21 November 2022

PharmaLab Pre-Conference Event
3rd International Mycoplasma qPCR Testing User Day

Room : Titus/Tiberius

12.15 -12.30 h:
Welcome and Introduction
Haidy Wafy, Roche

12.30 - 13.15 h:
Pitfalls and Issues on Mycoplasma Testing According to Pharmacopoeial Requirements - A Regulator´s View on ATMPs | *Jan Oliver Karo, PEI*

13.15 - 13.45 h:
Mycoplasma Testing – Lessons from Routine and Future Perspectives | *Dr Miriam Dormeyer, Sartorius*

13.45 - 14.15 h:
Challenges During the Validation of an Alternative Mycoplasma Detection Method
Christiana Schnitzler, Boehringer Ingelheim

14.15 - 14.45 h: Coffee Break

14.45 - 15.15 h:
Mycoplasma Testing for ATMPs: Rapid Methods and Validation Strategies | *Dr Stefanie Bayer, Labor LS*

15.15 - 15.45 h:
Mycoplasma Testing – An Update of RtR at Janssen Biologics BV | *Orm Nieuwenhuizen, Janssen Biologics*

15.45 - 16.15 h:
Validation of DNA Extraction Robots - The Balance between GMP Annex 11 v. Actual Best Performance
Jo Milne, Mycoplasma Experience

16.15 - 16.45 h: Coffee Break

16.45 - 17.00 h:
Recent revision proposal of Ph. Eur.-Chapter 2.6.7 "Mycoplasmas": What is proposed to be changed and why? | *Dr Sven M. Deutschmann, Roche*

17.00 - 17.30 h:
Alternative Adventitious Agents Detection Methods in Biopharmaceuticals: A Proposal for a Structured Best Practice Approach for their Evaluation, Validation and Implementation | *Dr Sven M. Deutschmann, Roche*

17.30 - 18.00 h:
Summary/Discussion

22 November 2022

TRACK 1 : QC Analytics
Analytical Procedure Life Cycle Management - ICHQ14/ICH Q2(R2)

Room : Titus/Tiberius

9.00 - 9.15 h: Welcome and Introduction | *Representative ECA*

09.15 - 10.00 h:
Congress Key Note
Biological Manufacturing – Future Quality Challenges
Dr. Tilman Rock, Boehringer, Site Head Biopharma, Vienna

10.00 - 10.45 h: Coffee Break and Exhibition

10.45 - 11.30 h:
ICH Q2(R2)/Q14: Mission accomplished?
Dr Joachim Ermer, Ermer Quality Consulting

11.30 - 12.15 h:
Lifecycle Management of Analytical Procedures, Instruments and Systems in the USP
Dr Chris Burgess,
ECA Analytical Quality Control Interest Group

12.15 - 13.45 h:

Lunch Break

(Take advantage of the break to visit the exhibition)

13.45 - 14.15 h:
Next Steps of Practical Life Cycle Management in Laboratories
Ulla Bondegaard, NovoNordisk

14.15 - 14.45 h:
Insights into ICH Q14: Analytical Procedure Development | *Dr Mario Ramos, Valicare*

14.45 - 15.15 h:
Impact of New ICH Q14 and Q2(R2) Draft Guidelines on Potency Assays – Focus on SPR
Simon Gaderer, VelaLabs

15.15 - 16.00 h:

Coffee Break

(Take advantage of the break to visit the exhibition)

16.00 - 16.30 h:
Repeat or Not to Repeat – Use of Development Data for Validation
Dr Joachim Ermer, Ermer Quality Consulting, Germany

16.30 - 17.00 h:
From Vision to Validation: The Method Live Cycle explained by the Example of a HPLC Method
Lukas Renner, Reference Analytics

17.00 - 17.30 h:
Development and Validation of a Customized Amplex UltraRed Assay for Sensitive Hydrogen Peroxide Detection in Pharmaceutical Water | *Dr Alexandra Heussner, Vetter*

17.30 - 18.00 h:
A Full Spin on Analytical Lifecycle Management: Proof of Concept
Dr Lúcia Volta e Sousa, Infosaúde - LEF Discussion

