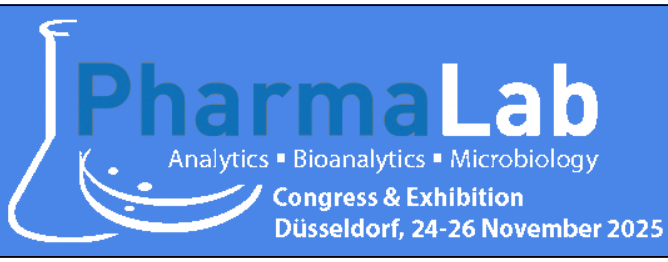

24 November 2025

Time	6th International Mycoplasma qPCR Testing User Day	Quality Control of mRNA/LNP Products	Time
11:00 h	Registration, Coffee and Snacks	Registration, Coffee and Snacks	11:00 h
11:15 h			11:15 h
11:30 h			11:30 h
11:45 h	**Welcome** Julian Mochayedi, Alexander Bartes, Roche		11:45 h
12:00 h	**Mycoplasma Testing – Authorities Experiences and New Developments** Jan Oliver Karo, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines	**Welcome**	12:00 h
12:15 h		**Microbiological Insights into the Analytical Life Cycle of mRNA-based Therapeutics** Dr Stefanie Bayer, Labor LS	12:15 h
12:30 h	**Nucleic Acid Testing for Mycoplasma detection: From regulatory requirements to GMP implementation** Dr Marc Meichenin, Clean Cells; Dr Caroline Kassim Houssenaly, bioMérieux		12:30 h
12:45 h		**Building Consensus, Standards, and Tools to Support mRNA Quality** Dr Dipankar Das, Senior Director Biologics, USP	12:45 h
13:00 h	**Detection of Mycoplasma and related Mollicutes by Droplet Digital PCR - A transition from qPCR to ddPCR** Denise Teber, Charles River Laboratories		13:00 h
13:15 h			13:15 h
13:30 h	Break	**Building a Robust CMC Framework for mRNA Therapeutics: From Raw Materials to Drug Product Release** Dr Mohamad Toutounji, Molgenium	13:30 h
13:45 h	**Leveraging the capabilities of qPCR in rapid mycoplasma validation study design and execution including a case study an application in investigation of a contamination event** Michel Brewer, Thermo Fisher Scientific		13:45 h
14:00 h		Break	14:00 h
14:15 h	**Reference Standard strains used as positive controls in the NAT based methods** Yoann Mainguy, Merck	**CMC Strategies for saRNA Therapeutics: Optimizing T7 Polymerase, IVT Processes, and Quality Control to Accelerate Clinical Translation** Mengqian Mao, Novoprotein	14:15 h
14:30 h			14:30 h
14:45 h	Break	**Setting up Specifications: Considerations and Approaches** Dr Jan M. Falcke, BioNTech	14:45 h
15:00 h	**Optimization and Implementation of the MycoSEQ SYBR and TaqMan Kits for Lot Release** Joleen Simpson, Lilly		15:00 h
15:15 h		**Homing In on Fit-for-Purpose Biophysical Techniques for mRNA and LNP Characterization** Dr Natalia Markova, BioGardia	15:15 h
15:30 h	**Update on Implementing a New Positive Control** Karen de Roy, J&J		15:30 h
15:45 h		Break	15:45 h
16:00 h	Break	**Endotoxin Detection via a Low-Cost Electrochemical Test Strip and Reader Approach** Prof Dr Damion Corrigan, AureumDX	16:00 h
16:15 h	**Bridging Speed and Sensitivity: Validation of a Hybrid Mycoplasma Detection Method for Complex Product Matrices** Dr Lori Daane, Bionique Testing Laboratories		16:15 h
16:30 h		**Case studies for mRNA Therapeutics – Developing Reliable and Robust Potency Methods** Dr Frances Reichert, Eurofins	16:30 h
16:45 h	**Summary and Plenum Discussion** Julian Mochayedi, Alexander Bartes, Roche		16:45 h
17:00 h		**mRNA Products as ATMP and as Vaccine - Same Technology but Different Requirements** Dr Sabine Hauck, dequra	17:00 h
17:15 h			17:15 h
17:30 h		Summary/Discussion	17:30 h

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Düsseldorf, 24-26 November 2025

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25 November 2025

Time	Cell and Gene Therapies/ ATMP - Quality and Safety	Artificial Intelligence in 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	Alternative and Rapid Microbiological Methods	Endotoxin and Pyrogen Testing – Pharmacopoeial and Scientific Developments	Analytical Quality and Lifecycle Concepts	Time
