

**Developments in Modern Pharmaceutical and Biopharmaceutical Laboratories** 

# Düsseldorf/Neuss, Germany

24 - 26 November 2025



Bioassays/Potency Assays – Regulatory Requirements,

Alternative and Rapid Microbiological Methods



**EUROPAS GRÖSSTE** GMP/GDP AKADEMIE

**Development and Routine Use** 

Endotoxin and Pyrogen Testing

# Two Pre-Conference Workshops on 24 November 2025

## 6th International Mycoplasma qPCR Testing User Day

This Pre-Conference Workshop is directed to responsible personnel involved in Quality Control testing of biopharmaceuticals and biologics. It is also useful for service providers, such as contract research organisations and contract manufacturers.

## **Programme & Speakers:**

Mycoplasma Testing - Authorities Point of View

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

Nucleic Acid Testing for Mycoplasma Detection: From Regulatory Requirements to GMP Implementation

Dr Marc Meichenin, CleanCells

Dr Caroline Kassim Houssenaly, bioMérieux

Leveraging the Capabilities of qPCR in Rapid Mycoplasma Validation Study Design and Execution including a Case Study on Application in Investigation of a Contamination Event

Michael Brewer, Thermo Fisher Scientific

Guidelines for Choosing the Appropriate Mycoplasma Standards for Method Validation by NAT

Yoann Mainguy, Merck

Optimization and Implementation of the MycoSEQ SYBR and TaqMan Kits for Lot Release

Joleen Simpson, Lilly

Bridging Speed and Sensitivity: Validation of a Hybrid Mycoplasma Detection Method for Complex Product Matrices

Dr Lori Daane, Bionique Testing Laboratories

Summary, Q&A and Plenum Discussion

Alexander Bartes, Roche

Mycoplasma Platform for Rapid QC in Short-Shelf Life ATMPs Dr Jonathan Hanley, Shimadzu

## Quality Control of mRNA/LNP Products

This Pre-Conference is directed to responsible personnel involved in Quality Control testing of mRNA or LNP based products.

## Programme & Speakers:

Microbiological Insights into the Analytical Life Cycle of mRNAbased Therapeutics

Dr Thomas Meindl, Labor LS

Addressing mRNA vaccines in the European Pharmacopoeia -New Ph. Eur. Texts

Dr Thuy Bourgeois, EDQM - Council of Europe

Building a Robust CMC Framework for mRNA Therapeutics: From Raw Materials to Drug Product Release

Dr Mohamad Toutounji, Molgenium

CMC Strategies for saRNA Therapeutics: Optimizing T7 Polymerase, IVT Processes, and Quality Control to Accelerate Clinical Translation

Mengqian Mao, Novoprotein

Setting up Specifications: Considerations and Approaches

Dr Jan M. Falcke, BioNTech

Homing In on Fit-for-Purpose Biophysical Techniques for mRNA and LNP Characterization

Dr Natalia Markova, Freelance Consultant

Endotoxin Detection via a Low-Cost Electrochemical Test Strip and Reader Approach

Prof Dr Damion Corrigan, Aureum DX

Case Studies for mRNA Therapeutics – Developing Reliable and Robust Potency Methods

Dr Frances Reichert, Eurofins

mRNA Products as ATMP and as Vaccine - Same Technology but Different Requirements

Dr Sabine Hauck, degura pharma consult hauck



## **Analytical Quality and Lifecycle Concepts**

25 November 2025

## A Track Organised by the ECA Analytical Quality Control Group



This conference track is intended for laboratory managers, supervisors and analysts, quality control managers, heads of quality control, qualified persons (QPs), analytical scientists, and senior laboratory staff.

