12th 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

PharmaLab Pre-Conference Event
5 th International Mycoplasma qPCR Testing User Day

11.00-11.45 h:
Registration, Coffee and Snacks

11.45 -12.00 h:
Welcome,
Haidy Wafy, Roche

12.00-12.45 h:
Update on the Revision of Ph. Eur. Texts Related to the Mycoplasma Project
Thuy Bourgeois, EDQM Strasbourg, France

12.45-13.15 h:
Rapid Mycoplasma Testing
Dr Rudolf Zirwes, independent

13.15-13.45 h:
Real-Time PCR-Based Mycoplasma Testing – Verification for the Intended Use: Data from a User
Dr Robert Hertel, Sartorius

13.45-14.15 h:
RT-qPCR based Mycoplasma Detection from a Developer's Perspective
Caroline Paeschke, Minerva

14.15-14.30 h:
Coffee Break

14.30-15.00 h:
Mycoplasma Testing of ATMPs: Current Regulations, Challenges and Trends
Rashid Idd Kihwelo, Shelys Pharmaceuticals

15.00-15.30 h:
Sensitive and Rapid Testing for Mycoplasma Contamination Using Digital PCR
Dr Francesca Di Pasquale, QIAGEN

15.30-16.00 h:
Replacement of a DNA extraction system in a validated Rapid Mycoplasma Method
Susan Hoefs, MSD

16.00-16.15 h:
Coffee Break

16.15-16.45 h:
Ultra-rapid NAT-based Method for Mycoplasma Testing – Implementation, Validation and Transfer Strategy
Yasmin Heynen, Labor LS

16.45-17.15 h:
Mycoplasma Testing – Authorities, Experiences and New Developments
Jan-Oliver Karo, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines

