calibrating or verifying correct operation.
- Computer validation (including interpretation of EU GMP Annex 11 and 21 CFR Part 11 and actual laboratory data integrity requirements)
- Development of suitable assays, analytical methods and microbiological tests for modern forms of therapy such as ATMP, CGT or mRNA vaccines

Especially for pharmaceutical products and active substances of biological origin, classical analytical and microbiological methods are not always 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.

Target Audience

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

Key Notes: 26/27 November

The Promise and Challenges of In Vitro and In Silico Models in Drug Development

Dr Julia Schöler, Charles River Laboratories

The presentation will highlight important developments in the drug development technology landscape influenced by the concept of 3R and the evolving legal landscape. General characteristics of the different applications, their translational relevance as well as adoption drivers will be discussed. Case studies from oncology drug development will help to elucidate these trends and their impact on future processes.

Trends & Challenges for the Development & Testing of Biotech Drug Products

Prof Dr Hanns-Christian Mahler, Chief Enablement Officer (CEO), ten23 health

**Congress
Key Note**

5th International Mycoplasma qPCR Testing User Day

PharmaLab Pre-Conference Workshop | 25 November 2024

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 biopharmaceutical 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
- Bioassay Developers
- Responsible Authority Employers

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

Programme

Update on the Revision of Ph. Eur. Texts related to the Mycoplasma Project

Thuy Bourgeois, EDQM Strasbourg, France

Rapid Mycoplasma Testing – Methodology, Pitfalls and Experiences

Dr Rudolf Zirwes, independent

Real-Time PCR-based Mycoplasma Testing – Verification for the Intended Use: Data from a User

Dr Robert Hertel, Sartorius

RT-qPCR based Mycoplasma Detection from a Developer's Perspective

Caroline Paeschke, Minerva Biolabs

Mycoplasma Testing of ATMPs: Current Regulations, Challenges and Trends

Rashid Idd Kihwelo, Shelys Pharmaceuticals

Sensitive and Rapid Testing for Mycoplasma Contamination using Digital PCR

Dr Francesca Di Pasquale, Qiagen

Replacement of a DNA extraction system in a validated Rapid Mycoplasma Method

Susan Hoefs, MSD

Ultra-Rapid NAT-based Method for Mycoplasma Testing – Implementation, Validation and Transfer Strategy

Yasmin Heynen, Labor LS

Mycoplasma Testing – Authorities Experiences and New Developments

Jan-Oliver Karo, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines

Programme

Current Pharmacopoeial Developments in the Field of Endotoxin and Pyrogen Detection

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

Approval of a Monocyte Activation Test as a Replacement of the Rabbit Pyrogen Test

Dr Sven M. Deutschmann, Roche

A Comparison of Recombinant Factor C and LAL Based Methods for Bacterial Endotoxin Testing

Hiram Huzeyfe Yakut, Turkish Medicines and Medical Devices Agency

Good Practice in LER Hold Time Study: the Choice of the Endotoxin

Alessandro Pauletto, bioMérieux

Addressing Low Endotoxin Recovery During Biological Development - from Early Stage to Submission

Melanie Jänsch und Jessica Stolzenberger, Boehringer

The Mitigation Concept - Understanding the Masking Impact on Drug Product Manufacturing of Biologicals

Martina Wespel, Boehringer and Dr Anthea Darius, Microcoat

Supramolecular Assembly of Micellar Aggregates is the Basis of Low Endotoxin Recovery (LER) in a Drug Formulation that Can be Resolved by a Whole Blood Assay

Prof Klaus Brandenburg, Brandenburg Antiinfektiva c/o Forschungszentrum Borstel

Developing Endotoxin Assays Based on a Novel LPS-binding Peptide

Prof Dirk Linke, University of Oslo

On the Detection and Quantification of the Endotoxic, or not Endotoxic, Lipopolysaccharides

Dr Flavien Dardelle, LPS-Bioscience

Update on the Status of the USP proposed General Chapter <86> Endotoxin Testing using Recombinant Reagents

Dr Mark Schweitzer, Chair of the USP General Chapters Microbiology Expert Committee

Validation of a Complex Drug Product Using Recombinant Cascade Reagent

Veronika Wills, Associates of Cape Cod

Endotoxin Testing of mRNA Vaccines: Ensuring Product Safety and Effectiveness

Dr Mohamad Toutounji, Lonza

The Lobster Hemocyte Lysate (LHL) Method for the Detection of Lipopolysaccharides (LPS), Peptidoglycans and (1,3)- β -D-Glucans

Rolando Perdomo Morales, Center for Pharmaceuticals Research and Development, Cuba

