Time	20 November 2023	21 November 2023		21 November 2023			Time
	PharmaLab Pre-Conference Event 4th International Mycoplasma qPCR Testing User Day Room : Markus/Konstantin	**TRACK 1 : GMP Compliance Trends in Analytical Laboratories/Outsourcing in Pharmaceutical Laboratories** Room : Markus/Konstantin	**TRACK 2 : Analytical Procedure Life Cycle Management/Validation of Analytical Procedures – ICH Q14/ICH Q2(R2) - Day 1 -** Room : Titus/Tiberius	**TRACK 3 : Endotoxin and Pyrogen Testing - Day 1 -** Room : Bacchus/Mars/Merkur	**TRACK 4 : Alternative and Rapid Microbiological Methods - Day 1 -** Room : Apollo	**TRACK 5 : Cell and Gene Therapies/ ATMPs - Quality and Safety - Day 1 -** Room : Augustus	
09.00 h		9.00 - 9.15 h: Welcome and Introduction		9.00 - 9.15 h: Welcome and Introduction			09.00 h
		Congress Key Note 09.15 - 10.00 h: **The Impact on the Revised Annex 1 for Rapid Microbiological Methods Implementation** *Dr Michael Miller, Microbiology Consultants*		Congress Key Note 09.15 - 10.00 h: **The Impact on the Revised Annex 1 for Rapid Microbiological Methods Implementation** *Dr Michael Miller, Microbiology Consultants*			
10.00 h		10.00 - 10.45 h: **Coffee Break and Exhibition** **(Take advantage of the break to visit the exhibition)**		10.00 - 10.45 h: **Coffee Break and Exhibition** **(Take advantage of the break to visit the exhibition)**			10.00 h
		10.45 - 11.15 h: **Data Integrity and Cloud Computing in GMP Compliant Laboratories – Presence, Future or a Contradiction? A perspective from the Eyes of a GxP Auditor** *Dr Timo Kretzschmar, Inosolve*	10.45 - 11.30 h: **Update on USP <1220> and <1058>** *Dr Christopher Burgess, Burgess Analytical Consultancy*	10.45 - 11.30 h: **Towards animal free pyrogens test in the Ph. Eur: latest progress** *Dr Gwenaël Ciréfice, EDQM*	10.45 - 11.30 h: **Future revision of Ph. Eur. chapters 5.1.6 Alternative methods for control of microbiological quality and 5.1.9 Guidelines for using the test for sterility** *Dr Solène Le Maux, EDQM*	10.45 - 11.30 h: **Analytical challenges in development of cell and gene therapies** *Alicja Fiedorowicz, Dark Horse Consulting*	
11.00 h		11.15- 11.45 h: **Business continuity in cGMP** *Alexander Pfülb, Labor LS*	11.30 - 12.15 h: **Introduction to the new ECA Analytical Quality Control Group (AQCG) Guide on Analytical Instrument Qualification and Software Validation (AIQ&SV)** *Dr Christopher Burgess, Burgess Analytical Consultancy* *Dr Bob McDowall, R.D. McDowall Limited*	11.30 - 12.15 h: **If it's not broken, why fix it?** *Jelena Novakovic Jovanovic, Galenika*	11.30 - 12.15 h: **New generation of solid phase cytometry for rapid sterility testing of pharmaceutical products (under Ph. Eur chapter 2.6.1)** *Dr Joseph Pierquin, Redberry* *Dr Silvia Scotti, Eurofins*	11.30 - 12.15 h: **Challenges of a point-of-care model for cell therapy from an analytical perspective** *Matthias Heemskerk, CellPoint a Galapagos company*	11.00 h
12.00 h	12.00 -12.15 h: **Welcome and Introduction** *Haidy Wafy, Roche*	11.45- 12.15 h: **Shelf life of Reagents in a Chemical-pharmaceutical Laboratory** *Dr Jochen Kolb, BioChem*					12.00 h
	12.15 - 13.00 h: **Current revision of Ph. Eur. chapter 2.6.7 Mycoplasmas and its impact on other Ph. Eur. Texts** *Dr Thuy Bourgeois, EDQM Strasbourg, France*	12.15 - 13.45 h: **Lunch Break** **(Take advantage of the break to visit the exhibition)**		12.15 - 13.45 h: **Lunch Break** **(Take advantage of the break to visit the exhibition)**			
13.00 h	13.00 - 13.30 h: **NAT-based Methods for Mycoplasma Testing – Validation Strategy European Pharmacopoeia Chapter 2.6.7s** | *Yasmin Heynen, Labor LS*	13.45 - 14.30 h: **Understanding & preventing Human Errors** *Dr Karl-Heinz Bauer, Boehringer Ingelheim*	13.45 – 15.15 h: **Product Life Cycle Concept from the Perspective of the Authorities - Enhanced Approach in Process Validation & Production Routine** *Dr Rainer Gnibl, Government of Upper Bavaria*	13.45 - 14.30 h: **Suitability of rFC-based endotoxin tests: a comparison study including different pharmaceutically relevant grades of water and product** *Dr Ana Gonzalez Hernandez, GSK*	13.45 - 14.15 h: **The Route to faster Bioburden and Sterility Testing with the Milliflex Rapid System 2.0** *Dr Anne-Grit Klees, Merck*	13.45 - 14.30 h: **Potency testing for ATMPs** *Dr Sascha Karassek, CRL*	13.00 h
