

Time (CET)	Live Online Conference: ECA – Endotoxin and Pyrogen Testing (Day 1)	Live Online Conference: ECA - Laboratory Optimization and Automation	Live Online Conference: ECA - Challenges in Bioanalytical and Analytical Laboratories - Day 1 - from Bioassays to ATMP Analytics	Time (CET)
9.00 h	Introduction and Organisationals			9.00 h
9.15 h				9.15 h
9.30 h	 Current European Pharmacopoeia Developments, with a Focus on Microbiology <i>Dr Emmanuelle Charton, EDQM, Head of Division B</i>			9.30 h
9.45 h				9.45 h
10.00 h				10.00 h
10.15 h	Break			10.15 h
10.30 h				10.30 h
10.45 h	Invention of rFC <i>Prof. Jeak Ling Ding, National University of Singapore</i>	The Future Laboratory beyond Digitization <i>Niek Janssen, Altran</i>	A journey beyond Automation in High-Content Analysis for Live-cell Imaging Research and Drug Discovery <i>Gerd Heimlich, Yokogawa</i>	10.45 h
11.00 h	Evaluation of rFC <i>Sophia Pfeiffer, Boehringer Ingelheim</i>	Reversed Phase HPLC Method Optimization for a Contrast Agent containing Drug Product <i>Johannes Repelnig, VelaLabs - A Tentamus Company</i>	A Complex Cell-based Bioassay for Efficient Lifecycle Management of Analytical Procedures <i>Melanie Wallisch, Rentschler</i>	11.00 h
11.15 h	The Changing BET Landscape and the Recombinant Alternatives <i>Veronika Wills, Associates of Cape Cod</i>	Success Factors of Lean Lab Transformations <i>Dr Wolf-Christian Gerstner, Geniu</i>	Development of a Cell-based Binding Assay according to QbD <i>Sabrina Rottal, VelaLabs</i>	11.15 h
11.30 h				11.30 h
11.45 h				11.45 h
12.00 h	Questions and Answers	Questions and Answers	Questions and Answers	12.00 h
12.15 h				12.15 h
12.30 h				12.30 h
12.45 h	Break			12.45 h
13.00 h				13.00 h
13.15 h				13.15 h
13.30 h				13.30 h
13.45 h	Data as clean as Water: The Criticality of Detecting Relevant Endotoxins in Global Pharmaceutical Water Samples <i>Nicola Reid, Charles River Laboratories</i>	Data Integrity critically examined in the Laboratory - Ubiquitous Traps in a Hybrid Environment <i>Timo Kretzschmar, Anapur</i>	Mass Spectrometric Evaluation of Host Cell Protein Patterns in Downstream Process and Biopharmaceutical Products <i>Dr Daniel M. Waldera-Lupa, Protagen Protein Services</i>	13.45 h
14.00 h	Symbols of Infection <i>Kevin Williams, BioMerieux</i>	Lean Lab Design: Laboratory Planning for new Buildings and Refurbishments <i>Dr Wolf-Christian Gerstner, Geniu</i>	Simultaneous Bioanalytical Monitoring of Cytotoxicity and Biomarker Release via Higher Throughput Assays <i>Jacob G. Tesdorpf, Perkin Elmer</i>	14.00 h
14.15 h				14.15 h
14.30 h				14.30 h
14.45 h	„Error-proofing“ and „Future-proofing“: Updating the Bacterial Endotoxins Test with Automation and Recombinant Reagents <i>Ruth Noé, Lonza</i>	Practical Handling of Laboratory Computerised Systems <i>Ulla Bondegaard, Novonordisk</i>	Validation of Bioanalytical Testing for a Therapeutic mAb using MesoScale-Discovery <i>Max Roucka, VelaLabs</i>	14.45 h
15.00 h				15.00 h
15.15 h	Break			15.15 h
15.30 h	Masking of Endotoxin during Sample Hold Time <i>René Ørving, Novo Nordisk</i>	Ideation Management & Continuous Improvement Processes - A sustainable Contribution to Laboratory Optimizations <i>Dr Karl-Heinz Bauer, Boehringer Ingelheim</i>	New Approaches for Analyzing ATMPs in GMP Environment <i>Dr Markus Fido, MFI Bio Consulting</i>	15.30 h
15.45 h				15.45 h
16.00 h	rFC – How to deal with rFC? <i>Dr Ingo Spreitzer, Paul-Ehrlich Institut (PEI)</i>	Fusion of a Microbiological with a Chemical / Analytical Laboratory <i>Dr Franz Tüchler, VelaLabs - A Tentamus Company</i>	Advanced Analytical Approaches for Accelerated Development of Gene Therapy Products <i>Dr Nicolas Brauckhoff, Protagen Protein Services</i>	16.00 h
16.15 h				16.15 h
16.30 h	Questions and Answers	Questions and Answers	Questions and Answers	16.30 h
16.45 h				16.45 h
17.00 h				17.00 h

Time (CET)	Live Online Conference: ECA – Endotoxin and Pyrogen Testing (Day 2)	Live Online Conference: ECA - Alternative Microbiological Methods	Live Online Conference: ECA - Challenges in Bioanalytical and Analytical Laboratories - Day 2 - Analytics - From Life Cycle Management to Real Time	Time (CET)
9:00 h	 RTRT - A Reality Check in the Small and Large Molecule World <i>Dr Lorenz Liesum, F. Hoffmann-La Roche</i>			9:00 h
