European GMP Conference

PharmaLab 2021

22- 26 November 2021

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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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**