09:00 h	Welcome and Introduction (at the Plenum)								09:00 h
09:15 h	**KEYNOTE: AI in Pharma: The Hype, The Hope, The How** Dr Marcel Franke, Senior Scientist Predictive Formulation, Process Solutions/Upstream & Process Materials R&D Merck Life Science								09:15 h
09:30 h									09:30 h
09:45 h									09:45 h
10:00 h	Coffee break / Conference Exhibition								10:00 h
10:15 h									10:15 h
10:30 h									10:30 h
10:45 h	**Update on ATMPs in the Ph. Eur.** Dr Solène Le Maux, EDQM	**AI-History in a Nutshell** Dr Karl-Heinz Bauer, Training - Beratung - Coaching	**From Spreadsheets and Paper to Digital Alternatives: Navigating Compliance, Reducing Errors, and Embracing Smarter Systems** Carsten Jasper, Jasper Consulting	**The Combined Analytical Identity Testing Strategy for Oligonucleotides** Dr Alexandra Heussner, Vetter Pharma-Fertigung	**Key Aspects of Assay Control throughout the Analytical Lifecycle** Dr Sonja Klingelhöfer, Richter Biologics	**Update on RMM in the Ph. Eur.** Thuy Bourgeois, EDQM	**Forty Years of Endotoxin Standardisation** Trusha Desai, National Institute for Biological Standards and Control, MHRA	**Introduction to the Track and AQCG** Dr Christopher Burgess, Chairman ECA AQCG	10:45 h
11:00 h								**The New AQCG Guideline on Sampling and Sample Management** Dr Christopher Burgess, Chairman ECA AQCG	11:00 h
11:15 h	**Understanding of Analytical Critical Quality Attributes (CQAs) for Viral Vector Characterization in Gene Therapy** Dr Maribel Navarro, Kymos Group		**Implementation of a LIMS - Lessons Learned** Dr Xaver Schratt, GBA Pharma	**mRNA Analytics: Last Chance for Platform Methods?** Dr Jan Falcke, BioNTech	**Reference Standard Qualifications and Re-Evaluations for Potency Assays** Dr Pieta Boon & Jos Weusten, MSD		**Procedure for BET Sample Hold Time Discrepancies at Boehringer Ingelheim** Dr Gertrud Lallinger-Kube, Boehringer Ingelheim		11:15 h
11:30 h		**AI needs Data Management and FAIR Data in the Lab** Christophe Girardey, wega				**Vision AI in Microbiology QC: Robust Models Ensure Reliable Outcomes** Niek Van Overberghe, Microtechnix		**Overview Instruments and Systems Lifecycle 'Fitness for Intended Use'** Dr Bob McDowall, R.D. McDowall Limited	11:30 h
11:45 h	**Strategy for Potency Determination of Gene Therapy Products** Dr Ulrike Herbrand, Charles River Laboratories		**Achieving Cost Excellence in GMP Labs – A Proven Maturity Model for Sustainable Results** Dr Johann Giegori, Author & Speaker	**Platform Methods - RNA Integrity as Case Study** Susanne Ulrich, BioNTech	**Bioassay Primer: Model-Based Confidence Interval Effects** Dr Florian Müller-Sallanz_Stegmann Systems		**Investigating Low Endotoxin Recovery (LER) and Pyrogenicity in Diverse Pharmaceutical Products** Dr Paryastis Sachs, Sanofi		11:45 h
12:00 h									12:00 h
12:15 h	Lunch Break / Conference Exhibition								12:15 h
12:30 h									12:30 h
12:45 h									12:45 h
13:00 h									13:00 h
13:15 h									13:15 h
13:30 h									13:30 h
