

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

Analytics ■ Bioanalytics ■ Microbiology

Developments in Modern Pharmaceutical and Biopharmaceutical Laboratories

Düsseldorf/Neuss,  
Germany  
25 - 27 November 2024

Conference Schedule


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Monday, 25. November		Tuesday, 26. November						
PharmaLab Pre-Conference Event 5 th International Mycoplasma qPCR Testing User Day		Track 1: Endotoxin and Pyrogen Testing	Track 2: Alternative/Rapid Microbiological Methods	Track 3: Bioassay/Potency Assays - Regulatory Requirements, Development and Routine Use	Track 4: Cell and Gene Therapies/ATMP	Track 5: GMP Compliance Trends in Analytical Laboratories	Track 6: Laboratory Optimization, Automation, Digitalization / Outsourcing in Pharmaceutical Analysis	Track 7: Analytical Instrument Qualification and System Validation
Time								
09.00 h	09.00-09.15 h: <b>Welcome and Introduction</b>							
	 09.15-10.00 h: <b>The Promise and Challenges of In Vitro and in Silico Models in Drug Development</b> <i>Dr Julia Schüller, Charles River Laboratories</i>							
10.00 h	10.00-10.45 h: <b>Coffee Break / Conference Exhibition</b>							
11.00 h <b>11.00-11.45 h: Registration, Coffee and Snacks</b>	10.45-11.15 h: <b>Current Regulatory Developments in the Field of Endotoxin and Pyrogen Detection</b> <i>Dr. Ingo Spreitzer, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines</i>	10.45-11.30 h: <b>European Pharmacopeia Perspective</b> <i>Dr Solène Le Maux, EDQM</i>	10.45-11.15 h: <b>Potency Testing Approaches: Challenges and Opportunities for mRNA Therapeutics</b> <i>Dr Jan Michel Falcke, BioNTech</i>	10.45-11.30 h: <b>Implementation of ICH Q14 and USP &lt;1220&gt;: A challenge in the Highly Competitive mRNA Vaccine Field</b> <i>Dr Isabelle Moineau, Aktehom &amp; Dr Marc Francois Heude, Sanofi</i>	10.45-11.30 h: <b>Getting inspected by the FDA for the first Time - our Experience</b> <i>Dr Katharina Elisabeth Scheidt, MicroCoat</i>	10.45-11.30 h: <b>Fortifying the Future: Advanced IT Security for Modern Labs</b> <i>Joachim Post, wega Informatik</i>	10.45-11.30 h: <b>Data Quality &amp; Data Integrity Lifecycle Overview</b> <i>Dr Christopher Burgess, Chairman ECA AQCG</i>	
	11.15-11.45 h: <b>Approval of a Monocyte Activation Test as a Replacement of the Rabbit Pyrogen Test</b> <i>Dr Sven M. Deuschmann, Roche</i>	11.30-12.15 h: <b>Evaluation of the New Generation of Solid Phase Cytometry as a Very Rapid Microbial Test of Cell and Gene Therapy Products</b> <i>Dr. Kirsten Høstgaard-Jensen, Novo Nordisk</i>	11.15-11.45 h: <b>Challenges with Bioassay Design for mRNA Therapeutics</b> <i>Thomas Ludwig, VelaLabs</i>	11.30-12.15 h: <b>European Pharmacopeia Perspective</b> <i>Dr Solène Le Maux, EDQM</i>	11.30-12.15 h: <b>PFAS in Pharmaceutical Products – a View on Findings and Potential Relevance</b> <i>Stephan Lebertz, SGS Institut Fresenius</i>	11.30-12.15 h: <b>Potentials of an ERP Managed Logistic System for the Pharmaceutical Laboratory</b> <i>Julia Abadir, VelaLabs</i>	11.30-12.15 h: <b>Overview of the ECA AQCG Guide to AIQ&amp;SV</b> <i>Dr Bob McDowall, R.D. McDowall Limited</i>	