Evaluating Synthetic Reagents for Endotoxin Testing

Poppy Cliffe, AstraZeneca

Recombinant Cascade Reagent and Limulus Amebocyte Lysate: A Detailed Analysis of Endotoxin Testing Methods

Dr Shady Kamal, Galderma

Out of the Endotoxin Box: Rethinking Pyrogens and Pyrogenicity

Dr Djikolngar Maouyo, PyroDex

Automation of the Monocyte Activation Test Method 2 with the Opentron OT-2 robot

Stéphanie Richard, Sanofi

LumiMAT™ : Rapid and easy MAT Using the Luciferase Reporter Assay

Tomohisa Nanao, FUJIFILM Wako Pure Chemical Corporation

Development of a Rapid MAT Test Using Immortalized Monocyte Cells (aMylc)

Kazuo Miyazaki, Mican Technologies

Programme

European Pharmacopoeial Update

Dr Solène Le Maux, EDQM

Evaluation of the New Generation of Solid Phase Cytometry as a Very Rapid Microbial Test of Cell and Gene Therapy Products

Dr Kirsten Høstgaard-Jensen, Novo Nordisk

Rapid Sterility Testing by NAT Method targeting RNA instead of DNA

Yotaro Yamamoto, FUJIFILM Wako Pure Chemical

Proposal of the New Rapid Sterility Test for Regenerative Medicine Using qPCR

Akari Teramoto, Shimadzu Diagnostics

Rapid Non-Destructive Growth-based Microbial Testing for In-Process Bioburden of Continuous Manufacturing Lines

Philip Junker Andersen, Intubio and

Dr Cedric Joossen, Johnson & Johnson Innovative Medicine

High Throughput Sequencing, a Rapid Method for Safety Analysis in Pharmaceutical Manufacturing

Dr Thomas Bovbjerg Rasmussen, Novo Nordisk

Assessing the Use of Solid-Phase Cytometry for Rapid Bioburden Testing

Sophie Drinkwater, AstraZeneca

How to Validate Non-CFU RMMs and Guidance on Setting New Acceptance Levels

Dr Michael Miller, Microbiology Consultants

Strategy for Accelerated Implementation of New Technologies (SAINT): Roche's Post-Approval Change Program for Control System-Updates of Biologics

Dr Christina Heinlein & Dr Sven Deutschmann, Roche

Digitalization of Environmental Monitoring in a New Facility

Alexandra Wagner and Martin Brandl, Daiichi Sankyo

Susan Cleary, Novatek

Microorganism Verification Testing of an Alternative Rapid Microbial Method

Meghan Provenzano, Veolia

Applications of Whole Genome Sequencing for Microbial Quality and Contamination Control

Dr Prasanna Khot, Charles River Laboratories

Lessons Learned from Feasibility of MOLDS on Maldi-TOF, What to Consider for Validation and Implementation in Routine

Marie-Laurence Baille, MSD

What are the Benefits of the Real Time Colony Counting in Microbial Analysis?

Dr Thomas Alexandre, Interscience

Feasibility Study of the 3P Station, an Automated Environmental Monitoring System

Annalena Tegethoff, Novartis

Strategy to Handle Low Viable Particle Count in Grade A Environment with an Advanced BFPC

Dr Svetlana Kiseleva, Plair



Programme

Potency Testing Approaches: Challenges and Opportunities for mRNA Therapeutics

Dr Jan Michel Falcke, BioNTech

Challenges with Bioassay Design for mRNA Therapeutics

Thomas Ludwig, VelaLabs

A Versatile Multiplexing Technology for Complex Drugs Characterization and Potency

Dr Rosaria Esposito, bioMérieux

Enhancing Bioassay Precision and Throughput with Modular Workflow Automation

Dr Sean Lin, Eurofins

Harnessing the Power of Automation for Potency Assays and for Large-Scale Potency Assay Cell Bank Production

Sheri Mahan-Hunter, Pfizer

Advancing Potency Assay Automation

Dr Katharina Künzel, Boehringer Ingelheim

Potency Assurance for Cellular and Gene Therapy Products

Dr Andrew Byrnes, FDA/CBER

Potency Assays as Part of Release Testing for ATMPs - Focus on AAV

Dr Christoph Mück, AGES

Development of Methods for Comparative Analysis of the Potency of Monoclonal Antibodies

Dr Liliya Miller, Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines

Qualification of Analytical Cells for GMP Potency Assays – Guidance from a Different World

Dr Oliver Wehmeier, acCELLerate

Partial Dose-Response Curves - Contributions to the Discussion on “Allowed” Non-Similarity in Biological Assays