13:45 h	**High-Throughput Single-Cell Potency Assays for Cell Therapy Development Using Droplet Microfluidics** Dr Stephanie van Loo, Livedrop		**Beyond the Visible: Automating the Quest for Subvisible Particles in Parenteral Products by means of Microflow Imaging** Dr Melanie Zerulla-Wermitz, Vetter Pharma-Fertigung	**A Platform ddPCR Method for the Detection of Residual DNA in mRNA Samples** Dr Christian Schiller, Eurofins	**Bioassay Relevant Texts in the Ph. Eur. as well as the Potency Strategy in the Ph. Eur. for mAbs** Dr Solène Le Maux, EDQM	**Unlocking Microbial Strain Typing with Whole Genome Sequences** Dr Sujan Timilsina, Charles River Laboratories	**Limit Test Validation – Balancing Business Risk and Patient Safety** Dr Anthea Darius, Microcoat, Claudia König, Sanofi	**Analytical Procedure Development Lifecycle** **'Fitness for Intended Purpose'** Patrick Jackson GSK and Board member of ECA AQCG	13:45 h
14:00 h									14:00 h
14:15 h			**From Traditional QC to Real-Time Volume Control: Enhancing Screening Data Quality** Tobias Brode, Liquimetrix	**CapillaryZone Electrophoresis for Oligonucleotide Quality Control – the Power of Gel-free Separations** Dr. Jakob Haglöf, University of Uppsala, Department of Medicinal Chemistry		**Approach for Validation Microbial Identification Methods: Primary and Limited Validations** Marie-Laurence Baille, MSD	**Advancements in Endotoxin Testing from the PSCI Report and Member Survey** Dr Shahjahan Shaid, GSK	**Performance Qualification of Analytical Procedures ICH Q2 (R2) & the revision of USP <1225>** Dr Gerd Jilge Board member of ECA AQCG	14:15 h
14:30 h									14:30 h
14:45 h	**Cell and Gene Therapy CQA Analysis using Mass Spectrometry** Dr Daniel Waldera-Lupa, Protagene	**Investigation and Root Cause Analysis using AI for Trending and Contamination Control** Parsa Famili, Novatek International	**QC-Automation: Development of a Fully Automated Bioburden Testing Solution** Anke Hossfeld, Merck Life Science	**Control of Process-Related Impurities (HCPs) and Regulatory Requirements** Dr Erika Friedl, Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines	**A (Former) CDER Reviewer's Perspective on Potency Assays** Gerry Feldman, formerly FDA	**Development of Long Read Sequencing for Adventitious Virus Detection** Dr Dominik Meisohle, Boehringer Ingelheim	**Recombinant Endotoxin Testing Case Study of Various Pharma Products** Poppy Cliffe, AstraZeneca	**Performance Qualification of Bioanalytical Procedures; Similarities and Differences** Margarita Sabater, Genmab and Board member of ECA AQCG	14:45 h
15:00 h									15:00 h
15:15 h	Coffee Break / Conference Exhibition								15:15 h
15:30 h									15:30 h
15:45 h									15:45 h
16:00 h	**Optimization of Analytical Methods for Engineered Cell Therapy Products: Lessons Learned** Dr David Svec & Dr Jan Blecha, SCTbio	**Responsible AI Development of Alternative Microbiological Methods used for Environmental Monitoring – a Case Study with the APAS Independence** Dr Steven Giglio, Clever Culture Systems	**The Role of AI and Automation in Environmental Monitoring (EM): Driving Standardization, Efficiency, and Innovation in Microbiology** Amalda Giambra, Cropan Group	**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** Julia Rauch, Charles River Laboratories	**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	**Next Generation Digital PCR Technology for Sterility Testing of Cell and Gene Therapy Products** Dr Robert Hertel, Sartorius	**Product Validation with rCR at Bayer** Sandra Wieger, Bayer	**AQbD and its Impact on the Analytical Procedure Lifecycle** Dr Amanda Guiraldelli Mahr, RIC Group and Board member of ECA AQCG	16:00 h
16:15 h									16:15 h