TRACK 2 : QC Endotoxin and Pyrogen Testing
- Day 1 -

Room : Bacchus/Mars/Merkur

10.45 - 11.15 h:
Pyrogenicity: The Transition from RPT to MATe
Dr Ingo Spreitzer, Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines

11.15 - 11.45 h:
Advantages of the Monocyte Activation Test in Quality Control Testing of Lifecycle Products
Dr Liliana Alleri, GSK

11.45 - 12.15 h:
Optimization of the Monocyte Activation Test to assess Reactogenicity of Outer Membrane Vesicle Vaccines
Dr Marijke Molenaar-de Backer, Sanquin

13.45 - 14.05 h: Generic Method and Specific Product Validation of the Monocyte Activation Test | *Dr Jonas van den Berg, Roche and Maria Gajewi, Microcoat*

14.00 - 14.25 h: Development and Validation of the MAT for Parenteral Preparations that still require RPT Testing for Regulatory Compliance | *Dr Koen Marijt, MAT Research*

14.25 - 14.45 h: MAT as the Sole Tool to identify Synergistic Effects when Parenteral Drugs are contaminated with Multiple Pyrogens | *Shabnam Solati, CTL-MAT*

14.45 - 15.05 h: MAT: A Pyrogen Detection Solution for Gene Therapy Products? | *Anne Claire Erba, Merck*
15.05 - 15.15 h: Discussion

16.00 - 16.30 h:
Alternative Pyrogen Methods: FDA Case Studies
Dr Reyes Candau-Chacon, FDA, USA

16.30 - 17.00 h:
Alternative Approaches to Medical Device Testing with the MAT
Dr Sandra Stoppelkamp, University Tübingen

17.00 - 17.30 h:
Interleukin Interference during MAT Testing
René Ørving, Novo Nordisk

17.30 - 18.00 h:
Validation of the Monocyte Activation Test with three Therapeutic Monoclonal Antibodies
Dr Ruth Daniels, Janssen

18.30 h:
Social Event for Congress Delegates, Speakers and Exhibitors

22 November 2022

TRACK 3 : QC Microbiology
Alternative and Rapid Microbiological Methods

Room : Apollo

9.00 - 9.15 h: Welcome and Introduction | *Representative ECA*

09.15 - 10.00 h:
Congress Key Note
Biological Manufacturing – Future Quality Challenges
Dr. Tilman Rock, Boehringer, Site Head Biopharma, Vienna

10.00 - 10.45 h: Coffee Break and Exhibition

10.45 - 11.00 h:
Welcome and Introduction
Dr Sven M. Deutschmann, Roche, Chair of ECA's Microbiology Working Group

11.00 - 11.30 h:
Game Changer? Use of Rapid Microbiological Methods (RMM) in the GMP - Quality Control Lab
Dr Philipp Kucera, VelaLabs

11.30 - 12.15 h:
Next Generation Sequencing: Current Trends and Perspectives for Pharma and Biotech
Dr Inanc Deger Erserim, Thermo Fisher

12.15 - 13.45 h:

Lunch Break

(Take advantage of the break to visit the exhibition)

13.45 - 14.15 h:
MS for ID - Regulatory Changes and their Influence of ID in Laboratory
Dr Gerold Schwarz, Bruker

14.15 - 14.45 h:
New Solid Phase Cytometry Method
Dr Wilfried Ablain, Microbs

14.45 - 15.15 h:
Case Studies on Burkholderia Cepacia Complex (BCC) Investigations, QC Lab Testing and Remediation
Dr Michael Miller, Microbiology Consultants

15.15 - 16.00 h:

Coffee Break

(Take advantage of the break to visit the exhibition)

16.00 - 16.30 h:
ATP Bioluminescence for Non-sterile Product Testing: Roadmap to Implementation
Inge van der Schoot, J&J

16.30 - 17.00 h:
Next Level Environmental Monitoring - Automated Filamentous Fungi Detection
Johannes Oberdörfer, Rapid Micro Biosystems