Dr Ralf Stegmann, Stegmann Systems

Trending and AI Prediction for Improving of Assay Performance

Dr Jan Amstrup, Novo Nordisk

Continuous Bioassay Monitoring and Troubleshooting in QC, 3 Case Studies

Dr Steffen Pahlich, Novartis

Unique Aspects of Bioassay OOS Investigations

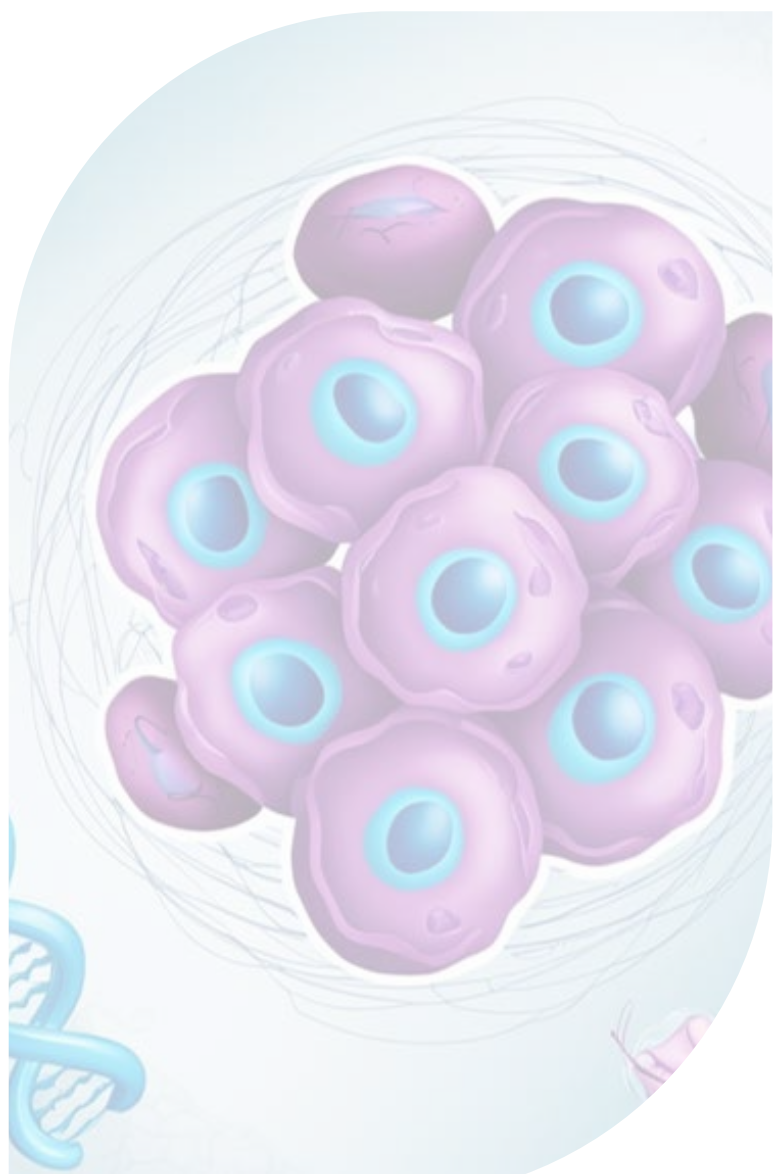
Dr Robert de Lange, Roche

MoA Reflective In-Vitro Potency Testing for Vaccines

Dr Sascha Karassek, Charles River Laboratories

Implementation of Concepts from ICH Q14 into Practice - Case Study for a Cell-Based Assay

Dr Simon Anderhub, Novartis



Cell and Gene Therapies/ATMPs – Quality, Safety

26/27 November 2024

TRACK 4

Programme

Efficient Microbial Control Concepts for ATMPs

Dr Holger Kavermann, Roche

Critical Quality Attributes of AAV based GT products

Dr Roland Pach, Roche

A ddPCR Method for Multiplex Determination of AAV Genome and Vector Titer

Dr Christian Schiller, Eurofins

Microbial Control for ATMP Facilities

Cecilia Pierobon, STERIS

Key Insights about CAR-T Therapy from Concept to Clinic

Dr Daniela Rozkova, SCTbio

Digital PCR Applications for Cell and Gene Therapy – Standardization for a High-Quality Process Development

Dr Andreas Hecker, QIAGEN

In-Process and Release Testing of Cell Therapy Applications

Caroline Paeschke, Minerva

European Pharmacopeia Perspective

Dr Solène Le Maux, EDQM

Spilling the Tea on a Robust CCS for ATMPs

Marsha Steed, Steed MicroBio

Test for Microbial Purity on MCB

Christine Weiß, Labor LS

What is the Value of Design-of-Experiment Approaches in the Development of Cell-based Potency Assays?