## **Programme & Speakers:**

KEYNOTE on 25 November 2025: Artificial Intelligence in Pharmaceutical Industries

Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D, Merck Life Science

#### Introduction to the Track and AQCG

Dr Christopher Burgess, Chairman ECA AQCG

# The new AQCG Guideline on Sampling and Sample Management

Dr Christopher Burgess, Chairman ECA AQCG

# Overview Instruments and Systems Lifecycle 'Fitness for Intended Use'

Dr Bob McDowall, R.D. McDowall Limited

# Analytical Procedure Development Lifecycle 'Fitness for Intended Purpose'

Patrick Jackson, GSK

# Performance Qualification of Analytical Procedures ICH Q2 (R2) & the revision of USP <1225>

Dr Gerd Jilge, Member of the ECA AQCG Board

# Performance Qualification of Bioanalytical Procedures; Similarities and Differences

Margarita Sabater, Genmab

# AQbD and its Impact on the Analytical Procedure Lifecycle

Dr Amanda Guiraldelli Mahr, RIC Group

# Ongoing Procedure Performance Verification (New USP Draft General Information Chapter <1221>)

Dr Joachim Ermer, Ermer Quality Consulting

# Good Documentation Practices and Data Integrity (USP <1229>)

Dr Christopher Burgess, Chairman ECA AQCG



# **GMP Compliance Trends in Analytical Laboratories**

26 November 2025

The aim of this conference is to address GMP compliance issues that are currently discussed as hot topics in analytical quality control laboratories and during GMP/FDA inspections.

## **Programme & Speakers:**

KEYNOTE on 26 November 2025: From Bog to Bedside: Lessons from the First Dedicated Phage Therapy Center in North America

Prof Dr Steffanie Strathdee, University of California San Diego School of Medicine/Co-Director at the Center for Innovative Phage Applications and Therapeutics



Why every Factor matters in a Contamination Investigation

Jeanne Moldenhauer, Excellent Pharma Consulting, Inc.

Small CROs and Validation & Conduction of (Bio)
Analytical Methods

Dr Timo G. Kretzschmar, TiKrESolution

Universal Study Design for Instrument Changes in Pharmaceutical Release Analytics

Dr Anne Ries, Boehringer Ingelheim Pharma

Auditing Audit Trails - QA vs QC Perspective

Martina Gjorgjevska, The FORCE CT Apostol Todorovsk, Sinceritas **Audit Trail Requirements for Digitalised GMP Laboratories**Dr Bob McDowall, R.D. McDowall Limited

Evaluation of Stability Data: Extrapolation of Shelf-Life by Statistical Analysis

Dr Joachim Ermer, Ermer Quality Consulting

Improving Analytical Procedure Transfers in the Pharmaceutical Industry

Ulla Bondegaard, Novo Nordisk



# Laboratory Optimization, Automation and Digitalization/ **Outsourcing in Pharmaceutical Laboratories**

25/26 November 2025

This conference provides practical tools and strategies to optimize laboratory processes, improve efficiency through automation and digitalization, and ensure GMP-compliant outsourcing of analytical activities. It is aimed at laboratory and quality control professionals as well as service providers in the pharmaceutical industry.

### Programme & Speakers:

From Spreadsheets and Paper to Digital Alternatives: Navigating Compliance, Reducing Errors, and Embracing **Smarter Systems** 

Carsten Jasper, Jasper Consulting

Implementation of a LIMS - Lessons Learned

Dr Xaver Schratt, GBA Pharma

Achieving Cost Excellence in GMP Labs - A Proven Maturity Model for Sustainable Results

Dr Johann Gregori, Author & Speaker

Beyond the Visible: Automating the Quest for Subvisible Particles in Parenteral Products by means of Microflow

Dr Melanie Zerulla-Wernitz, Vetter Pharma

From Traditional QC to Real-Time Volume Control: **Enhancing Screening Data Quality** 

Tobias Brode, Liquimetrix

QC-Automation: Development of a Fully Automated **Bioburden Testing Solution** 

Anke Hossfeld, Merck Life Science

The Role of AI and Automation in Environmental Monitoring (EM): Driving Standardization, Efficiency, and Innovation in Microbiology

Arnalda Giambra, Copan Group

From EM to Product Release: Transforming QC labs with connected EM Systems

Bernard Corcoran, Lonza

Accelerate Journey towards Pharma 4.0 with Next Gen Lab Solutions

Rajasekhar Gollapinni, Caliber

#### KEYNOTE on 25 November 2025: Artificial Intelligence in Pharmaceutical Industries

Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D, Merck Life Science

KEYNOTE on 26 November 2025: From Bog to Bedside: Lessons from the First Dedicated Phage Therapy Center in North America

Prof Dr Steffanie Strathdee, University of California San Diego School of Medicine/Co-Director at the Center for Innovative Phage Applications and Therapeutics

#### Practical Examples on Digitalization, Optimization & Simplification in QC-Labs

Dr Karl-Heinz Bauer, Training - Beratung - Coaching

From Instrument to Knowledge: How to Organize the Digitalization of your Laboratory?

