European GMP Conference

PharmaLab 2021

22- 26 November 2021

Schedule – Laboratory Automation and Optimization

Monday, 22 November 2021 (ALL TIMES IN CET)

11.00 – 11.15 h	**Welcome and Introduction** Axel H. Schroeder
11.15 – 11.45 h	**Continuous Improvement & Idea Management Process (CIP & IMP)** Karl-Heinz Bauer, Boehringer Ingelheim
11.45 – 12.15 h	**Digitization of Workflows and Method Developments in a Pharmaceutical Testing Laboratory** Lars M.H. Reinders, IUTA
12.15 – 13.00 h	**KPIs for Performance-Measurement** Karl Heinz Bauer, Boehringer Ingelheim
13.00 – 13.30 h	**Q&A**
13.30 – 14.00 h	Coffee Break
14.00 – 14.30 h	**Efficient Cleaning Techniques: A Good Starting Point for a Successful Trace Metal Analysis** Fabio Brito, LEF – Infosaúde
14.30 – 15.15 h	**IT and Computers in the Laboratory** Ulla Bondegaard, Novo Nordisk
15.15 – 15.30 h	Coffee Break
15.30 – 16.00 h	**The Integrated, Automated Lab of the Future** Robert Lutskus, Lonza
16.00 – 16.30 h	**Accuracy of Human Visual Inspection in Pétri Dishes Enumeration** Laurent Leblanc, bioMerieux
16.30 – 17.00 h	**Microbial Identification: Maximising the Data Value of Pharmaceutical Flora** Miriam Guest, AstraZenca
17.00 – 17.30 h	**Q&A**

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Schedule - Analytical Procedure Life Cycle Management and Method Validation

Tuesday, 23 November 2021 (ALL TIMES IN CET)

09.00 – 09.15 h	**Welcome and Oragnisationals** Axel H. Schroeder
09.15 – 09.30 h	**Introduction** Dr Joachim Ermer, Ermer Quality Consulting
09.30 – 10.00 h	**USP 1220** Dr Joachim Ermer, Ermer Quality Consulting
10.00 – 10.30 h	**Analytical Procedure Lifecycle Management, Stage 2 - Transfer of Analytical Procedures** Ulla Bondegaard, Novo Nordisk
10.30 – 10.45 h	Coffee-break
10.45 – 11.15 h	**Analytical development & control for complex therapeutics – an expedition via several set-ups** Dr Markus Fido, MFI Bioconsulting
11.15 – 11.45 h	**Established Conditions for Analytical Procedures & Application During the Analytical Life Cycle Management** Isabelle Moineau, Aktehom /Jean Francois Dierick, GSK
11.45 – 12.15 h	**Q&A**
12.15 – 13.15 h	Lunch
13.15 – 13.45 h	**How to Establish ATP for Small Molecules** Patrick Jackson, GSK
13.45 – 14.15 h	**Update TMU** Xaver Schratt, GBA Pharma
14.15 – 14.45 h	**Use of ATP to Guide Analytical Method Changes of Large Molecules** Dr Gerald Gellermann, Novartis
14.45 – 15.00 h	Coffee Break
15.00 – 15.30 h	**Analytical Procedure Lifecycle Management, Practical Implementation of Stage 3.** Ulla Bondegaard, Novo Nordisk
15.30 – 16.00 h	**Optimization, Qualification and Validation of FcgR binding using SPR** Alexander Gill, Vela Labs

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16.00 – 16.30 h	**Deriving Fit-to-Purpose Validation Acceptance Criteria Based on Actual Testing Procedures by HPLC** Pavel Parkhomyuk, Teva
16.30 – 17.00 h	**Q&A**

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Schedule - Alternative and Rapid Microbiological Methods

Wednesday, 24 November 2021 (ALL TIMES IN CET)

09.00 – 09.15 h	**Welcome and Introduction** A. Schroeder/Sven M. Deutschmann
09.15 – 09.45 h	**The Journey of Implementing an Alternative Rapid Sterility Test** Jonas van den Berg, Roche
09.45 – 10.15 h	**Demonstrating an Approach to Rapid Microbiological Testing for Cell-based Therapies** Brice Chasey, CRL
10.15 – 10.30 h	Coffee-break
10.30 – 11.15 h	**Celsis Advance – Analyzing Cell Containing Sterility Samples** Johannes Oberdörfer, Boehringer / Stefan Gärtner, Labor LS
11.15 – 11.45 h	**BFPC Rapid-C Projekt** Denis Kiselev, Plair / Ronny Zingre, MBV
11.45 – 12.00 h	**Q&A**
12.00 – 13.00 h	Lunch
13.10 – 13.30 h	**Mycoplasma Testing – Evolution towards RtR at Janssen Biologics BV** Alex van den Meer, Janssen
13.30 – 14.00 h	**Updates in Rapid Hybrid Mycoplasma Testing** Marleen Hoozemans, MSD
14.00 – 14.30 h	**Application of Next Generation Sequencing for Microbial Identification, Typing and Profiling.** Tara Cassidy / Prasanna Khot, CRL
14.30 – 15.00 h	**Two Hours T2R - From Complex Sample Matrix to Direct Viability Count & Identification, Typing and Profiling | Discussion of the GramRay Toolbox & Strategies**, Oliver Valet, mibiC
15.00 – 15.15 h	Coffee Break
15.15 – 15.45 h	**Colony Counters: How to Evaluate Vision Algorithm Performance** David Jones, Rapid Micro Biosystems

