

# 14<sup>th</sup> PharmaLab Congress

Analytics ■ Bioanalytics ■ Microbiology

Developments in Modern Pharmaceutical and Biopharmaceutical Laboratories

Darmstadt, Germany  
(near Frankfurt Airport)  
23 - 25 November 2026

## Pre-Conferences Events on 23 Nov 2026

- 7th International Mycoplasma qPCR Testing User Day
- **NEW!** Data Quality Management of Aberrant Results
- Quality Control of mRNA/LNP Products

## Conferences on 24/25 Nov 2026

- Alternative and Rapid Microbiological Methods
- Endotoxin and Pyrogen Testing
- Analytical Procedure Lifecycle Management (APLM)
- Artificial Intelligence in Laboratories
- GMP Compliance Trends in Analytical Laboratories
- Laboratory Optimization, Automation and Digitalization/Outsourcing in Pharmaceutical Laboratories
- Bioanalytical Control of Biological Drug Substances and Products
- Bioassays/Potency Assays – Regulatory Requirements, Development and Routine Use
- Cell and Gene Therapies/ ATMPs - Quality and Safety

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# Pre-Conference Workshops:

## 7th International Mycoplasma qPCR Testing User Day

23 November 2026

### Highlights

- EP 2.6.7: User Challenges, Troubleshooting, and Best Practices
- Ensuring Robust qPCR-Based Mycoplasma Detection
- From Plates and Curves to Partitions: Mycoplasma Testing Goes Digital
- Validation Experiences and Case Studies
- Regulatory Developments and Regulators Experiences and Expectations

### Objectives

The contamination of biopharmaceutical products, i.e. classic biologics, but also modern cell and gene therapy products with mycoplasmas, e.g. due to contamination of cell cultures during the manufacturing process, poses a potential health risk to patients. Mycoplasma can influence virtually every parameter of cell culture, often with only minor visible effects, leading to uncontrollable conditions that are undesirable in the pharmaceutical industry. Regulatory authorities therefore require manufacturers to test their biopharmaceutical products and ensure that the released products are free of mycoplasma. Most regulatory authorities have issued guidelines that include protocols for mycoplasma testing, and some provide recommendations for the validation of rapid NAT (nucleic acid amplification techniques) testing methods. This provides you with a scientifically sound introduction to the field of rapid mycoplasma testing with a special focus on NAT and, in particular, qPCR methods. It includes lectures, case studies and interactive roundtable discussions by users for users.

### Moderators

Julian Mochayedí & Alexander Bartes, *Roche*

## Data Quality Management of Aberrant Results

23 November 2026

NEW TOPIC

### Highlights

- Regulatory expectations and guidance for OOS/OOT: how to stay compliant
- Hands-on evaluation: trend analysis tools + interactive Excel workshop
- OOS for small molecules and in biopharmaceutical analysis: specific challenges, examples, and best practices

### Objectives

This pre-conference workshop aims to strengthen participants' capability to manage data quality and investigate aberrant results in pharmaceutical laboratories by:

- providing a structured approach to handling Out of Specification (OOS) and Out of Trend (OOT) results,
- explaining key regulatory and guidance expectations and how they translate into practical lab procedures,
- applying trend analysis tools and statistical rules to evaluate OOT signals – incl. understanding common pitfalls and misinterpretations – through an interactive Excel-based exercise.

### Moderators

Dr Christopher Burgess, *Chairman ECA Analytical Quality Control Group*

## Quality Control of mRNA/LNP Products

23 November 2026

### Highlights

- Regulatory Developments and Regulators Experiences and Expectations
- Sanger Sequencing vs Nanopore
- Common issues with QC
- Latest developments in RNA analytics
- mRNA vs CAR-T

### Objectives

Innovations in cell therapy are transforming pharma and biotech by enabling treatments for previously incurable diseases. However, traditional viral transduction methods face challenges such as limited scalability, high costs and potential immunogenicity. Virus-free approaches, particularly RNA-based technologies like mRNA and lipid nanoparticles (LNPs), offer safer and more flexible alternatives. They enable precise, transient genetic modification without risks of genomic integration.

With the rapid advancement of mRNA/LNP platforms, robust quality control becomes essential to ensure safety, efficacy and regulatory compliance. Adherence to standards such as Pharm. Eur., USP and GMP is critical. The pre-conference track on Quality Control for mRNA/LNP Products provides insights into regulatory requirements, microbiological aspects and advanced analytical methods, while facilitating exchange on current challenges and future developments.