16:30 h			**From EM to Product Release: Transforming QC Labs with Connected EM Systems** Bernard Corcoran, Lonza	Discussion Day 1	**Case Study: Validation and Bridging of a Flow Cytometry Potency Assay for a Therapeutic Monoclonal Antibody** Dr Frances Reichert, Eurofins	**Rapid, Phenotypic Sterility Testing for Cell and Gene Therapy Products: Validation of a Three-Day Protocol Using the calScreener+ Platform** Dr Wilhelm Paulander, Symcel	**Streamlined Validation of Recombinant Cascade Reagents: A Novel Approach Using Advanced Microfluidic Technology** Meg Provenzano, Veolia	**Ongoing Procedure Performance Verification (New USP Draft General Information Chapter <1221>** Dr Joachim Ermer, Ermer Quality Consulting and Board member of ECA AQCG	16:30 h
16:45 h	**Validation of VCN Determination by dPCR on a Retroviral CAR-T Cell Product in Compliance with ICH Q14 and Q2(R2)** Dr Katy Haussmann, Charité & Dr Daniel Lindemeier, Labor LS	**AI and GxPs: A Contradiction?** Dr Karl-Heinz Bauer, Training - Beratung - Coaching							16:45 h
17:00 h			**Accelerate Journey towards Pharma 4.0 with Next Gen Lab Solutions** Rajasekhar Gollapinni, Caliber		**Of Mice and (Wo)Men** Simona Tomaschek, Roche	**Moving the Needle for Sterility Testing: Towards a New, Rapid Sterility Test to Allow Faster Release of CAR-T Drug Products** Dr Nore Struyf, Dr Cedric Joossen, Johnson & Johnson	**Update on the Pyrogenicity in the Ph. Eur.** Dr Solène Le Maux, EDQM	**Good Documentation Practices and Data Integrity (USP <1029>** Dr Christopher Burgess, Chairman ECA AQCG	17:00 h
17:15 h									17:15 h
17:30 h	Discussion Day 1	Discussion Day 1	Discussion Day 1		Discussion Day 1	Discussion Day 1	**RSE, CSE or Crude LPS preparations? A Closer Look at Detection Variability** Luisa Burgmaier, Microcoat	Q&A Panel Discussion	17:30 h
17:45 h									17:45 h
18:00 h									18:00 h

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26 November 2025

Time	Cell and Gene Therapies/ ATMP - Quality and Safety	Artificial Intelligence in 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	Alternative and Rapid Microbiological Methods	Endotoxin and Pyrogen Testing – Pharmacopoeial and Scientific Developments	GMP Compliance Trends in Analytical Laboratories	Time
09:00 h	Welcome and Introduction (at the Plenum)								09:00 h
09:15 h	**KEYNOTE: Phage Therapy: History, Current Challenges and Perspectives** Dr Frédérique Vieville, CEO, SQBD-Biotech								09:15 h
09:30 h									09:30 h
09:45 h									09:45 h
10:00 h	Coffee break / Conference Exhibition								10:00 h
10:15 h									10:15 h
10:30 h									10:30 h
10:45 h	**Developing Control Strategies for Off-the-shelf Allogenic Cell Therapy Products** Dr Steven Braem, 3D-PharmXchange	**Case Study: Machine Learning for Mold vs Bacteria Identification** Nour El Ghazal & Lisa Mallam, bioMérieux	**Practical Examples on Digitalization, Optimization & Simplification in QC-Labs** Dr Karl-Heinz Bauer, Training - Beratung – Coaching	**The Role of Platform Host Cell Protein ELISAs in Biopharmaceutical Quality Control** Dr Florian Semmelmann, Roche	**Case Study of an Enhanced Development for a Bioassay** Dr Simon Anduthuh, Novartis	**Update/Additions to Performing Statistical Calculations for Quantitative Rapid Method Validation Criteria** Dr Michael Miller, Microbiology Consultants	**MAT: Thoughts on Test Sensitivity, Pyrogen Limits, MVD and Readout System** Dr Ingo Spreitzer, PEI	**Set-up of a QC Laboratory as Part of Greenfield Facility** Ivana Heckel, Ion23 health	10:45 h