17.00 - 17.30 h:
Non-inferiority Testing for Qualitative Microbiological Methods: Assessing and improving the Approach in USP <1223> | *Dr Pieta IJzerman-Boon, MSD*

17.30 - 18.00 h:
Discussion

TRACK 4 : QC Bioanalytics/Biotech
Cells, Tissues and ATMP – Quality Control

Room : Markus/Konstantin

10.45 - 11.15 h:
Welcome/Analytical Toolbox AAV Virus
Dr Sabine Hauck, Leucocare

11.15 - 11.45 h:
Analysis Strategies for Cell and Gene Therapy Products
Dr Mohamad Toutounji, Molgenium

11.45 - 12.15 h:
Personal Experience of Biological Raw Material Sourcing for an Early Stage ATMP and Considerations for later Clinical Stage Development
Sidonie Karlsson, Amniotics

13.45 - 14.15 h:
Cells of Quality: ICH in the Lab - ICH S6, Q5A-D in the Context of Cell Banking Cell Substrates for the Production of ATMPs | *Dr Simon Schulz, Entourage*

14.15 - 14.45 h:
Batch Release and Stability Studies, especially for ATMPs – a Challenge?
Dr Markus Fido, MFI Bio-Consulting

14.45 - 15.15 h:
Bioactivity Testing for Cell and Gene Therapy Products
Dr Ulrike Herbrand, Charles River

16.00 - 16.30 h:
Analytical Quality by Design Approach: a Challenge for Viral Vector Testing in Gene Therapies
Dr Isabelle Moineau, AKTEHOM & Dr Anne Sophie Cottard, Yposkesi

16.30 - 17.00 h:
Automation of Hematopoietic Progenitor Cell (HPC) Processing: a Platform for ATMP Manufacturing
Dr Bechara Mfarrej, Institut Paoli-Calmettes

17.00 - 17.30 h:
Development of a Cell-based Potency Bioassay for mRNA Medicine
Sabrina Rottal, VelaLabs

17.30 - 18.00 h:
Discussion

TRACK 5 : QC Trends (DE)
Aktuelle Trends im QC/QA Labor (Tag 1)

Room : Augustus

09.00 - 09.15 Uhr: Welcome and Introduction
Axel Schroeder, Concept Heidelberg

10.45 - 11.15 Uhr:
Validierung von Restlösemittelmethoden. Herausforderungen bei Transfer und Validierung
Daniela Weisi, Reference Analytics

11.15 - 11.45 Uhr:
Validierung von Methoden zur Spurenanalysen – Probleme und Lösungen
Susanne Becker, Intertek

11.45 - 12.15 Uhr:
Validierung spezifischer Methoden für inhalative Produkte
Manfred Fischer, Consultant

13.45 - 14.15 Uhr:
Methodenvalidierungen im Fokus des Audits
Timo Kretzschmar, Insolve

14.15 - 14.45 Uhr:
Aktuelle Trends: Das Qualitätsmetrikprogramm der FDA
Karl-Heinz Bauer, Boehringer

14.45 - 15.15 Uhr:
Implementierung eines elektronischen Laborjournals
Sabrina Rottal, VelaLabs

16.00 - 16.30 Uhr:
Menschliche Fehler – Verstehen und Vorbeugen
Karl Heinz Bauer, Boehringer

16.30 - 17.00 Uhr:
Spezifische Aspekte der Datenintegrität und Validierung im Labor
Christophe Girardey, Wega

17.00 - 17.30 Uhr:
Methodenoptimierung validierter Methoden. Darf es ein bisschen mehr sein?
Alexander Doppelreiter, Reference Analytics

17.30 - 18.00 Uhr:
Diskussion

18.30 h:
Social Event for Congress Delegates, Speakers and Exhibitor

23 November 2022

TRACK 1 : QC Analytics
Laboratory Optimization, Automation and Digitalization (Day 2)