	11.45-12.00 h: <b>Welcome</b> <i>Haidy Wafy, Roche</i>							
12.00-12.45 h: <b>Update on the Revision of Ph. Eur. Texts Related to the Mycoplasma Project</b> <i>Thuy Bourgeois, EDQM Strasbourg, France</i>	12.00 h	11.45-12.15 h: <b>A Comparison of Recombinant Factor C and LAL Based Methods for Bacterial Endotoxin Testing</b> , <i>Hiram Huzeyfe Yakut, Turkish Medicines and Medical Devices Agency</i>	11.45-12.15 h: <b>A Versatile Multiplexing Technology for Complex Drugs Characterization and Potency</b> <i>Dr Rosaria Esposito, bioMérieux</i>					
12.45-13.15 h: <b>Rapid Mycoplasma Testing</b> <i>Dr Rudolf Zirwes, Independent</i>	13.00 h	12.15-13.45 Uhr: <b>Lunch Break / Conference Exhibition</b>						
13.15-13.45 h: <b>Real-Time PCR-Based Mycoplasma Testing – Verification for the Intended Use: Data from a User</b> <i>Dr Robert Hertel, Sartorius</i>								
13.45-14.15 h: <b>RT-qPCR based Mycoplasma Detection from a Developer's Perspective</b> <i>Caroline Paeschke, Minerva</i>	14.00 h	13.45-14.15 h: <b>Good Practice in LER Hold Time Study: the Choice of the Endotoxin</b> <i>Alessandro Pauletto, bioMérieux</i>	13.45-14.15 h: <b>Rapid Sterility Testing by NAT Method Targeting RNA Instead of DNA</b> <i>Yotaro Yamamoto, Fujifilm</i>	13.45-14.15 h: <b>Enhancing Bioassay Precision and Throughput with Modular Workflow Automation</b> <i>Dr Sean Lin, Eurofins</i>	13.45-14.30 h: <b>Spilling the Tea on a Robust CCS for ATMPs</b> <i>Marsha Steed, Steed MicroBio</i>	13.45-14.30 h: <b>Machine Learning in the GMP Lab - Regulation, Validation and Case Studies</b> <i>Dr Ulrich Köllisch, GxP-CC</i>	13.45-14.30 h: <b>Process Mapping and Redesign as the Basis for Laboratory Digitalisation</b> <i>Dr Bob McDowall, R.D. McDowall Limited</i>	13.45-14.15 h: <b>Risk Assessment in AIQ&amp;SV</b> <i>Dr Christopher Burgess, Chairman ECA AQCG</i>
14.15-14.30 h: <b>Coffee Break</b>		14.15-14.45 h: <b>Addressing Low Endotoxin Recovery During Biological Development - from Early Stage to Submission</b> <i>Melanie Jaensch, and Jessica Stolzenberger, Boehringer Ingelheim</i>	14.15-14.45 h: <b>Proposal of the New Rapid Sterility Test for Regenerative Medicine Using qPCR</b> <i>Akari Teramoto, Shimadzu Diagnostics</i>	14.15-14.45 h: <b>Harnessing the Power of Automation for Potency Assays and for Large-Scale Potency Assay Cell Bank Production</b> <i>Sheri Mahan-Hunter, Pfizer</i>	14.30-15.15 h: <b>What is the Value of Design-of-Experiment Approaches in the Development of Cell-based Potency Assays?</b> <i>Dr Johannes Solzin, Boehringer Ingelheim</i>	14.30-15.15 h: <b>Optimizing Precision: Strategies for Validating Analytical Platforms</b> <i>Dr Mohamad Toutounji, Molgenium</i>	14.30-15.15 h: <b>Sub-Visible Particulate Matter Testing – Reduce Variability in Blank Values with Automatization and Optimization – a Practical Case Study on Different Techniques</b> <i>Dr Melanie Zerulla-Wernitz, Vetter Pharma Fertigung</i>	14.15-14.45 h: <b>Application of the AIQ&amp;SV Approach to a Bioassay Analytical Instrument and Software</b> <i>Margarita Sabater, Genmab</i>