Dr Johannes Solzin, Boehringer Ingelheim

Implementation of ICH Q14 and USP <1220>: A challenge in the Highly Competitive mRNA Vaccine Field

Dr Isabelle Moineau, Aktehom

Dr Marc Francois Heude, Sanofi

Continuous Microbial Monitoring in ATMP Facilities in Compliance with the New EU GMP Annex 1

Dr Emad Albarouki, Particle Measuring System (PMS)

GMP Compliance Trends in Analytical Laboratories

26/27 November 2024

TRACK 5

Programme

Getting inspected by the FDA for the first Time - our Experience

Dr Katharina Elisabeth Scheidt, Microcoat Biotechnologie

PFAS in Pharmaceutical Products – a View on Findings and Potential Relevance

Stephan Lebertz, SGS Institut Fresenius

Machine Learning in the GMP Lab - Regulation, Validation and Case Studies

Dr Ulrich Köllisch, GxP-CC

Optimizing Precision: Strategies for Validating Analytical Platforms

Dr Mohamad Toutounji, Molgenium

Analytical Method Validation in Pharmaceutical Products according to ICH Q2 and in Biological Matrices according to ICH M10 using HPCL-UV, HPLC-MS and ELISA

Dr Reingard Raml, JOANNEUM RESEARCH Forschungsgesellschaft

Data Integrity and CSV of the Computerised Systems used to Manage GxP data – a Necessary Precondition for a Valid (Bio)Analytical Method?

Dr Timo G. Kretzschmar, TiKrESolution

Digitalisation and Automation of Validation Activities

Christophe Girardey, wega Informatik

Unraveling Out-of-Trend Stability Results: A Case Study in Identification and Investigation

Sanja Despotovska, Alkaloid

Concepts to Prevent Lab Errors & Unconfirmed OOS in QC Laboratories

Dr Karl-Heinz Bauer, Boehringer Ingelheim

Health Authority Challenges to the Well Established Dissolution Specification of a Mature Drug Product - a Case Study

Dr Lukas Sonnenschein, Merck Healthcare

Hard Facts about Softgels: Analytical Challenges and Regulatory Gaps

Dr Ana Petkovska, Patheon by Thermo Fisher Scientific

Applying Life Cycle and Validation Principles to the Customized Amplex UltraRed Assay

Dr Alexandra Heussner, Vetter Pharma

Programme

Fortifying the Future: Advanced IT Security for Modern Labs

Joachim Post, wega Informatik

Potentials of an ERP Managed Logistic System for the Pharmaceutical Laboratory

Julia Abadir, VelaLabs

Process Mapping and Redesign as the Basis for Laboratory Digitalisation

Dr Bob McDowall, R.D. McDowall Limited

Sub-Visible Particulate Matter Testing – Reduce Variability in Blank Values with Automatization and Optimization – a Practical Case Study on Different Techniques

Dr Melanie Zerulla-Wernitz, Vetter Pharma Fertigung

Foster Environmental Monitoring Results with Advanced Automated Systems

Laurent Leblanc, bioMérieux

Automation of Environmental Monitoring Workflow

Adele Gisselmann, Merck

Practical Examples of 5s Optimizations in Offices & QC-Labs

Dr Karl-Heinz Bauer, Boehringer Ingelheim

Transfer of Analytical Procedures. Practical Handling of Transfers to Different Types of CMO's

Ulla Bondegaard, Novo Nordisk

Construction of a New Hazardous Materials Storage Facility for a Contract Laboratory

Dr Jochen Kolb, BioChem Labor für biologische und chemische Analytik

Regulatory Considerations for E&L Labs and Methods. From Pharmaceuticals to Medical Devices and in between - Combination Products

Dr Andreas Nixdorf, SGS INSTITUT FRESENIUS

Outsourcing of Qualification Management

Dr Carsten Börger, Valicare



Programme

Data Quality & Data Integrity Lifecycle Overview

Dr Christopher Burgess, Chairman ECA AQCG

Overview of the ECA AQCG Guide to AIQ&SV

Dr Bob McDowall, R.D. McDowall Limited

Risk Assessment in AIQ&SV

Dr Christopher Burgess, Chairman ECA AQCG

Application of the AIQSV Approach to a Bioassay Analytical Instrument and Software