Room : Markus/Konstantin

TRACK 2 : QC Endotoxin and Pyrogen Testing
- Day 2 -

Room : Bacchus/Mars/Merkur

Time	TRACK 1 : QC Analytics	TRACK 2 : QC Endotoxin and Pyrogen Testing
09.00 h	09.15 - 10.00 h: **Impurities - USP Draft Chapter <477> User-Determined Reporting Thresholds (UDRT), and Other Relevant Chapters** *Dr. Christian Zeine, Senior Manager Scientific Affairs EMEA*	
10.00 h	10.00 - 10.45 h: **Coffee Break and Exhibition**	
11.00 h	10.45 - 11.15 h: **Operation of PCs & Networks in GMP-Labs** *Karl-Heinz Bauer, Boehringer* 11.15 - 11.45 h: **Laboratory Control from the Cloud, SaaS and Data Integrity – an Excurse** *Timo Kretzschmar, Insolve*	10.45 – 11.05 h: **LER Challenges and their Solutions – A Case Study** *Dr Harald Meissner, Morphosys* 11.05 – 11.35 h: **Validation of a Dedicated Sample Preparation Method** *Dr Gertrud Lallinger-Kube, Boehringer Ingelheim & Dr Michael Kracklauer, Microcoat*
12.00 h	11.45 - 12.15 h: **Qualification of Automated Laboratory Systems Including Required Computer System Validation** *Carsten Börger, Valicare*	11.35 – 11.55 h: **Reducing the Environmental Impact on LAL Testing and Improving Employee Sustainability Utilizing Microfluidic Technology for BET** *Hayden Skalski, SUEZ* 11.55 – 12.15 h: **T Custom Made iPSC-Derived Macrophages as an Efficient Tool for Next Generation Pyrogen Testing** *Shifaa Abdin, Hannover Medical School*
13.00 h	12.15 - 13.45 h: **Lunch Break** **(Take advantage of the break to visit the exhibition)**	
14.00 h	13.45 -14.15 h: **MACSQuant Analyzer - a Flow Cytometry Instrument for the GMP Use Case** *Dmitry Fridman, Milteny* 14.15 - 14.45 h: **Implementation of a LIMS integrated with the ERP** *Flavio Kawakami, Convatec/ISPE*	13.45 – 14.05 h: **Depyrogenation by Moist Heat: How Removing Endotoxins in an Autoclave; Time/Temperature Results on different Endotoxins located in/on Different Substrates** *Maria Luisa Bernuzzi, Fedegari & Alessandro Pauletto, CRL* 14.05 – 14.25 h: **How to increase Sustainability in QC Testing? Future Proofing Pyrogen Detection** *Allen Burgenson Lonza* 14.25 – 14.45 h: **Implementing Annex 1 Revisions: Improving Biofilm Detection in WFI Systems Using Rapid LAL Methods** | *Jordi Iglesias, CRL*
15.00 h	14.45 - 15.15 h: **How Do I Find the Best LIMS for my Lab?** *Joachim Post, WEGA*	14.45 – 15.15 h: **Endotoxin Testing: LAL, rFC and Semi-Automation** *Marine Marius, Sanofi*
	15.15-16.00 h: **Coffee Break** **(Take advantage of the break to visit the exhibition)**	
16.00 h	16.00-16.30 h: **Optimization and Real-Time Documentation During the Test for Sterility in Cleanrooms** *Olivia Halamoda, Labor LS* 16.30-17.00 h: **Annex 1 in The Age of Digitization: Reimagining Contamination Control** *Parsa Famili, Novatek & Anne-Grit Klees, Merck*	16.00 - 16.30 h: **The rFC Journey: Validation for Water Testing Completed – What's Next?** *Carmen Marín Delgado de Robles, Roche* 16.30 - 17.00 h: **Recombinant Reagents for BET – Regulatory Landscape, Comparability Studies and Their Future Routine Use including Automation** *David Guy, ACC*
17.00 h	17.00-17.30 h: **How to Transfer your Innovation from Lab Scale to Manufacturing?** *Dana Quaden, Medace* 17.30-18.00 h: **The Lab of the Future – Today** *Sinead Cowman, Lonza*	17.00 - 17.30 h: **Diversity, Complexity, and Originality of Lipopolysaccharides Structures** *Dr Martine Caroff, LPS Biosciences* 17.30 - 18.00 h: **Discussion**
18.00 h		