9:15 h				9:15 h
9:30 h				9:30 h
9:40 h	Short Break			9:40 h
9:45 h				9:45 h
10:00 h	The Endotoxin Hypothesis of Neurodegeneration <i>Professor Guy C. Brown, Department of Biochemistry, University of Cambridge</i>	Validation of Alternative Methods: the Perspective from the European Pharmacopoeia <i>Dr Emmanuelle Charton, EDQM</i>	Analytical Procedure Lifecycle Management, practical Implementation of Routine for Process Verification <i>Ulla Bondegaard, Novo Nordisk</i>	10:00 h
10:15 h				10:15 h
10:30 h	Use of Monocyte Activation Test for Evaluation of Pyrogenicity associated with typical Environmental Contaminants <i>Dr Anja Fritsch, Confarma</i>	From Visual Counting to Automation of Water Monitoring with the Growth Direct <i>Johannes Oberdörfer, Boehringer Ingelheim</i>	Life Cycle Management of Analytical Procedures - Regulatory Perspective <i>Ketan Agravat, rK3 Solutions</i>	10:30 h
10:45 h				10:45 h
11:00 h	Break			11:00 h
11:15 h	Improving the Robustness of MAT Testing by understanding Donor Variability <i>Koen Marijt, MAT Research</i>	Validation and Implementation of an Automated Colony Counter for Product Bioburden Testing <i>Dr Sven M. Deutschmann, Roche Diagnostics</i>	Key Performance Indicators in Pharmaceutical Quality Control Laboratories - Tools to measure and monitor Optimizations <i>Dr Karl-Heinz Bauer, Boehringer Ingelheim</i>	11:15 h
11:30 h				11:30 h
11:45 h	Pyrogen Detection on Cellular Preparations and other Short Shelf Life Pharmaceuticals <i>Stefan Gärtner, Labor LS</i>	Non-inferiority Testing for RMM Validation: Two use Cases <i>Dr Viviane Grunert da Fonseca, Roche Diagnostics</i>	The value of Pharmacopeial RS: A Story about Uncertainties, associated Guard Bands and Secondary RS <i>Dr Christian Zeine, USP</i>	11:45 h
12:00 h				12:00 h
12:15 h	Questions and Answers			12:15 h
12:30 h				12:30 h
12:45 h	Break			12:45 h
13:00 h				13:00 h
13:15 h				13:15 h
13:30 h				13:30 h
13:45 h	Using the Monocyte Activation Test to determine the Pyrogenicity of an OMV Vaccine <i>Dr Marijke Molenaar-de Backer, Sanquin</i>	Development and Validation of a Rapid Sterility Test using BacT/ALERT Dual T <i>Dr Marja Claassen, MSD</i>	Small Molecule Drugs & Analytics - SWOT Analysis on the OOS/OOT/OOE established System <i>Laura-Felicia Cristescu, STADA Hemofarm SRL (STADA Group)</i>	13:45 h
14:00 h				14:00 h
14:15 h	The Monocyte Activation Test (MAT): The Road forward for Pyrogen Testing <i>Shabnam Solati, CTL-MAT</i>	Validating a Rapid Sterility Test: Practical Strategies to Ensure Regulatory Compliance <i>Dr Michael Miller, Microbiology Consultants</i>	Validation of Analytical Methods <i>Judith Kernbichler, Takeda</i>	14:15 h
14:30 h				14:30 h
14:45 h	Pyrogenic activation measured in the MAT: Is it always related to contaminants? <i>Dr Sandra Stoppelkamp, University Hospital Tübingen</i>	Rapid Microbial Test for Short Shelf Life Pharmaceuticals <i>Dr Alexandra Müller-Scholz, Sartorius</i>	OOS, OOT, OOE – Update from practical Experiences <i>Dr Jörg Neumann, Jörg Neumann Beratung</i>	14:45 h
15:00 h				15:00 h
15:15 h	Break			15:15 h
15:30 h	The Truth of Endotoxin Values - Points for Consideration During Investigation of Aberrant BET Results <i>Dr Johannes Delp, Microcoat Biotechnologie</i>	A Real-time PCR Assay designed to fulfill Mycoplasma Detection Regulatory Requirements <i>Suzy Brown, Thermo Fisher Scientific</i>	Strategic Design of HCP Analysis during Clinical Phases <i>Kai Kottwitz, Rentschler</i>	15:30 h
15:45 h				15:45 h
16:00 h	Endotoxin OOS, OOT and Atypic Results – the ECA Guide on Microbiological Deviation Chapter 2 <i>Jordi Iglesias, Charles River Laboratories</i>	Making the Switch: the Evaluation, Implementation and Validation of bringing Rapid Mycoplasma Testing in-house to expedite Lot Release of Recombinant Protein Product <i>Dr Kent Persson, Octapharma</i>	Real-time Measurements of Starting Materials used in Tablet Production <i>Roland Koch, Gasporox</i>	16:00 h
16:15 h		BPOG's framework for the evaluation, validation and implementation of alternative microbiological testing methods <i>Dr Sven M. Deutschmann, Roche Diagnostics</i>		16:15 h
16:30 h	Questions and Answers			16:30 h
16:45 h				16:45 h
17:00 h				17:00 h