Dr Steven van Helden, wega

Future Labs: Architecture, Automation and AI

Kambiz Hajizadeh-Zaker, Vollack GmbH & Co. KG Christian Ziegler, BAT GmbH

Smart Organization in the Laboratory: 47% Time Savings with 100% Precision

Mario Schneider, Better Basics Laborbedarf

#### Standardization inside a Network of GMP Contract Laboratories

Dr Christoph Höppner, Eurofins BioPharma Product Testing

The Art of Partnership: Managing Expectations in Pharma-**CRO Relationships** 

Malin Molander, Svar Life Science

Microbial Qualification of Cleanrooms: Not only CFU counts - Big projects in different spotlights

Alexander Pfülb, Labor LS



## Artificial Intelligence in Laboratories

25/26 November 2025

This conference aims to address the impact of Artificial Intelligence (AI) on pharmaceutical laboratories and explore AI applications in analytical processes, regulatory compliance, and quality control.

#### **Programme & Speakers:**

#### AI-History in a Nutshell

Dr Karl-Heinz Bauer, Training - Beratung - Coaching

Al needs Data Management and FAIR Data in the Lab Christophe Girardey, wega

Accelerating Analytical Method Development with Predictive Modelling and AI

Dr Raquel Figueiredo, BIAL

Investigation and Root Cause Analysis using AI for Trending and Contamination Control

Susan Cleary, Novatek International

Responsible AI Development of Alternative Microbiological Methods used for Environmental Monitoring – a Case Study with the APAS Independence

Dr Steven Giglio, Clever Culture Systems

AI and GxPs: A Contradiction?

Dr Karl-Heinz Bauer, Training - Beratung - Coaching

Case Study: Machine learning for Mold vs Bacteria Identification

Lisa Mallam, bioMérieux

Case Study: AI-Based Automated Solution for Incubation and Colony Counting in Microbiological Quality Control

Camilla Giardini, Copan NewLab

# KEYNOTE on 25 November 2025: Artificial Intelligence in Pharmaceutical Industries

Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D, Merck Life Science

KEYNOTE on 26 November 2025: From Bog to Bedside: Lessons from the First Dedicated Phage Therapy Center in North America

Prof Dr Steffanie Strathdee, University of California San Diego School of Medicine/Co-Director at the Center for Innovative Phage Applications and Therapeutics

Utilizing ChatGPT to Establish Company-Wide
Harmonized Equipment and System Validation Standards
Isabella Küfner, Boehringer Ingelheim

Large Language Models in the Service of Quality: Analyzing the Quality of Documentation

Dr Colin Lischik, Boehringer Ingelheim

AI-powered Pharma: Transforming Drug Discovery, Development and Production

Siobhan Fleming, SIEMENS



## **Testimonials**

Dr Sara Albarran, ABclonal Germany GmbH, Düsseldorf, Germany

"The PharmaLab Congress was an incredible opportunity to forge valuable connections and engage in insightful discussions, featuring exceptional speakers. I'm thrilled to have won the iPad and grateful for the experience!"

Marleen Hoozemans, MSD Biotech BV, Oss, The Netherlands

"I always enjoy visiting the stands during PharmaLab to see all the cool new technologies that are available each time. The event is a great way to connect with peers in the industry and to share and generate ideas. I also loved the photobooth to capture the good vibes that were going on at the event. I never thought I would win the lottery, although I always participate in the hope to win it one day! I was very delighted to be the winner of this year's lottery."

# Cell and Gene Therapies/ATMP - Quality and Safety

25/26 November 2025

This conference focuses on microbiological and analytical quality requirements, suitable methods, and validation for manufacturers and developers of cells, tissues, cell- and tissue-based products, and ATMPs. Experts from authorities and industry will share insights on current regulations and practical implementation.