23 November 2022

TRACK 3: QC Microbiology/ TRACK 4: QC Bioanalytics/ Biotech
Cells, Tissues and ATMP and Alternative Microbiological Methods (Day 2)

Room : Apollo

TRACK 5 : QC Trends (DE)
Aktuelle Trends im QC/QA Labor (Tag 2)

Room : Augustus

Time	TRACK 3: QC Microbiology/ TRACK 4: QC Bioanalytics/ Biotech	TRACK 5 : QC Trends (DE)
09.00 h	09.15 - 10.00 h: **Impurities - USP Draft Chapter <477> User-Determined Reporting Thresholds (UDRT), and Other Relevant Chapters** *Dr. Christian Zeine, Senior Manager Scientific Affairs EMEA*	
10.00 h	10.00 - 10.45 h: **Coffee Break and Exhibition**	
11.00 h	10.45 - 11.15 h: **Regulatory Expectations for Rapid Sterility Testing of ATMPs** *Michael Miller, Microbiology Consultants* 11.15 - 11.45 h: **Implementation of a Comprehensive Rapid Microbial Contamination Control Platform for Testing of Sterile Pharmaceuticals and Cell-Based Therapies using ATP Bioluminescence** *Stefan Gärtner, Labor LS & Lucia Ceresa, CRL*	10.45 - 11.15 Uhr: **Bioanalytik via Durchflusszytometrie – Virustiterbestimmung** *Chrsitina Pospisil, IDT* 11.15 - 11.45 Uhr: **Qualifizierung von Heiz- und Kühlgeräten in der QC** *Patrick Koch, Thermo Fisher Scientific*
12.00 h	11.45 - 12.15 h: **Ultra-rapid microbial detection in Cell & Gene Therapy products: the closest you can be to Real-Time Release** *Corinne de la Foata, bioMerieux*	11.45 - 12.15 Uhr: **DIN EN ISO 7704 – Neue Anforderungen an Leistungsprüfung von Membranfiltern** *Barbara Gerten, Merck*
13.00 h	12.15 - 13.45 h: **Lunch Break** **(Take advantage of the break to visit the exhibition)**	
14.00 h	13.45 - 14.30 h: **Viral safety – Evaluation of eukaryotic cell bank purity with a special focus on adventitious agents and replication competent viruses** *Martine Jorge Miranda, Tentamus* 14.30 - 15.15 h: **Short shelf life and sterility testing - challenges of cell based ATMP market supply** *Mareike Klingler, Tetec*	13.45 - 14.30 Uhr: **Implementierung des rFC** *Carmen Marin Delgado de Robles, Roche* 14.30 - 15.15 Uhr: **Die Umsetzung einer Kontaminationskontrollstrategie (CCS), gemäß Annex 1 im Auftragslabor für Sterilgutprüfungen** *Eva Maria Wolz, Labor LS*
15.00 h	15.15 - 16.00 h: **Coffee Break** **(Take advantage of the break to visit the exhibition)**	
16.00 h	16.00 - 16.30 h: **Rapid Sterility by qPCR for ATMPs** *Anja Fritsch, Confarma* 16.30 - 17.00 h: **ScanRDI System- Validation and implementation of an alternative sterility test (Solid Phase Cytometry) for a cell and gene therapy product** *Mahsa Mohammadi, Novartis*	16.00 - 16.45 Uhr: **Umsetzung des USP Kapitels <1117>** *Dr Marcel Goverde, MGP* 16.45 - 17.30 Uhr: **Moderne Monitoring Systeme zur Online-Wasserüberwachung (OWBA)** *Hans-Joachim Anders, Novartis*
17.00 h	17.00 - 17.30 h: **Implementation of a Real Time PCR-based Method for Release Testing the Sterility of ATMPs, a Practical Approach** *Yasmin Heynen, Labor LS* 17.30 - 18.00 h: **Discussion**	17.30 - 18.00 Uhr: **Diskussion**
18.00 h		

**Contents and times are subject to changes./ Änderungen von Inhalten und Zeiten vorbehalten.*