Margarita Sabater, Genmab

Risk-Based Qualification of HPLC Systems

Martina Gjorgjevska, THE FORCE CT

Eurachem Guide for The Fitness for Purpose of Analytical Equipment

Dr Ernst Halder, Eurachem

Ongoing Monitoring in Analytical Instrument Performance Qualification

Dr Joachim Ermer, Ermer Quality Consulting

Overview of General Chapter <1220> Analytical Procedure Lifecycle

Dr Christopher Burgess, Chairman ECA AQCG

Using the Analytical Target Profile (ATP) for Efficient Procedure Lifecycle Management and Enhanced Analytical Platform Adoption

Dr Amanda Guiraldelli Mahr, formerly USP

Importance of Change Control and Deviation Management over the Lifecycle

Silviya Dimitrova, TEVA Pharmaceuticals Industries

Efficient Analytical Instrument Qualification - Bridging Laboratory Needs and GMP Compliance

Dr Nadine Mendl, ten23 health

Lifecycle Roles and Responsibilities

Patrick Jackson, GSK

Comparison of ICH Q2(R2), ICH Q14 & USP <1220> with the Draft General Chapter in the Chinese Pharmacopeia

Dr Gerd Jilge, Board Member ECA AQCG

Consideration of Uncertainty in Evaluation of Accuracy and Precision according to the New ICH Q2(R2)

Dr Joachim Ermer, Ermer Quality Consulting



The Exhibitor

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.

Different stand packages are available:

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

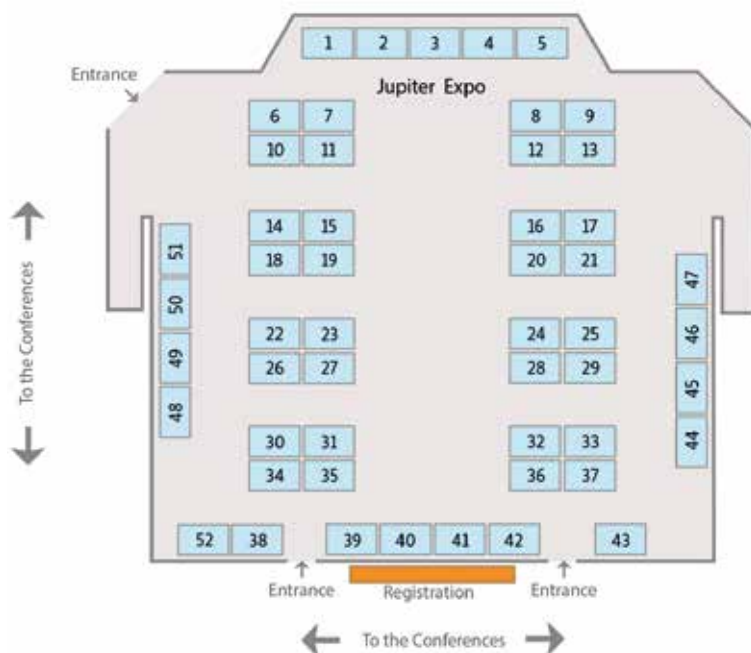
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- Named as a premium sponsor and logo in all congress-specific print and online media
- Your logo on all name badges and the exhibition plan
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Costs: € 13,960.00 plus VAT



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



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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 Manager), phone: +49 (0) 6221/84 44-51

E-Mail: strohwal@concept-heidelberg.de

The Fees

A one-day ticket/two-day ticket will enable you to visit the congress (26/27 November 2024) 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 25 November 2024 for € 590,- + VAT can be combined with the congress.

Charges are payable after receipt of invoice.

Social Event

On the evening of the first congress day, on 26 November 2024, 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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For questions regarding reservation, hotel, organisation, exhibition etc.:

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Content last updated:

The status of the content is as of **30.10.2024**.

The latest content can be found on the PharmaLab website at <https://www.pharmalab-congress.com>.

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To avoid incorrect information, please give us the exact address and full name of the participant.



- 25 November 2024: Pre-Conference - 590 € plus VAT
- 26+27 November 2024: PharmaLab Congress & Exhibition (day 1 + 2) - 1.380 € plus VAT
- 26 November 2024: PharmaLab Congress & Exhibition (day 1 only) - 690 € plus VAT
- 27 November 2024: PharmaLab Congress & Exhibition (day 2 only) - 690 € plus VAT

Conference Language: The official conference language will be English.

Particularities of the PharmaLab Congress:

With a one-day ticket/two-day ticket for the PharmaLab Conferences (26/27 November 2024) 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, please choose the conference you are most interested in during the online registration process.

Please note



There will be no hotel/ room reservations via Concept Heidelberg. Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice. There will not be any print-outs at the Congress. Instead you will receive all presentations prior to the Congress as downloads. presentations of this Course will be available for download and your print-out one week before the conference.



Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.



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