17.15-17.30 h:
Summary/Discussion
Haidy Wafy, Roche

Tuesday, 26. November

Time	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
09.00 h	09.00-09.15 h: **Welcome and Introduction**						
	09.15-10.00 h: **The Promise and Challenges of In Vitro and in Silico Models in Drug Development** *Dr Julia Schüler, Charles River Laboratories* (Congress Key Note)						
10.00 h	**10.00-10.45 h: Coffee Break / Conference Exhibition**						
11.00 h	10.45-11.15 h: **Current Regulatory Developments in the Field of Endotoxin and Pyrogen Detection** *Dr. Ingo Spreitzer, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines*	10.45-11.30 h: **European Pharmacopeia Perspective** *Dr Solène Le Maux, EDQM*	10.45-11.15 h: **Potency Testing Approaches: Challenges and Opportunities for mRNA Therapeutics** *Dr Jan Michel Falcke, BioNTech*	10.45-11.30 h: **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*	10.45-11.30 h: **Getting inspected by the FDA for the first Time - our Experience** *Dr Katharina Elisabeth Scheidt, MicroCoat*	10.45-11.30 h: **Fortifying the Future: Advanced IT Security for Modern Labs** *Joachim Post, wega Informatik*	10.45-11.30 h: **Data Quality & Data Integrity Lifecycle Overview** *Dr Christopher Burgess, Chairman ECA AQCG*
	11.15-11.45 h: **Approval of a Monocyte Activation Test as a Replacement of the Rabbit Pyrogen Test** *Dr Sven M. Deutschmann, Roche*	11.30-12.15 h: **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*	11:15-11.45 h: **Challenges with Bioassay Design for mRNA Therapeutics** *Thomas Ludwig, VelaLabs*	11.30-12.15 h: **European Pharmacopeia Perspective** *Dr Solène Le Maux, EDQM*	11.30-12.15 h: **PFAS in Pharmaceutical Products – a View on Findings and Potential Relevance** *Stephan Lebertz, SGS Institut Fresenius*	11.30-12.15 h: **Potentials of an ERP Managed Logistic System for the Pharmaceutical Laboratory** *Julia Abadir, VelaLabs*	11.30-12.15 h: **Overview of the ECA AQCG Guide to AIQ&SV** *Dr Bob McDowall, R.D. McDowall Limited*
12.00 h	11.45-12.15 h: **A Comparison of Recombinant Factor C and LAL Based Methods for Bacterial Endotoxin Testing,** *Hiram Huzeyfe Yakut, Turkish Medicines and Medical Devices Agency*		11.45-12.15 h: **A Versatile Multiplexing Technology for Complex Drugs Characterization and Potency** *Dr Rosaria Esposito, bioMérieux*				
13.00 h	12.15-13.45 Uhr: **Lunch Break / Conference Exhibition**						
14.00 h	13.45-14.15 h: **Good Practice in LER Hold Time Study: the Choice of the Endotoxin** *Alessandro Pauletto, bioMérieux*	13.45-14.15 h: **Rapid Sterility Testing by NAT Method Targeting RNA Instead of DNA** *Yotaro Yamamoto, Fujifilm*	13.45-14.15 h: **Enhancing Bioassay Precision and Throughput with Modular Workflow Automation** *Dr Sean Lin, Eurofins*	13.45-14.30 h: **Spilling the Tea on a Robust CCS for ATMPs** *Marsha Steed, Steed MicroBio*	13.45-14.30 h: **Machine Learning in the GMP Lab - Regulation, Validation and Case Studies** *Dr Ulrich Köllisch, GxP-CC*	13.45-14.30 h: **Process Mapping and Redesign as the Basis for Laboratory Digitalisation** *Dr Bob McDowall, R.D. McDowall Limited*	13.45-14.15 h: **Risk Assessment in AIQ&SV** *Dr Christopher Burgess, Chairman ECA AQCG*