## **Programme & Speakers:**

**Update on ATMPs in the Ph. Eur.**Dr Solène Le Maux, EDQM

Understanding of Analytical Critical Quality Attributes (CQAs) for Viral Vector Characterization in Gene Therapy Dr Maribel Navarro, Kymos

Strategy for Potency Determination of Gene Therapy Products

Dr Ulrike Herbrand, Charles River Laboratories

High-Throughput Single-Cell Potency Assays for Cell Therapy Development Using Droplet Microfluidics Dr Stephanie van Loo, LiveDrop

Cell and Gene Therapy CQA Analysis using Mass Spectrometry

Daniel Waldera-Lupa, Protagene

Enhanced Precision and Robustness in CAR-T Manufacturing: A Comparative Study of qPCR and dPCR Dr Daniela Rozkova, SCTBio

Validation of VCN Determination by dPCR on a Retroviral CAR-T Cell Product in Compliance with ICH Q14 and Q2(R2) Katy Haussmann, Virchow Klinikum der Charité Berlin Dr Daniel Lindemeier, Labor LS

Developing Control Strategies for an Off-the-Shelf Allogenic Cell Therapy Product: A Case Study Dr Steven Braem, 3D-PharmXchange

Considerations of Viral Safety Strategies for Cell Therapies – A Suggested Approach for What to Include in Viral Safety Packages for Cell Therapies Dr Kerstin Brack, Charles River Laboratories

# KEYNOTE on 25 November 2025: Artificial Intelligence in Pharmaceutical Industries

Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D Merck Life Science

KEYNOTE on 26 November 2025: From Bog to Bedside: Lessons from the First Dedicated Phage Therapy Center in North America

Prof Dr Steffanie Strathdee, University of California San Diego School of Medicine/Co-Director at the Center for Innovative Phage Applications and Therapeutics

Avoiding Common Sterility Testing Compliance Gaps and Regulatory Observations During ATMP Sterility Testing Marsha Steed, Steed MicroBio LLC

Enhancing Microbiological Quality Control with Ready-to-Use Microorganisms

Dr Megha Bajaj, bioMérieux

How to Build a Digitalized End-to-End Process for Environmental Monitoring for ATMPs Release Johannes Oberdörfer, Rapid Micro Biosystems Willem Dullaers, Lonza

The New Guideline on ATMPs and Further Regulatory Update on ATMPs

Dr Sabine Hauck, ECA ATMP Interest Group





# Bioanalytical Control of Biological Drug Substances and Products

25/26 November 2025

This conference offers insights into modern analytical methods for biological drug substances and products, with a focus on regulatory requirements and practical implementation. It is aimed at professionals involved in method selection, validation, and lifecycle management of laboratory methods.

## **Programme & Speakers:**

The combined Analytical Identity Testing Strategy for Oligonucleotides (Nucleotides)

Dr Alexandra Heussner, Vetter Pharma

mRNA Analytics: Last Chance for Platform Methods? (Nucleotides)

Dr Jan M. Falcke, BioNTech

Platform Methods - RNA Integrity as Case Study
Susanne Ulrich, BioNTech

A Platform ddPCR Method for the Detection of Residual DNA in mRNA Samples (Nucleotides)

Dr Christian Schiller, Eurofins

Control of Process-Related Impurities (HCPs) and Regulatory Requirements (HCP/Regulatory)

Dr Erika Friedl, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines

Mass Spectrometry in risk-oriented Host Cell Protein Analysis: The Role and Integration of LC-MS/MS for Qualitative and Quantitative Risk Assessment of HCPs in Biopharmaceuticals (HCP)

Julia Rauch, Charles River Laboratories

The Role of Platform Host Cell Protein ELISAs in Biopharmaceutical Quality Control (HCP)

Dr Florian Semmelmann, Roche

Real Time Release Control Strategy for a Biotech Drug Product (Release)

Dr Susanne Gawenda, Roche

Implementation of a Cartridge-based CE-SDS/cIEF Instrument for Routine Measurement of Drug Product (Implementation)