14.30-15.00 h: <b>Mycoplasma Testing of ATMPs: Current Regulations, Challenges and Trends</b> <i>Rashid Idd Kihwelo, Shelys Pharmaceuticals</i>		14.45-15.15 h: <b>The Mitigation Concept - Understanding the Masking Impact on Drug Product Manufacturing of Biologicals</b> <i>Martina Wespel, Boehringer Ingelheim and Dr Anthea Darius, Microcoat</i>	14.45-15.15 h: <b>Rapid Non-Destructive Growth-Based Microbial Testing for In- Process Bioburden of Continuous Manufacturing Lines</b> <i>Phillip Junker Andersen, Intubio Dr Cedric Joossen, Janssen</i>	14.45-15.15 h: <b>Advancing Potency Assay Automation</b> <i>Dr Katharina Künzel, Boehringer Ingelheim</i>				14.45-15.15 h: <b>Risk-Based Qualification of HPLC Systems</b> <i>Martina Gjorgjevaska, THE FORCE CT</i>
15.00-15.30 h: <b>Sensitive and Rapid Testing for Mycoplasma Contamination Using Digital PCR</b> <i>Dr Francesca Di Pasquale, QIAGEN</i>	15.00 h	15.15-16.00 h: <b>Coffee break / Conference Exhibition</b>						
15.30-16.00 h: <b>Replacement of a DNA extraction system in a validated Rapid Mycoplasma Method</b> <i>Susan Hoefs, MSD</i>								
16.00-16.15 h: <b>Coffee Break</b>	16.00 h	16.00-16.30 h: <b>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</b> <i>Prof. Klaus Brandenburg, Forschungszentrum Borstel</i>	16.00-16.30 h: <b>High Throughput Sequencing, a Rapid Method for Safety Analysis in Pharmaceutical Manufacturing</b> <i>Dr. Thomas Bovbjerg Rasmussen, Novo Nordisk</i>	16.00-16.30 h: <b>Potency Assurance for Cellular and Gene Therapy Products</b> <i>Dr Andrew Byrnes, FDA/CBER</i>	16.00-16.45 h: <b>Key Insights about CAR-T Therapy from Concept to Clinic</b> <i>Dr Daniela Rozkova, SCTBio</i>	16.00-16.45 h: <b>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</b> <i>Dr Reingard Raml, JOANNEUM RESEARCH</i>	16.00-16.30 h: <b>Foster Environmental Monitoring Results with Advanced Automated Systems</b> <i>Laurent Leblanc, bioMérieux</i>	16.00-16.45 h: <b>Eurachem Guide for The Fitness for Purpose of Analytical Equipment</b> <i>Dr Ernst Halder, Eurachem</i>
16.15-16.45 h: <b>Ultra-rapid NAT-based Method for Mycoplasma Testing – Implementation, Validation and Transfer Strategy</b> <i>Yasmin Heynen, Labor LS</i>		16.30-17.00 h: <b>Developing Endotoxin Assays Based on a Novel LPS-Binding Peptide</b> <i>Prof. Dirk Linke, Univ. of Oslo</i>	16.30-17.00 h: <b>Assessing the Use of Solid-Phase Cytometry for Rapid Bioburden Testing</b> <i>Sophie Drinkwater, AstraZeneca</i>	16.30-17.00 h: <b>Potency Assays as Part of Release Testing for ATMPs – Focus on AAV Products</b> <i>Dr Christoph Mück, AGES</i>	16.45-17.30 h: <b>Critical Quality Attributes of AAV based GT Products</b> <i>Dr Roland Pach, Roche</i>	16.45-17.30 h: <b>Data Integrity and CSV of the Computerised Systems used to Manage GxP data – a Necessary Precondition for a Valid (Bio) Analytical Method?</b> <i>Dr Timo G. Kretzschmar, TIKrESolution</i>	16.30-17.00 h: <b>Automation of Environmental Monitoring Workflow</b> <i>Adele Gisselmann, Merck</i>	16.45-17.30 h: <b>Ongoing Monitoring in Analytical Instrument Performance Qualification</b> <i>Dr Joachim Ermer, Ermer Quality Consulting</i>