### Moderators

Dr Sabine Hauck, *Chair of the ECA ATMP Board & Yasmin Heynen, Labor LS*

# Alternative and Rapid Microbiological Methods

24/25 November 2026

## Highlights

- Optimising of Rapid Methods like ATP Bioluminescence, 16S rRNA, etc.
- Rapid Methods for special Cases like Radiopharmaceuticals
- Update on ISO 16140 – How to learn from other industries
- NGS – Opportunities and Experiences
- And more

## Objectives

Within the framework of this conference, current developments in regulatory requirements and scientific methodologies will be presented. Particular emphasis will be placed on experiences with the implementation and validation of alternative and rapid methods, both for in-process control and for product release testing. In addition, examples of real-time and online monitoring will be regularly addressed. The conference offers a platform to discuss the latest technological advances as well as practical challenges and considerations in meeting regulatory expectations. Presentations by distinguished speakers from regulatory authorities, industry, and academia in the field of microbiological detection and identification will provide a comprehensive overview.

These topics are driven by rapid scientific progress in cell and molecular biotechnology, which has led to the accelerated development of biopharmaceuticals, tissue-engineered products, and advanced therapy medicinal products (ATMPs). In this context, ensuring the safety of these technologies and products is becoming increasingly critical. A key aspect of risk assessment and safety assurance is the potential contamination with microorganisms and mycoplasmas. Their reliable detection, prevention, and control through rapid and appropriate methods are therefore essential for maintaining product safety and quality.

## Moderators

Dr Michael Miller, *Microbiology Consultants* & Dr Ulrich Herber, *Charles River Laboratories*

# Endotoxin and Pyrogen Testing – Pharmacopoeial and Scientific Developments

24/25 November 2026

## Highlights

- Novel Technologies
- Equivalence and Comparability Studies
- Rapid MAT Testing
- LER Experiences
- Regulatory Developments and Regulators Experiences and Expectations

## Objectives

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

You become informed about

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

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

## Moderators

Dr Johannes Reich, *Microcoat*, Dr Sven M. Deutschmann, *Roche* – *Members of the ECA Microbiology Working Group*



# Analytical Procedure Lifecycle Management (APLM)

24 November 2026

## Highlights

- What's new in USP <1221>/<1225>
- Risk-based validation decisions
- Practical case studies (ATP, risk assessment, validation strategy, precision/replication, platform procedures, OPPV)

## Objectives

This track aims to provide a lifecycle-based, risk-driven framework for developing, validating, and maintaining analytical procedures from early development through registration and post-approval change. Participants will learn how to apply current USP updates and use practical case studies (ATP, risk assessment, MODR, validation strategies, precision/replication, platform methods, and OPPV) to define fit-for-purpose validation scope, ensure method robustness and independence, and manage changes in an inspection- and dossier-ready way.

## Moderators

Dr Christopher Burgess, *Chairman ECA Analytical Quality Control Group*

# Artificial Intelligence in Laboratories

24/25 November 2026

## Highlights

- AI in GxP laboratories
- QC/analytics case studies
- Regulatory expectations & future trends

## Objectives

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.

Artificial Intelligence is transforming pharmaceutical laboratories by enhancing automation, data interpretation, and compliance monitoring. With the rise of machine learning, deep learning, and big data analytics, AI enables predictive analytics, anomaly detection, and process optimization, reducing human error and increasing efficiency. Regulatory authorities are increasingly focusing on these innovations to ensure AI implementation aligns with Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) guidelines. This track will present case studies and discuss current trends, challenges, and opportunities for AI-driven laboratory operations.

## Moderators

Dr Karl-Heinz Bauer, *Training - Beratung - Coaching (Day 1)*

Isabella Küfner, *Boehringer Ingelheim (Day 2)*

# GMP Compliance Trends in Analytical Laboratories

25 November 2026

## Highlights

- GMP “hot topics” for analytical QC labs (EU & US)
- Inspection readiness: current expectations & common findings (GMP/FDA)
- Practical implementation of regulatory updates in QC operations

## Objectives

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.

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

## Moderator

N.N.

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

24/25 November 2026

## Highlights

- Optimisation in practice
- Turn improvements into measurable results
- GMP-ready outsourcing with control

## Objectives

The pressure that the pharmaceutical industry is under today to reduce costs and increase efficiency and effectiveness applies equally to analytical laboratories. Often, waiting for the results of quality control is still a speed-limiting step in the entire production process. With this conference, participants will get to know tools for more effective and efficient control of laboratory activities.