	13.30 - 14.00 h: **Next Generation PCR Closed System Allowing for 1-Hour Mycoplasma Release Test of CGT Products** *Dr Caroline Kassim, bioMérieux*	14.30 - 15.15 h: **Microbiology Testing in Contract Labs** *Dr Radhakrishna Tirumalai, MSD, formerly at USP*		14.30 - 15.15 h: **Establishment of a rFC assay for the detection of bacterial endotoxins** *Dr Holger Kühn, BioChem*	14.15 - 14.45 h: **Rapid Micro QC Test- Ensuring Product Safety When It Really COUNTS** *Johannes Oberdörfer, RMB*	14.30 - 15.15 h: **Analytical Methods to support mRNA-LNP formulation development** *Dr Sabine Hauck, Leukocare*	
14.00 h	14.00 - 14.15 h: **Coffee Break**				14.45 - 15.15 h: **Physical and biological sampling efficiency for active microbial air samplers** *Dr Miriam Schönenberger, MBV*		14.00 h
	14.15 - 14.45 h: **Development of a digital PCR-based Mycoplasma Detection Kit** | *Dr Nicole Paland, Minerva Biolabs*						
15.00 h	14.45 - 15.15 h: **Mycoplasma Real-Time PCR: Generic method validation of T-cell culture** *Dr Alexander Bartes, Roche*	15.15 - 16.00 h: **Coffee Break** **(Take advantage of the break to visit the exhibition)**		15.15 - 16.00 h: **Coffee Break** **(Take advantage of the break to visit the exhibition)**			15.00 h
	15.15 - 15.45 h: **Change of mycoplasma NAT-based method: management of a kit discontinuation** *Marine Marius, Sanofi*						
	15.45 - 16.00 h: **Coffee Break**						
16.00 h	16.00 - 16.30 h: **Mycoplasma testing & evaluation for ATMPs – lessons learned!** *Olga Müller, Tetec*	16.00 - 16.45 h: **Transfer to external partners - Overcoming Pitfalls in Analytical Method Transfers** *Dr Holger Bauer, Merck*	16.00 - 16.30 h: **Iterative Validation Approach for Precision: Stage 1 or Stage 2?** *Dr Joachim Ermer, Ermer Quality Consulting*	16.00 - 16.30 h: **Novel recombinant cascade reagent (rCR) as equivalent of LAL for sustainable BET** *Dr Hiroki Fukuchi, Fujifilm*	16.00 - 16.30 h: **Automated Environmental Monitoring Plate Reading Powered by AI** *Andrew Gravett, AstraZeneca*	16.00 - 16.30 h: **Achieve lower LLOQs for siRNA quantification in plasma using microflow LC**| *Dr Ferran Sanchez, Sciex*	16.00 h
	16.30 - 17.00 h: **Mycoplasma Testing – Experiences and Thoughts** *Jan-Oliver Karo, Paul-Ehrlich Institut, German Federal Institute for Vaccines and Biomedicines*		16.30 - 17.00 h: **The Impact of the new ICH Q14 on the Practical Approach to Transfer of Analytical Procedures** *Ulla Bondegaard, Novo Nordisk*	16.30 - 17.00 h: **A Validation Approach for Implementing a Sustainable, Scientifically Sound Recombinant Cascade Reagent** | *Jordi Iglesias, CRL*	16.30 - 17.00 h: **Building the House of Rapid Sterility - A Successful Platform Approach to introducing Rapid Methods** *Sophie Drinkwater, AstraZeneca*	16.30 - 17.00 h: **Low energy electron irradiation (LEEI)** *Dr Sebastian Ulbert, Fraunhofer Institut*	
17.00 h	17.00 - 17.30 h: **Summary/Discussion**	16.45 - 17.30 h: **Case Study: Technologies that make Lab of the Future and drive Collaborative Innovation** *Lukasz Paciorkowski, A4BEE*	17.00 - 17.30 h: **Case Study: Standard and Extended Use of a Validated, customized Amplex UltraRed assay for Sensitive Hydrogen Peroxide Detection in Pharmaceutical Water** *Dr Alexandra Heussner, Vetter Pharma*	17.00 - 17.30 h: **Seamless software integration allows for complete automation of the entire endotoxin testing workflow** *Sinéad Cowman, Lonza*	17.00 - 17.30 h: **A unique instrument combining real-time viable particle counting and traditional growth-based sampling. Validation approach and results** | *Dr Svetlana Kiseleva, Plair*	17.00 - 17.30 h: **Different Analytical Tools to characterize ATMPs - from Assay Development to Release Testing** *Dr Markus Fido, MFI Consulting*	17.00 h
		17.30 - 18.00 h: **Final Discussion**	17.30 - 18.00 h: **Discussion**	17.30 - 18.00 h: **Transformative developments in endotoxin testing** *Dr Veronika Wills, Associates of Cape Cod*	17.30 - 18.00 h: **Discussion**	17.30 - 18.00 h: **Discussion**	
18.00 h							18.00 h
	18.30 h: Social Event for Congress Delegates, Speakers and Exhibitors			18.30 h: Social Event for Congress Delegates, Speakers and Exhibitor			