16.45-17.15 h: <b>Mycoplasma Testing – Authorities, Experiences and New Developments</b> <i>Jan-Oliver Karo, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines</i>		17.00 h	17.00-17.30 h: <b>On the Detection and Quantification of the Endotoxin, or Not Endotoxin, Lipopolysaccharides</b> <i>Dr Flavien Dardelle, LPS-Bioscience</i>	17.00-17.45 h: <b>How to Validate Non-CFU RMMs and Guidance on Setting New Acceptance Levels</b> <i>Dr. Michael Miller, Microbiology Consultants</i>	17.00-17.30 h: <b>Development of Methods for Comparative Analysis of the Potency of Monoclonal Antibodies</b> <i>Dr Lilija Miller, Paul-Ehrlich Institut</i>		17.00-17.30 h: <b>Practical Examples of 5s Optimizations in Offices &amp; QC-Labs</b> <i>Dr Karl-Heinz Bauer, Boehringer Ingelheim</i>	
17.15-17.30 h: <b>Summary/Discussion</b> <i>Haidy Wafy, Roche</i>		17.30-18.00 h: <b>Update on the Status of the USP proposed General Chapter &lt;86&gt; Endotoxin Testing using Recombinant Reagents</b> <i>Dr Mark Schweitzer, USP</i>	17.45-18.00 h: <b>Discussion</b>	17.30-18.00 h: <b>Discussion</b>	17.30-18.00 h: <b>Discussion</b>	17.30-18.00 h: <b>Discussion</b>	17.30-18.00 h: <b>Discussion</b>	
18.00 h	18.00 h: <b>Social Event</b>							

Wednesday, 27. November

Time	Track 1: Endotoxin and Pyrogen Testing	Track 2: Alternative/Rapid Microbiological Methods	Track 3: Bioassays/Potency Assays - Regulatory Requirements, Development and Routine Use	Track 4: Cell and Gene Therapies/ATMP - Quality and Safety	Track 5: GMP Compliance Trends in Analytical Laboratories	Track 6: Laboratory Optimization, Automation, Digitalization / Outsourcing in Pharmaceutical Analysis	Track 7: Analytical Instrument Qualification and System Validation
09.00 h	09.00-09.15 h: Welcome and Introduction						
	 09.15-10.00 h: <b>Trends &amp; Challenges for the Development &amp; Testing of Biotech Drug Products</b> <i>Prof Dr Hanns-Christian Mahler, ten23 health</i>						
10.00 h	10.00-10.45 h: Coffee Break / Conference Exhibition						
11.00 h	10.45-11.15 h: <b>Validation of a Complex Drug Product Using Recombinant Cascade Reagent</b> <i>Veronika Wills, ACC</i>	10.45-11.30 h: <b>Strategy for Accelerated Implementation of New Technologies (SAINT) ): Roche's Post-Approval Change Program for Control System-Updates of Biologics</b> <i>Christina Heinlein und Sven Deutschmann, Roche</i>	10.45-11.30 h: <b>Qualification of Analytical Cells für GMP Potency Assays – Guidance from a Different World</b> <i>Dr Oliver Wehmeier, acCELLerate</i>	10.45-11.15 h: <b>Digital PCR Applications for Cell and Gene Therapy – Standardization for a High-Quality Process Development</b> <i>Dr Andreas Hecker, QIAGEN</i>	10.45-11.30 h: <b>Digitalisation and Automation of Validation Activities</b> <i>Christophe Girardey, wega Informatik</i>	10.45-11.30 h: <b>Transfer of Analytical Procedures. Practical Handling of Transfers to Different Types of CMO's</b> <i>Ulla Bondegaard, Novo Nordisk</i>	10.45-11.30 h: <b>Overview of General Chapter &lt;1220&gt; Analytical Procedure Lifecycle</b> <i>Dr Christopher Burgess, Chairman ECA AQCG</i>