Johannes Führer, VelaLabs/Tentamus Clemens Graf, VelaLabs/Tentamus

# KEYNOTE on 25 November 2025: Artificial Intelligence in Pharmaceutical Industries

Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D Merck Life Science

KEYNOTE on 26 November 2025: From Bog to Bedside: Lessons from the First Dedicated Phage Therapy Center in North America

Prof Dr Steffanie Strathdee, University of California San Diego School of Medicine/Co-Director at the Center for Innovative Phage Applications and Therapeutics

ICH Q5A - Prior Knowledge in Virus Testing and Clearance Studies

Dr Martin Spruth, AGES – Austrian Agency for Health and Food Safety

Pragmatic Implementation of ICH Q14: Capillary Electrophoresis for Virus Quantification (ICH Q14/Viruses) Dr Ewoud van Tricht, Kantisto BV

Development of HPLC-based Methods for Separation and Subsequent Characterization of Morphological Subspecies of a VSV-based Therapeutic Virus

Dr Johannes Solzin, Boehringer Ingelheim

Mastering hcDNA: A Harmonized Approach for AAV Gene Therapies (Viruses/hcDNA)

Dr Denise Teber, Charles River Laboratories



# Bioassays/Potency Assays – Regulatory Requirements, Development and Routine Use

25/26 November 2025

This conference offers Insights into the development, validation, and regulatory expectations for bioassays and potency assays across various biopharmaceutical modalities, including ATMPs and vaccines.

## **Programme & Speakers:**

Key Aspects of Assay Control throughout the Analytical Lifecycle

Dr Sonja Klingelhöfer, Richter Biologics

Reference Standard Qualifications and Re-Evaluations for Potency Assays

Dr Pieta Boon, MSD Ios Weusten, MSD

Bioassay Primer: Model-Based Confidence Interval Effects Dr Florian Müller-Sallanz, Stegmann Systems

Bioassay Relevant Texts in the Ph. Eur. as well as the Potency Strategy in the Ph. Eur. for mAbs

Dr Solène Le Maux, EDQM

A (Former) CDER Reviewer's Perspective on Potency Assays

Gerry Feldman, Formerly FDA

Challenges in Optimization and Validation of Potency Assays in a State Batch Testing Laboratory

Dr Lilija Miller, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines

Case Study: Validation and Bridging of a Flow Cytometry Potency Assay for a Therapeutic Monoclonal Antibody Dr Frances Reichert, Eurofins

Of Mice and (Wo)Men - Development and Validation of a Cell-Based Bioassay for a Commercial Biopharmaceutical Offering an Ethical and Efficient Alternative to the Conventional In Vivo Mouse Assay

Simone Tomaschek, Roche

Case Study of an Enhanced Development for a Bioassay Dr Simon Anderhub, Novartis

'Where Fat and Sugar Meet' - Setup of a Glucose Uptake Assay in Differentiated Adipocytes Dr Ella Rosenzweig, VelaLabs

# KEYNOTE on 25 November 2025: Artificial Intelligence in Pharmaceutical Industries

Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D Merck Life Science

KEYNOTE on 26 November 2025: From Bog to Bedside: Lessons from the First Dedicated Phage Therapy Center in North America

Prof Dr Steffanie Strathdee, University of California San Diego School of Medicine/Co-Director at the Center for Innovative Phage Applications and Therapeutics

Advancing Bioassay Technologies with NanoBiT Split Luciferase

Dr Jamison Grailer, Promega

Combination of Cell-based Potency Assay with Digital Droplet PCR® Readout as Innovative and New Methodology for Characterization of RNAi Therapeutic Qfitlia®(Fitusiran)

Christine Graf, Sanofi

Development and Optimization of the Infectious Titer Assay (TCID50) for Recombinant AAV

Annemie Wielant, UCB

A Case Study on the Challenges of Establishing a Robust Cell-Based Bioassay for Plasmid DNA Potency Determination

Dr Thomas Danielsen, Novo Nordisk

Ensuring Consistency in Bioassay Method Transfer: Strategies for Overcoming Variability Jessica Weaver, BioAqilytix

Making Cell-Based Potency Assays Work Better for QC: A Simpler, Stronger Solution
Peter Wolff, AGC Biologics

Optimizing Cell-Based Assays: A Case Study on Overcoming Development Challenges Morgane Gesquière, UCB

# Alternative and Rapid Microbiological Methods

25/26 November 2025

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 will provide a comprehensive overview.