22 November 2023

TRACK 1 : Laboratory Optimization, Automation and Digitalization

Room : Markus/Konstantin

09.00 - 9.15 h: Welcome and Introduction

09.15 - 10.00 h: (Congress Key Note)
Preparedness in Pandemic Vaccine Manufacturing and Deployment
Prof Dr Isabelle Bekeredjian-Ding, Paul-Ehrlich-Institut

10.00 - 10.45 h:
Coffee Break and Exhibition
(Take advantage of the break to visit the exhibition)

10.45 - 11.15 h:
Annex 1: Data Analysis and Trending for Contamination Control
Dr Christina Müller, Boehringer Ingelheim Pharma
Susan Cleary, Novatek International

11.15 - 11.45 h:
Future QC Testing using Automation and Robotics – a Digitalized Foundation of Sterility Testing
Anke Hossfeld, Merck

11.45 - 12.15 h:
Agile Validation
Mathias Fuchs, Wega

12.15 - 13.45 h:
Lunch Break
(Take advantage of the break to visit the exhibition)

13.45 -14.15 h:
Challenges and Solution for the Performance Validation of EM Automation
Dr Laura Bailac, bioMérieux

14.15 - 14.45 h:
From Theory to Practice: Current Requirements for Microbiological Monitoring – Establishing Efficient Strategies for Microbiological Monitoring based on Integrated, Proprietary Software Tools | *Melissa Schülein, Labor LS*

14.45 - 15.15 h:
Considerations when introducing Automated EM Systems in a Large Biopharmaceutical Company
Niels Visschers, MSD

15.15-16.00 h:
Coffee Break
(Take advantage of the break to visit the exhibition)

16.00-16.30 h:
Key to Digitalisation: Understanding and Redesigning Your Laboratory Processes
Dr Bob McDowall , R.D. McDowall Limited

16.30-17.00 h:
Is my Contract Laboratory big enough for becoming Paper-Less? A Case Study
Alexander Doppelreiter, Reference Analytics

17.00-17.30 h:
Key Performance Indicators (KPIs) in Pharmaceutical Quality Control Laboratories – Tools to measure and monitor Optimizations
Dr Karl-Heinz Bauer, Boehringer Ingelheim

17.30-18.00 h:
Final Discussion & Q&A Session

TRACK 2 : Analytical Procedure Life Cycle Management/Validation of Analytical Procedures – ICH Q14/ICH Q2(R2) - Day 2 -

Room : Titus/Tiberius

10.45 – 11.15 h:
Opportunities and Challenges from ICH Q2 (R2) and Q14 for the Analytical Lifecycle
Jean-Francois Dierick, GSK

11.15 – 11.45 h:
Analytical Target Profile (ATP) for Large Molecules
Annick Gervais, UCB

11.45 – 12.15 h:
Validation for MAA/NDA
Dr Xaver Schratt, GBA Pharma

13.45 – 14.15 h:
Implementation of Quality by Design Principles for Analytical Assay Development and Validation
Dr Mohamad Toutounji, Molgenium

14.15 – 14.45 h:
HPLC Stability-indicating Procedure Design using Analytical Procedure Lifecycle Approach and AQbD Principles | *Dr Amanda Guiraldelli, USP*

14.45 – 15.15 h:
The Use of Design of Experiment to ensure appropriate Understanding throughout a Method's Lifecycle
Patrick Jackson, GSK

16.00 - 16.45 h:
Strategies of Overcoming Risks of changing Analytical Methods
Dr Stephan Kirsch, Novartis

16.45 - 17.30 h:
Validation of Specific Methods for Inhalation Drug Products
Dr Manfred Fischer, Fischer Consulting