	11.15-11.45 h: <b>Endotoxin Testing of mRNA Vaccines: Ensuring Product Safety and Effectiveness</b> <i>Dr Mohamad Toutounji, Lonza</i>	11.30-12.15 h: <b>Digitalization of Environmental Monitoring in a New Facility</b> <i>Alexandra Wagner und Martin Brandl, DAIICHI SANKYO and Susan Cleary, Novatek</i>	11.30-12.15 h: <b>Partial Dose-Response Curves - Contributions to the Discussion on "Allowed" Non-Similarity in Biological Assays</b> <i>Dr Ralf Stegmann, Stegmann Systems</i>	11.15-11.45 h: <b>In-Process and Release Testing of Cell Therapy Applications</b> <i>Caroline Paeschke, Minerva</i>	11.30-12.15 h: <b>Unraveling Out-of-Trend Stability Results: A Case Study in Identification and Investigation</b> <i>Sanja Despotovska, Alkaloid</i>	11.30-12.15 h: <b>Construction of a New Hazardous Materials Storage Facility for a Contract Laboratory</b> <i>Dr Jochen Kolb, BioChem Labor für biologische und chemische Analytik</i>	11.30-12.15 h: <b>Using the Analytical Target Profile (ATP) for Efficient Procedure Lifecycle Management and Enhanced Analytical Platform Adoption</b> <i>Dr Amanda Guiraldelli Mahr, USP</i>
12.00 h	11.45-12.15 h: <b>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</b>			11.45-12.15 h: <b>A ddPCR Method for Multiplex Determination of AAV Genome and Vector Titer</b> <i>Dr Christian Schiller, Eurofins</i>			
13.00 h	12.15-13.45 Uhr: Lunch Break / Conference Exhibition						
14.00 h	13.45-14.15 h: <b>Evaluating Synthetic Reagents for Endotoxin Testing</b> <i>Poppy Cliffe, AstraZeneca</i>	13.45-14.15 h: <b>Microorganism Verification Testing of an Alternative Rapid Microbial Method</b> <i>Meg Provenzano, Veolia</i>	13.45-14.15 h: <b>Trending and AI Prediction for Improving of Assay Performance</b> <i>Dr Jan Amstrup, Novo Nordisk</i>	13.45-14.30 h: <b>Test for Microbial Purity on MCBs</b> <i>Christine Weiß, Labor LS</i>	13.45-14.30 h: <b>Concepts to Prevent Lab Errors &amp; Unconfirmed OOS in QC Laboratories</b> <i>Dr Karl-Heinz Bauer, Boehringer Ingelheim</i>	13.45-14.30 h: <b>Regulatory Considerations for E&amp;L Labs and Methods. From Pharmaceuticals to Medical Devices and in between -Combination Products</b> <i>Dr Andreas Nixdorf, SGS INSTITUT FRESENIUS</i>	13.45-14.15 h: <b>Importance of Change Control and Deviation Management over the Lifecycle</b> <i>Silviya Dimitrova, TEVA Pharmaceuticals Industries</i>
	14.15-14.45 h: <b>Recombinant Cascade Reagent and Limulus Amebocyte Lysate: A Detailed Analysis of Endotoxin Testing Methods</b> <i>Dr Shady Kamal, Galderma</i>	14.15-14.45 h: <b>Applications of Whole Genome Sequencing for Microbial Quality and Contamination Control</b> <i>Dr Prasanna Khot, Charles River</i>	14.15-14.45 h: <b>Continuous Bioassay Monitoring and Troubleshooting in QC, 3 Case Studies</b> <i>Dr Steffen Pahlich, Novartis</i>	14.30-15.15 h: <b>Microbial Control for ATMP Facilities</b> <i>Cecilia Pierobon, STERIS</i>	14.30-15.15 h: <b>Health Authority Challenges to the Well Established Dissolution Specification of a Mature Drug Product - a Case Study</b> <i>Dr Lukas Sonnenschein, Merck Healthcare</i>	14.30-15.15 h: <b>Outsourcing of Qualification Management</b> <i>Dr Carsten Börger, Valicare</i>	14.15-14.45 h: <b>Efficient Analytical Instrument Qualification - Bridging Laboratory Needs and GMP Compliance</b> <i>Dr Nadine Mendl, ten23 health</i>