## **Programme & Speakers:**

Update on RMM in the Ph. Eur.

Dr Thuy Bourgeois, EDQM

Vision AI in Microbiology QC: Robust Models Ensure Reliable Outcomes

Niek Van Overberghe, Microtechnix

Unlocking Microbial Strain Typing with Whole Genome Sequences

Dr Sujan Timilsina, Charles River Laboratories

Approach for Validation Microbial Identification Methods: Primary and Limited Validations

Marie-Laurence Baille, MSD

Development of Long Read Sequencing for Adventitious Virus Detection

Dr Dominik Meisohle, Boehringer Ingelheim

Next Generation digital PCR Technology for Sterility Testing of Cell and Gene Therapy Products

Dr Alexandra Müller-Scholz, Sartorius

Rapid, Phenotypic Sterility Testing for Cell and Gene Therapy Products: Validation of a Three-Day Protocol Using the calScreener+ Platform

Dr Wilhelm Paulander, Symcel

Moving the Needle for Sterility Testing: Towards a New, Rapid Sterility test to Allow Faster Release of CAR-T Drug Products

Dr Nore Struyf, Johnson & Johnson

Update/Additions to Performing Statistical Calculations for Quantitative Rapid Method Validation Criteria

Dr Michael Miller, Microbiology Consultants

**Evaluation of an Automated Readout of APS** 

Simon Braun, Roche Matthieu Giletti, Roche

# KEYNOTE on 25 November 2025: Artificial Intelligence in Pharmaceutical Industries

Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D, Merck Life Science

KEYNOTE on 26 November 2025: From Bog to Bedside: Lessons from the First Dedicated Phage Therapy Center in North America

Prof Dr Steffanie Strathdee, University of California San Diego School of Medicine/Co-Director at the Center for Innovative Phage Applications and Therapeutics

## Evaluation of RMBNucleus™ Mold Alarm Software

Dr Yu-Wei Shieh, Boehringer Ingelheim

Automated Solid Phase Cytometry Applications: Bioburden Troubleshooting in Production and Sterility Testing Feasibility for mRNA Vaccines

Dr Thierry Bonnevay, Sanofi

Primary Validation of Rapid-C+, Advanced BFPC, for Real-Time Viable Particle Monitoring

Dr Svetlana Kiseleva, Plair

EM Plate Reading Using the APAS Independence Juan González, Pfizer

Accelerating Release of Short Shelf-Life Therapies Through Automated Growth-Based Method Optimization and Application of USP<72> "Safety Margin" Guidelines

Dr Caroline Kassim-Houssenaly, bioMérieux

Bridging ISO Standards and ARMM for Effective Air Monitoring

Corina Keller, MBV



# Endotoxin and Pyrogen Testing – Pharmacopoeial and Scientific Developments

25/26 November 2025

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.