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15.45 – 16.15 h	**Automation and digitalization of the Environmental Monitoring manual steps**, Arnaud Paris, bioMérieux
16.15 – 16.45 h	**Method Validation and Implementation of the GD for Performing of Environmental Controls in Sterile Production**, H.J. Anders, Novartis
16.45 – 17.15 h	**Vitek MS Prime: Innovation in MALDI-TOF MS - Next levele experiences** Victoria Girard, bioMérieux
17.15 – 17.30 h	**Q&A**

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Schedule – Endotoxin and Pyrogen Testing

Thursday, 25 November 2021 (ALL TIMES IN CET)

09.00 – 09.15 h	**Welcome and Introduction**
09.15 – 09.45 h	**Towards an animal-free pyrogenicity testing strategy in the European Pharmacopoeia;** Emmanuelle Charton, EDQM
09.45 – 10.15 h	**Inspection Experiences** Rainer Gallitzendörfer, Government of Upper Bavaria
10.15– 10.45 h	**Regulatory Perspectives in Europe, USA and Japan on the Validation and Industrial Implementation of the rFC Method;** Arnaud Paris, bioMerieux
10.45 – 11.00 h	Coffee-break
11.00 – 11.30 h	**Sustainability in Bacterial Endotoxin Testing – A Holistic Approach;** Veronika Wills, ACC
11.30 – 12.00 h	**The Journey of LER;** Dr Michael Kracklauer, Microcoat
12.00 – 12.30 h	**Q&A**
12.30 – 13.30 h	Lunch
13.30 – 14.00 h	**FDA updates - Current Thinking on Endotoxin- and Pyrogen Testing;** Reyes Candau-Chacon, FDA
14.00 – 14.30 h	**Horseshoe Crab Conservation and Reducing LAL in Testing;** Nicola Reid, CRL
14.30 – 14.45 h	Coffee Break
14.45 – 15.15 h	**Fully Automated, High Speed & High Throughput Endotoxin Testing with the Fluent Gx and rFC** Stefan Haberstock, Tecan
15.15 – 15.45 h	**Centripetal Microfluidic Automation for Optimized Endotoxin Testing;** David Wadsworth, Suez
15.45 – 16.15 h	**Error-Proofing and Futureproofing: Part Deux** Ruth Noe, Lonza
16.15 – 16.45 h	**Scalable Generation of Fully Defined Monocyte/Macrophages from Human iPSC to Assess Pyrogens in Parenteral drugs and Medical Products** Nico Lachmann, Medizinische Hochschule Hannover
16.45 – 17.30 h	**Q&A**

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Schedule – Endotoxin and Pyrogen Testing

Friday, 26 November 2021 (ALL TIMES IN CET)

09.00 – 09.30 h	**The Monocyte Activation Test (MAT) Can Predict Reactions to Medical Devices in Contact with Blood** Sandra Stoppelkamp, Uni Tübingen
09.30 – 10.00 h	**Waive and Replace the Rabbit Pyrogen Test in Lifecycle Vaccine Release** Shahjahan Shaid, GSK Vaccines
10.30 – 11.00 h	**Method Validation Strategy for Endotoxin Testing of Water Samples with Recombinant Factor C in Adherence to 3R Principle for Animal Welfare** Carmen Marín Delgado de Robles, F. Hoffmann-La Roche / Viviane Grunert da Fonseca, Roche Diagnostics
11.00 – 11.30 h	**From Cell Preparation to ELISA Execution: Key Aspects for a Successful Implementation of the MAT** Eelo Gitz, Sanquin
11.30 – 11.45 h	Coffee-break
11.45 – 12.15 h	**MAT- Identifying Innate Immune Response Modulating Impurities** Sophia Pfeiffer, Boehringer Ingelheim
12.15 – 12.35 h	**Feasibility of the Monocyte Activation Test for Cell-Based Samples** Anne-Clair Erba, Merck
12.35 – 12.55 h	**Monocyte Activation Test: Understanding and Mitigating Patient Safety Risks Arising from the Synergistic Effects of Mixed Pyrogens** Shabnam Solati, CTL-MAT
12.55 – 13.15 h	**Next-generation Monocyte Activation Test: Increasing Accuracy/Reliability for High Throughput Sample Testing** Koen Marijt, MAT-Research
13.15 – 13.30 h	**Q&A**