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

You will be informed about:

- Optimization of laboratory processes
- Cost-efficient design of a laboratory
- Automation and optimization of environmental monitoring
- Case studies for laboratory automation/digitalization
- New analysis methods for the optimization of processes in the laboratory
- Practical aspects to consider when outsourcing activities
- Transfer of analytical procedures
- Practical aspects to consider when establishing contracts

## Moderators

N.N. (Day 1)

Dr Karl-Heinz Bauer, *Training - Beratung - Coaching* (Day 2)

# Bioanalytical Control of Biological Drug Substances & Products

24/25 November 2026

## Highlights

- ICH Q14 – Using Development Data
- Control strategies and smart statistical approaches in the analytical method performance evaluation for biological drugs
- Strategic Analytical Method Transfer: A Practical Guide to Seamless Transitions between R&D and Quality Control
- Application of a combined analytical ID testing strategy
- And more

## Objectives

The number of biopharmaceutical products in development and on the market is growing steadily, driven by innovative therapies such as cell and gene therapy, mRNA platforms and phage-based treatments. Many of these products are characterised by exceptional precision, though this is often accompanied by a high degree of complexity. Consequently, robust analytical methods are essential for evaluating the structure, purity, stability, etc., of biopharmaceutical active substances and medicinal products, and for investigating any residues, such as host cell proteins.

However, analytical techniques alone are not sufficient to fully characterise a product's functionality and safety. Complementary non-analytical approaches, such as cell-based assays or efficacy tests, are often necessary to comprehensively assess their functionality and safety. The development of biopharmaceuticals is inherently multidisciplinary and requires collaboration across various scientific and technical fields.

Following its success in 2025, this conference track once again addresses the analytical control of biological active substances and medicinal products, with a focus on identity, purity, residues/impurities and the associated analytical strategies. Techniques such as HPLC, CE, IEF and MS will be covered, amongst others.

## Moderators

Prof Dr Cari Sanger-van de Griend & Dr Ewoud van Tricht, *Kantisto*

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

24/25 November 2026

## Highlights

- Multi Specific Potency and Supporting Methods
- Development Data and Qualification Case Studies for Next-Generation Potency Assays
- MOA-Reflective Assays – Method Design, Use and GMP Validation
- Phase Appropriate Bioassays for ADCs
- Ongoing procedure performance verification (OPPV) for potency methods
- And more

## Objectives

The conference on bioassays and potency assays, now in its third year in 2026, will focus on both existing and emerging regulatory guidelines. Representatives from regulatory authorities will provide insights into relevant requirements, monographs, as well as their expectations and practical experience. In addition, experts from industry, contract research organisations and CDMOs, as well as scientists from fields such as cell banking, mathematics and statistics, will present their work on the development, validation and routine application of potency assays. The event will cover a range of product classes – from traditional proteins to ATMPs and vaccines – as well as current topics such as the automation of processes and the use of artificial intelligence. The aim of the event is to create a platform for exchange between academia, industry and regulatory authorities to jointly discuss experiences, expectations and perspectives.

The background to this conference is the steady growth of biopharmaceutical products in clinical development and on the market, particularly in the field of cell and gene therapies (ATMPs). These products are often highly complex, meaning that their bioactivity cannot be determined using conventional analytical methods alone. Additional challenges arise, among other things, from difficult scalability, the handling of very small batches, the quality of starting materials, and limited shelf lives. The development of suitable potency assays is therefore often challenging, especially as multiple testing procedures are usually required for a single product, reference standards are lacking, and the transition from development to the GMP-regulated environment does not always proceed smoothly. At the same time, the determination of bioactivity is an indispensable critical quality attribute (CQA) for release testing. Furthermore, the regulatory framework for these new forms of therapy is still under development, and relevant guidelines and monographs from regulatory authorities and pharmacopoeias have in some cases only recently been published or are still under development.

## Moderator

Dr Alexander Knorre, *Eurofins*

# Cell and Gene Therapies/ATMP – Quality and Safety

24/25 November 2026

## Highlights

- Strategies for decentralized ATMP manufacturing
- Technological Innovations: NGS, Vector Packaging Technology
- Regulators Experiences and Expectations
- Insights into alternative approaches: Bacteriophages, specific quality control strategies for cell therapies

## Objectives

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

## Moderators

Dr Sabine Hauck, *Chair of the ECA ATMP Board* & Dr Ulrike Herbrand, *Charles River Laboratories*

## Media Partners 2026:



# 14<sup>th</sup> PharmaLab Congress

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## 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 24 & 25 November 2026

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

### Networking Opportunities

- Social Event on the first evening on 24 November 2026
- Meet and exchange with delegates, speakers, exhibitors

## Tickets & Fees

**One-Day Ticket: ~~790~~ 690 EUR + VAT**  
690 EUR until 31 August

- Access on 24 OR 25 November only

**Two-Day Ticket: ~~1.580~~ 1.380 EUR + VAT**  
1.380 EUR until 31 August

- Access on both 24 & 25 November

**Pre-Conference (23 November): 690 EUR + 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 Organiser

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The status of the content is as of 15 April 2026. Further details and the latest content can be found online.

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## The New Location

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## The Trade Exhibition on 24 & 25 November 2026

Take the opportunity to visit the accompanying trade exhibition. More than 60 companies will be present. Have a look at them at

[www.pharmalab-congress.com/exhibitors-plan.html](http://www.pharmalab-congress.com/exhibitors-plan.html)