17.30 - 18.00 h:
Final Discussion & Q&A Session

22 November 2023

TRACK 3 : Endotoxin and Pyrogen Testing - Day 2 -

Room : Bacchus/Mars/Merkur

9.00 - 9.15 h: Welcome and Introduction

09.15 - 10.00 h: (Congress Key Note)
Preparedness in Pandemic Vaccine Manufacturing and Deployment
Prof Dr Isabelle Bekeredjian-Ding, Paul-Ehrlich-Institut

10.00 - 10.45 h: **Coffee Break and Exhibition**
(Take advantage of the break to visit the exhibition)

10.45 - 11.30 h:
A trimeric coiled-coil motif binds bacterial lipopolysaccharides with picomolar affinity
Prof Dirk Linke, University Oslo

11.30 - 12.15 h:
All endotoxins are lipopolysaccharides, but all lipopolysaccharides are not endotoxins!
Dr Martine Caroff, LPS -Biosciences

12.15 - 13.45 h:
Lunch Break
(Take advantage of the break to visit the exhibition)

13.45 - 14.15 h:
Endotoxin Masking – dependency on LPS mutant and matrix formulation
Luisa Burgmaier, Microcoat

14.15 - 14.45 h:
Preselection of NEP-reference materials in different MAT-setups
Dr Josephine Hubloher, Paul-Ehrlich-Institut

14.45 - 15.15 h:
Implementing new type of Monocyte Activation Test Method to detect and quantify pyrogens
Dr Kasia Marciniak-Darmochwal, CRL

15.15 - 16.00 h:
Coffee Break
(Take advantage of the break to visit the exhibition)

16.00 - 16.30 h:
Advancing Pyrogen Testing with Automated MAT
Ruben Huis in 't Veld, MAT Research

16.30 - 17.00 h:
Development of a novel MAT test product (MyIc-MAT) using immortalized monocyte cells (aMyIc cell) derived from peripheral blood mononuclear cells
Kazuo Miyazaki, MiCAN Technologies Inc

17.00 - 17.30 h:
MAT Investigation on two non-endotoxin pyrogen
Peter Brügger, Lonza/MAT Research

17.30 - 18.00 h:
Final Discussion & Q&A Session

TRACK 4 : Alternative and Rapid Microbiological Methods - Day 2 -

Room : Apollo

10.45 - 11.30 h:
Alternatives and Rapid Microbiological methods and Pharmacopeias Regulation (Europe, US, Japan and China)
Dr Thierry Bonnevay, Sanofi

11.30 - 12.15 h:
A Review of the Next Revision to PDA Technical Report #33
Dr Michael Miller, Microbiology Consultants

13.45 - 14.15 h:
Primary Validation of Flow Cytometry as an Alternative Plate Count Method
Dr Jürgen Illerhaus, BWT Aqua

14.15 - 14.45 h:
Next generation pyrogen testing method developed for rapid, ELISA free and variety of pyrogen detection
Dr Tomohisa Nanao, Fujifilm

14.45 - 15.15 h:
Validation of methods for the detection of DNase and RNase contaminations in pharmaceuticals and single use devices | *Annemarie Jordan, Labor LS*

16.00 - 16.45 h:
NGS in Microbiology
Dr Oleg Krut, Paul-Ehrlich-Institut

16.45 - 17.30 h:
NGS Strategies from Sample to Report for Microbial Identification and Viral Contamination Detection in Pharma
Dr Inanc Erserim, Thermo Fisher Scientific

17.30 - 18.00 h:
Final Discussion & Q&A Session

TRACK 5 : Cell and Gene Therapies/ATMPs - Quality and Safety - Day 2 -

Room : Augustus

10.45 - 11.30 h:
Innovations in Quality Control for Cell and Gene Therapy using Digital PCR
Dr Mahdieh Rahmatollahi, Thermo Fisher Scientific

11.30 - 12.15 h:
Development of a digital PCR-based system for the detection of residual DNA in pharmaceutical products
Dr Nicole Paland, Minerva Biolabs

13.45 - 14.15 h:
Selection of appropriate methods for detection of microbiological contaminations in ATMPs
Dr Stefanie Bayer, Labor LS

14.15 - 14.45 h:
Transfer of complex analytical methods for ATMPs
Dr Cornelia Rosner, Minaris

14.45 - 15.15 h:
Mycoplasma testing & evaluation for ATMPs – lessons learned!
Olga Müller, Tetec

16.00 - 16.45 h:
Challenges of Endotoxin Detection During Development of a Novel product
Dr Ruth Röder, Microcoat

16.45 - 17.30 h:
Automating the Future of Cell and Gene Therapy: Streamlining Endotoxin Detection, Data Integrity and Compliance Solutions with recombinant Factor C
Christian Faderl, bioMerieux

17.30 - 18.00 h:
Final Discussion & Q&A Session

**Contents and times are subject to changes.*