	14.15-14.45 h: **Addressing Low Endotoxin Recovery During Biological Development - from Early Stage to Submission** *Melanie Jaensch, and Jessica Stolzenberger, Boehringer Ingelheim*	14.15-14.45 h: **Proposal of the New Rapid Sterility Test for Regenerative Medicine Using qPCR** *Akari Teramoto, Shimadzu Diagnostics*	14.15-14.45 h: **Harnessing the Power of Automation for Potency Assays and for Large-Scale Potency Assay Cell Bank Production** *Sheri Mahan-Hunter, Pfizer*	14.30-15.15 h: **What is the Value of Design-of-Experiment Approaches in the Development of Cell-based Potency Assays?** *Dr Johannes Solzin, Boehringer Ingelheim*	14.30-15.15 h: **Optimizing Precision: Strategies for Validating Analytical Platforms** *Dr Mohamad Toutounji, Molgenium*	14.30-15.15 h: **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*	14.15-14.45 h: **Application of the AIQSV Approach to a Bioassay Analytical Instrument and Software** *Margarita Sabater, Genmab*
	14.45-15.15 h: **The Mitigation Concept - Understanding the Masking Impact on Drug Product Manufacturing of Biologicals** *Martina Wespel, Boehringer Ingelheim and Dr Anthea Darius, Microcoat*	14.45-15.15 h: **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*	14.45-15.15 h: **Advancing Potency Assay Automation** *Dr Katharina Künzel, Boehringer Ingelheim*				14.45-15.15 h: **Risk-Based Qualification of HPLC Systems** *Martina Gjorgjevska, THE FORCE CT*
15.00 h	15.15-16.00 h: **Coffee break / Conference Exhibition**						
16.00 h	16.00-16.30 h: **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, Forschungszentrum Borstel*	16.00-16.30 h: **High Throughput Sequencing, a Rapid Method for Safety Analysis in Pharmaceutical Manufacturing** *Dr. Thomas Bovbjerg Rasmussen, Novo Nordisk*	16.00-16.30 h: **Potency Assurance for Cellular and Gene Therapy Products** *Dr Andrew Byrnes, FDA/CBER*	16.00-16.45 h: **Key Insights about CAR-T Therapy from Concept to Clinic** *Dr Daniela Rozkova, SCTbio*	16.00-16.45 h: **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*	16.00-16.30 h: **Foster Environmental Monitoring Results with Advanced Automated Systems** *Laurent Leblanc, bioMérieux*	16.00-16.45 h: **Eurachem Guide for The Fitness for Purpose of Analytical Equipment** *Dr Ernst Halder, Eurachem*
	16.30-17.00 h: **Developing Endotoxin Assays Based on a Novel LPS-Binding Peptide** *Prof. Dirk Linke, Univ. of Oslo*	16.30-17.00 h: **Assessing the Use of Solid-Phase Cytometry for Rapid Bioburden Testing** *Sophie Drinkwater, AstraZeneca*	16.30-17.00 h: **Potency Assays as Part of Release Testing for ATMPs – Focus on AAV** *Dr Christoph Mück, AGES*	16.45-17.30 h: **Critical Quality Attributes of AAV based GT Products** *Dr Roland Pach, Roche*	16.45-17.30 h: **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*	16.30-17.00 h: **Automation of Environmental Monitoring Workflow** *Adele Gisselmann, Merck*	16.45-17.30 h: **Ongoing Monitoring in Analytical Instrument Performance Qualification** *Dr Joachim Ermer, Ermer Quality Consulting*
17.00 h	17.00-17.30 h: **On the Detection and Quantification of the Endotoxic, or Not Endotoxic, Lipopolysaccharides** *Dr Flavien Dardelle, LPS-Bioscience*	17.00-17.45 h: **How to Validate Non-CFU RMMs and Guidance on Setting New Acceptance Levels** *Dr. Michael Miller, Microbiology Consultants*	17.00-17.30 h: **Development of Methods for Comparative Analysis of the Potency of Monoclonal Antibodies** *Dr Lilija Miller, Paul-Ehrlich Institut*			17.00-17.30 h: **Practical Examples of 5s Optimizations in Offices & QC-Labs** *Dr Karl-Heinz Bauer, Boehringer Ingelheim*	
	17.30-18.00 h: **Update on the Status of the USP proposed General Chapter <86> Endotoxin Testing using Recombinant Reagents** *Dr Mark Schweitzer, USP*	17.45-18.00 h: **Discussion**	17.30-18.00 h: **Discussion**	17.30-18.00 h: **Discussion**	17.30-18.00 h: **Discussion**	17.30-18.00 h: **Discussion**	17.30-18.00 h: **Discussion**
18.00 h	**Social Event**						