## **Programme & Speakers:**

#### Forty Years of Endotoxin Standardisation

Trusha Desai, National Institute for Biological Standards and Control, MHRA

# Procedure for BET Sample Hold Time Discrepancies at Boehringer Ingelheim

Dr Gertrud Lallinger-Kube, Boehringer Ingelheim

# Investigating Low Endotoxin Recovery (LER) and Pyrogenicity in Diverse Pharmaceutical Products

Dr Parysatis Sachs, Sanofi

# Limit Test Validation – Balancing Business Risk and Patient Safety

Dr Anthea Darius, Microcoat Claudia Köniq, Sanofi

# Advancements in Endotoxin Testing from the PSCI Report and Member Survey

Dr Shahjahan Shaid, GSK

# **Endotoxin Testing of Pharmaceutical Products using Synthetic Reagents**

Poppy Cliffe, AstraZeneca

#### Product Validation with rCR at Bayer

Sandra Wieger, Bayer AG

# Streamlined Validation of Recombinant Cascade Reagents: A Novel Approach Using Advanced Microfluidic Technology

Meg Provenzano, Veolia

#### Update on the Pyrogenicity in the Ph. Eur.

Dr Solène Le Maux, EDQM

# RSE, CSE or Crude LPS Preparations? A Closer Look at Detection Variability

Luisa Burgmaier, Microcoat

# MAT: Thoughts on Test Sensitivity, Pyrogen limits, MVD and Readout System

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

# KEYNOTE on 25 November 2025: Artificial Intelligence in Pharmaceutical Industries

Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D Merck Life Science

#### KEYNOTE on 26 November 2025: From Bog to Bedside: Lessons from the First Dedicated Phage Therapy Center in North America

Prof Dr Steffanie Strathdee, University of California San Diego School of Medicine/Co-Director at the Center for Innovative Phage Applications and Therapeutics

# Shaping the Future of Pyrogen Testing: Regulatory Updates and the Role of MAT

Case Study: Qualification of a Reporter Gene-Based Monocyte Activation Test (MAT)

Dr Nicole Rieth

Dr Luca Benedan, Eurofins

#### Implementing A New Type of Monocyte Activation Test Method to Detect and Quantify Pyrogens in GMP Environment

Dr Katarzyna Marciniak-Darmochwal, Charles River Laboratories

# MHRA – Results of Survey and Discussions/Podium Discussion

Dr Elliot Lilley, UK National Centre for the Replacement, Refinement & Reduction of animals in research

# Next Generation MAT – Analytical Precision Meets Regulatory Confidence

Dr Eva Kritikou, MAT Research

Addressing the Major Flaw of Applying MAT Method 2 to Products with Low Endotoxin Recovery Effects, and Presenting a New Generation of Rapid, Simplified and Sensitive PBMC based MAT with FBS-free Medium

Dr Shabnam Solati, CTL-MAT LLC

# HyPerMAT – Discover the Future of in Vitro Pyrogen Testing

Dr Johannes Lichti, HyQuality Dx





## PharmaLab: Key Points

#### Flexible Attendance

- Create your own individual conference programme
- Move freely between sessions and conference rooms
- One-day or two-day tickets available

#### Trade Exhibition on 25 & 26 November 2025

- Discover products & services in analytics, bioanalytics, microbiology
- Access to an accompanying exhibition (trade exhibition)

#### **Networking Opportunities**

- Social Event on the first evening on 25 November 2025
- Meet and exchange with delegates, speakers, exhibitors

## Tickets & Fees

€ 690,- until 31.08.

One-Day Ticket: € 790 + VAT

Access on 25 OR 26 November only

€ 1.380,- until 31.08.

Two-Day Ticket: € 1.580,- + VAT

Access on both 25 & 26 November

#### Pre-Conference (24 November): € 690,- + VAT

Can be combined with the congress

All tickets include lunch and beverages during the conferences and in breaks.

Scan the QR Code to go to registration page:



## The 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 Trade Exhibition on 25 & 26 November 2025

Take the opportunity to visit the accompanying trade exhibition. More than 40 companies will be present. Have a look a them at

www.pharmalab-congress.com/ exhibitor-infos.html





## The Organiser

CONCEPT HEIDELBERG – On behalf of the ECA Academy

P.O. Box 10 17 64, D-69007 Heidelberg Phone +49 (0) 6221/84 44 0 E-mail: info@concept-heidelberg.de www.concept-heidelberg.com

#### For questions regarding Microbiology:

Axel H. Schroeder (Operations Director) Phone: +49 (0) 6221/84 44 10

E-mail: schroeder@concept-heidelberg.de

#### For questions regarding Analytics:

Dr Markus Funk (Operations Director) Phone: +49 (0) 6221/84 44 40, E-mail: funk@concept-heidelberg.de

#### For questions regarding Bioanalytics:

Clemens Mundo (Operations Director) Phone: +49 (0) 6221/84 44 42 E-mail: mundo@concept-heidelberg.de

#### For questions regarding reservation, hotel, organisation, exhibition etc.:

Ronny Strohwald (Organisation Manager)

Phone: +49 (0) 6221/84 44 51

E-mail: strohwald@concept-heidelberg.de