	14.45-15.15 h: <b>Out of the Endotoxin box: Rethinking Pyrogens and Pyrogenicity</b> <i>Dr Djikolngar Maouyo, Pyrodex</i>	14.45-15.15 h: <b>Lessons Learned from Feasibility of MOLDS on Maldi-TOF, what to Consider for Validation and Implementation in Routine</b> <i>Marie-Laurence Baille, MSD</i>	14.45-15.15 h: <b>Unique Aspects of Bioassay OOS Investigations</b> <i>Dr Robert de Lange, Roche</i>				14.45-15.15 h: <b>Lifecycle Roles and Responsibilities</b> <i>Patrick Jackson, GSK</i>
15.00 h	15.15-16.00 h: Coffee break / Conference Exhibition						
16.00 h	16.00-16.30 h: <b>Automation of the Monocyte Activation Test Method 2 with the Opentron OT-2 Robot</b> <i>Stephanie Richard, Sanofi</i>	16.00-16.30 h: <b>What are the Benefits of the Real Time Colony Counting in Microbial Analysis?</b> <i>Thomas Alexandre, Interscience</i>	16.00-16.45 h: <b>MoA Reflective In Vitro Potency Testing for Vaccines</b> <i>Dr Sascha Karasek, Charles River Laboratories</i>	16.00-16.45 h: <b>Efficient Microbial Control Concepts for ATMPs</b> <i>Dr Holger Kavermann, Roche</i>	16.00-16.45 h: <b>Hard Facts about Softgels: Analytical Challenges and Regulatory Gaps</b> <i>Dr Ana Petkovska, Patheon by Thermo Fisher Scientific</i>		16.00-16.45 h: <b>Comparison of ICH Q2(R2), ICH Q14 &amp; USP &lt;1220&gt; with the Draft General Chapter in the Chinese Pharmacopeia</b> <i>Dr Gerd Jilge, Board Member ECA AQCG</i>
	16.30-17.00 h: <b>LumiMAT™: Rapid and Easy MAT Using the Luciferase Reporter Assay</b> <i>Tomohisa Nanao, Fujifilm Wako</i>	16.30-17.00 h: <b>Feasibility Study of the 3P Station, an Automated Environmental Monitoring System</b> <i>Annalena Tegethoff, Novartis</i>	16.45-17.30 h: <b>Implementation of Concepts from ICH Q14 into Practice - Case study for a Cell-Based Assay</b> <i>Dr Simon Anderhub, Novartis</i>	16.45-17.30 h: <b>Continuous Microbial Monitoring in ATMP Facilities in Compliance with the New EU GMP Annex1</b> <i>Dr Emad Albarouki, Particle Measuring System (PMS)</i>	16.45-17.30 h: <b>Applying Life Cycle and Validation Principles to the Customized Amplex UltraRed Assay</b> <i>Dr Alexandra Heussner, Vetter Pharma</i>		16.45-17.30 h: <b>Consideration of Uncertainty in Evaluation of Accuracy and Precision according to the New ICH Q2(R2)</b> <i>Dr Joachim Ermer, Ermer Quality Consulting</i>
17.00 h	17.00-17.30 h: <b>Development of a Rapid MAT Test Using Immortalized Monocyte Cells (aMylc)</b> <i>Kazuo Miyazaki, Mican</i>	17.00-17.30 h: <b>Strategy to Handle Low Viable Particle Count in grade A Environment with an Advanced BFPC</b> <i>Dr Svetlana Kiseleva, Plair</i>		17.30-18.00 h: <b>Final Discussion and Q&amp;A Session</b>	17.30-18.00 h: <b>Final Discussion and Q&amp;A Session</b>		17.45-18.00 h: <b>Final Discussion and Q&amp;A Session</b>
18.00 h							