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**						
	Congress Key Note 09.15-10.00 h: **Trends & Challenges for the Development & Testing of Biotech Drug Products** *Prof Dr Hanns-Christian Mahler, ten23 health*						
10.00 h	**10.00-10.45 h: Coffee Break / Conference Exhibition**						
11.00 h	10.45-11.15 h: **Validation of a Complex Drug Product Using Recombinant Cascade Reagent** *Veronika Wills, ACC*	10.45-11.30 h: **Strategy for Accelerated Implementation of New Technologies (SAINT): Roche's Post-Approval Change Program for Control System-Updates of Biologics** *Christina Heinlein und Sven Deutschmann, Roche*	10.45-11.30 h: **Qualification of Analytical Cells für GMP Potency Assays – Guidance from a Different World** *Dr Oliver Wehmeier, acCELLerate*	10.45-11.15 h: **Digital PCR Applications for Cell and Gene Therapy – Standardization for a High-Quality Process Development** *Dr Andreas Hecker, QIAGEN*	10.45-11.30 h: **Digitalisation and Automation of Validation Activities** *Christophe Girardey, wega Informatik*	10.45-11.30 h: **Transfer of Analytical Procedures. Practical Handling of Transfers to Different Types of CMO's** *Ulla Bondegaard, Novo Nordisk*	10.45-11.30 h: **Overview of General Chapter <1220> Analytical Procedure Lifecycle** *Dr Christopher Burgess, Chairman ECA AQCG*
	11.15-11.45 h: **Endotoxin Testing of mRNA Vaccines: Ensuring Product Safety and Effectiveness** *Dr Mohamad Toutounji, Lonza*	11.30-12.15 h: **Digitalization of Environmental Monitoring in a New Facility** *Alexandra Wagner und Martin Brandl, DAIICHI SANKYO and Susan Cleary, Novatek*	11.30-12.15 h: **Partial Dose-Response Curves - Contributions to the Discussion on "Allowed" Non-Similarity in Biological Assays** *Dr Ralf Stegmann, Stegmann Systems*	11.15-11:45 h: **In-Process and Release Testing of Cell Therapy Applications** *Caroline Paeschke, Minerva*	11.30-12.15 h: **Unraveling Out-of-Trend Stability Results: A Case Study in Identification and Investigation** *Sanja Despotovska, Alkaloid*	11.30-12.15 h: **Construction of a New Hazardous Materials Storage Facility for a Contract Laboratory** *Dr Jochen Kolb, BioChem Labor für biologische und chemische Analytik*	11.30-12.15 h: **Using the Analytical Target Profile (ATP) for Efficient Procedure Lifecycle Management and Enhanced Analytical Platform Adoption** *Dr Amanda Guiraldelli Mahr, USP*
12.00 h	11.45-12.15 h: **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*			11.45-12:15 h: **A ddPCR Method for Multiplex Determination of AAV Genome and Vector Titer** *Dr Christian Schiller, Eurofins*			
13.00 h	12.15-13.45 Uhr: **Lunch Break / Conference Exhibition**						
14.00 h	13.45-14.15 h: **Evaluating Synthetic Reagents for Endotoxin Testing** *Poppy Cliffe, AstraZeneca*	13.45-14.15 h: **Microorganism Verification Testing of an Alternative Rapid Microbial Method** *Meg Provenzano, Veolia*	13.45-14.15 h: **Trending and AI Prediction for Improving of Assay Performance** *Dr Jan Amstrup. Novo Nordisk*	13.45-14.30 h: **Test for Microbial Purity on MCBs** *Christine Weiß, Labor LS*	13.45-14.30 h: **Concepts to Prevent Lab Errors & Unconfirmed OOS in QC Laboratories** *Dr Karl-Heinz Bauer, Boehringer Ingelheim*	13.45-14.30 h: **Regulatory Considerations for E&L Labs and Methods. From Pharmaceuticals to Medical Devices and in between -Combination Products** *Dr Andreas Nixdorf, SGS INSTITUT FRESENIUS*	13.45-14.15 h: **Importance of Change Control and Deviation Management over the Lifecycle** *Silviya Dimitrova, TEVA Pharmaceuticals Industries*
	14.15-14.45 h: **Recombinant Cascade Reagent and Limulus Amebocyte Lysate: A Detailed Analysis of Endotoxin Testing Methods** *Dr Shady Kamal, Galderma*	14.15-14.45 h: **Applications of Whole Genome Sequencing for Microbial Quality and Contamination Control** *Dr Prasanna Khot, Charles River*	14.15-14.45 h: **Continuous Bioassay Monitoring and Trouble-shooting in QC, 3 Case Studies** *Dr Steffen Pahlich, Novartis*				14.15-14.45 h: **Efficient Analytical Instrument Qualification - Bridging Laboratory Needs and GMP Compliance** *Dr Nadine Mendl, ten23 health*
	14.45-15.15 h: **Out of the Endotoxin box: Rethinking Pyrogens and Pyrogenicity** *Dr Djikolngar Maouyo, Pyrodex*	14.45-15.15 h: **Lessons Learned from Feasibility of MOLDS on Maldi-TOF, what to Consider for Validation and Implementation in Routine** *Marie-Laurence Baille, MSD*	14.45-15.15 h: **Unique Aspects of Bioassay OOS Investigations** *Dr Robert de Lange, Roche*	14.30-15.15 h: **Microbial Control for ATMP Facilities** *Cecilia Pierobon, STERIS*	14.30-15.15 h: **Health Authority Challenges to the Well Established Dissolution Specification of a Mature Drug Product - a Case Study** *Dr Lukas Sonnenschein, Merck Healthcare*	14.30-15.15 h: **Outsourcing of Qualification Management** *Dr Carsten Börger, Valicare*	14.45-15.15 h: **Lifecycle Roles and Responsibilities** *Patrick Jackson, GSK*
15.00 h	15.15-16.00 h: **Coffee break / Conference Exhibition**						
16.00 h	16.00-16.30 h: **Automation of the Monocyte Activation Test Method 2 with the Opentron OT-2 Robot** *Stephanie Richard, Sanofi*	16.00-16.30 h: **What are the Benefits of the Real Time Colony Counting in Microbial Analysis?** *Thomas Alexandre, Interscience*	16.00-16.45 h: **MoA Reflective In Vitro Potency Testing for Vaccines** *Dr Sascha Karassek, Charles River Laboratories*	16.00-16.45 h: **Efficient Microbial Control Concepts for ATMPs** *Dr Holger Kavermann, Roche*	16.00-16.45 h: **Hard Facts about Softgels: Analytical Challenges and Regulatory Gaps** *Dr Ana Petkovska, Patheon by Thermo Fisher Scientific*		16.00-16.45 h: **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*
	16.30-17.00 h: **LumiMAT™: Rapid and Easy MAT Using the Luciferase Reporter Assay** *Tomohisa Nanao, Fujifilm Wako*	16.30-17.00 h: **Feasibility Study of the 3P Station, an Automated Environmental Monitoring System** *Annalena Tegethoff, Novartis*	16.45-17.30 h: **Implementation of Concepts from ICH Q14 into Practice - Case study for a Cell-Based Assay** *Dr Simon Anderhub, Novartis*	16.45-17.30 h: **Continuous Microbial Monitoring in ATMP Facilities in Compliance with the New EU GMP Annex1** *Dr Emad Albarouki, Particle Measuring System (PMS)*	16.45-17.30 h: **Applying Life Cycle and Validation Principles to the Customized Amplex UltraRed Assay** *Dr Alexandra Heussner, Vetter Pharma*		16.45-17.30 h: **Consideration of Uncertainty in Evaluation of Accuracy and Precision according to the New ICH Q2(R2)** *Dr Joachim Ermer, Ermer Quality Consulting*
17.00 h	17.00-17.30 h: **Development of a Rapid MAT Test Using Immortalized Monocyte Cells (aMylc)** *Kazuo Miyazaki, Mican*	17.00-17.30 h: **Strategy to Handle Low Viable Particle Count in grade A Environment with an Advanced BFPC** *Dr Svetlana Kiseleva, Plair*					
	17.30-18.00 h: **Final Discussion and Q&A Session**	17.30-18.00 h: **Final Discussion and Q&A Session**	17.30-18.00 h: **Final Discussion**	17.30-18.00 h: **Final Discussion and Q&A Session**	17.30-18.00 h: **Final Discussion**		17.45-18.00 h: **Final Discussion and Q&A Session**
18.00 h							