11:00 h									11:00 h
11:15 h				**Real time release control strategy for a Biotech drug product** Dr Susanne Gawenda, Roche	**"Where Fat and Sugar Meet" - Setup of a Glucose Uptake Assay in Differentiated Adipocytes** Dr Ella Rosenzweig, Vela Labs			**Why every Factor matters in a Contamination Investigation** Jeanne Moldenhauer, Excellent Pharma Consulting	11:15 h
11:30 h	**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, CRL	**Case Study: AI-Based Automated Solution for Incubation and Colony Counting in Microbiological Quality Control** Camilla Giardini, Copan NewLab	**From Instrument to Knowledge: How to Organize the Digitalization of your Laboratory?** Dr Steven van Helden , wega Informatik			**Evaluation of an Automated Readout of APS** Simon Braun & Matthieu Giletti, Roche	**Shaping the Future of Pyrogen Testing: Regulatory Updates and the Role of MAT** Dr Luca Benedan, Eurofins **Case Study: Qualification of a Reporter Gene-based Monocyte Activation Test (MAT)** Dr Nicole Rieth, Dr Luca Benedan Eurofins		11:30 h
11:45 h				**Implementation of a Cartridge-based CE-SDS/cIEF Instrument for Routine Measurement of Drug Product** Johannes Fühner, VelaLabs/Tentamus	**Advancing Bioassay Technologies with NanoBiT Split Luciferase** Dr Jamison Graller, Promega			**Small CROs and Validation & Conduction of (Bio)analytical Methods** Dr Timó G. Knetzschmar, TiKiESolution	11:45 h
12:00 h									12:00 h
12:15 h	Lunch Break / Conference Exhibition								12:15 h
12:30 h									12:30 h
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13:15 h									13:15 h
13:30 h									13:30 h
13:45 h	**Avoiding Common Sterility Testing Compliance Gaps and Regulatory Observations During ATMP Sterility Testing** Marsha Steed, Steed MicroBio LLC	**Utilizing ChatGPT to Establish Company-Wide Harmonized Equipment and System Validation Standards** Isabella Küfner, Boehringer Ingelheim	**Future Labs: Architecture, Automation and AI** Kambiz Hajizadeh Zaker, Vollack & Christian Ziegler, BAT	**ICH QSA – Prior Knowledge in Virus Testing and Clearance Studies** Dr Martin Spruth, AGES - Austrian Agency for Health and Food Safety	**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	**Evaluation of RMBNucleus™ Mold Alarm Software Feature** Dr Yu-Wie Shieh, Boehringer Ingelheim	**Implementing A New Type of Monocyte Activation Test Method to Detect and Quantify Pyrogens in GMP Environment** Dr Katarzyna Marciniak-Darmochwal, CRL	**Universal Study Design for Instrument Changes in Pharmaceutical Release Analytics** Dr Anne Ries, BI Pharma	13:45 h
14:00 h									14:00 h
14:15 h			**Smart Organization in the Laboratory: 47% Time Savings with 100% Precision** Mario Schneider, Better Basics Laborbedarf	**Pragmatic Implementation of ICH Q14: Capillary Electrophoresis for Virus Quantification** Dr Ewoud van Tricht, Kantisto BV	**Development and Optimization of the Infectious Titer Assay (TCID50) for Recombinant AAV** Annemie Welant, UCB	**Automated Solid Phase Cytometry Applications: Bioburden Troubleshooting in Production and Sterility Testing Feasibility for mRNA Vaccines** Dr Thierry Bonnaiay, Sanofi	**NCSRs– Results of Survey and Discussions/Podium Discussion** Dr Elliot Lilley, UK National Centre for the Replacement, Refinement & Reduction of animals in research	**Auditing Audit Trails - QA vs QC Perspective** Apostol Todorovski, GMP Insiders	14:15 h
14:30 h	**Enhancing Microbiological Quality Control with Ready-to-Use Microorganisms** Dr Megha Bajaj, bioMérieux	**Large Language Models in the Service of Quality: Analyzing the Quality of Documentation** Dr Colin Lischik, Boehringer Ingelheim							14:30 h
14:45 h			**Standardization inside a Network of GMP Contract Laboratories** Dr Christoph Höppner, Eurofins BioPharma Product Testing Europe	**Development of HPLC-based Methods for Separation and Subsequent Characterization of Morphological Subspecies of a VSV-based Therapeutic Virus** Dr Johannes Soltin, Boehringer Ingelheim	**A Case Study on the Challenges of Establishing a Robust Cell-based Bioassay for Plasmid DNA Potency Determination** Dr Thomas Danielsen, Novo Nordisk	**Accelerating Release of Short Shelf-Life Therapies Through Automated Growth-Based Method Optimization and Application of USP<72> "Sa** Dr Caroline Kassim, bioMérieux		**Audit Trail Requirements for Digitalised GMP Laboratories** Dr Bob McDowall & Mahboubeh Lotfinia	14:45 h
15:00 h									15:00 h
15:15 h	Coffee Break / Conference Exhibition								15:15 h
15:30 h									15:30 h
15:45 h									15:45 h
16:00 h	**How to Build a Digitalized End-to-End Process for Environmental Monitoring for ATMPs Release** Johannes Obentörfer, Rapid Micro Biosystems & Willem Dullaers, Lonza	**AI-powered Pharma: Transforming Drug Discovery, Development and Production** Siobhan Fleming, Siemens	**The Art of Partnership: Managing Expectations in Pharma-CRO Relationships** Malin Molander, Svar Life Science	**Mastering hcDNA: A Harmonized Approach for AAV Gene Therapies** Dr Denise Teber, Charles River Laboratories	**Making Cell-Based Potency Assays Work Better for QC: A Simpler, Stronger Solution** Peter Wolff, AGC Biologics	**EM Plate Reading Using the APAS Independence** Juan González, Pfizer	**Next Generation MAT – Analytical Precision meets Regulatory Confidence** Dr Eva Kritikou, MAT Research	**Evaluation of Stability Data: Extrapolation of Shelf-Life by Statistical Analysis** Dr Joachim Ermer, Ermer Quality Consulting	16:00 h
16:15 h									16:15 h
16:30 h			**Microbial Qualification of Cleanrooms: Not only CFU Counts - Big Projects in Different Spotlights** Alexander Pfüllb & Mélanie Braun, Labor LS	Final Discussion	**Ensuring Consistency in Bioassay Method Transfer: Strategies for Overcoming Variability** Jessica Weaver, BioAgilytix	**Primary Validation of Rapid-Cr, Advanced BFPC, for Real-Time Viable Particle Monitoring** Dr Svetlana Kiseleva, Pfair	**Major Flaw of Applying MAT Method 2 to Products with LER Effects, New Generation of Rapid, Simplified and Sensitive PBMC-based MAT with FBS-free Medium** Dr Shabnam Solati, CTL-MAT LLC	**Improving Analytical Procedure Transfers in the Pharmaceutical Industry** Ulla Bondegaard, Novo Nordisk	16:30 h
16:45 h	**The New Guideline on ATMPs and Further Regulatory Update on ATMPs** Dr Sabine Hauck, dequra pharma consult	Final Discussion & Q&A Session							16:45 h
17:00 h			Final Discussion & Q&A Session		**Case Study on the Development of a Cell-based Assay** Morgane Gesquière, UCB	**Bridging ISO Standards and ARMM for Effective Air Monitoring** Corina Keller, MBV	**HyPerMAT – Discover the Future of in vitro Pyrogen Testing** Dr. Johannes Lichti, HyQuality Dx	Final Discussion & Q&A Session	17:00 h
17:15 h									17:15 h
17:30 h	Final Discussion				Final Discussion	Final Discussion & Q&A Session	Final Discussion & Q&A Session		17:30 h
17:45 h									17:45 h
18:00 h									18:00 h