



Time	ECA – Computerised Systems in Analytical Laboratories	ECA – Validation Approach of Bioassays using Statistical Methods (Workshop Day 1)	ECA – Endotoxin and Pyrogen Testing (Day 1)	ECA - Rapid Microbiological Methods & Mycoplasma Testing	Time	ECA – cGMP Compliance Trends in Analytical Laboratories	ECA – Validation Approach of Bioassays using Statistical Methods (Workshop Day 2)	ECA – Endotoxin and Pyrogen Testing (Day 2)	ECA - Pharmacopoeial Microbiology Update: US & EP Developments	Time
9.00 h	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction	9.00 h	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction	9.00 h
9:15 h	 A Risk-Driven Approach to Data Integrity <i>Niek Janssen, ALTRAN Netherlands</i>				9:15 h	 Challenges for QC Network <i>Dr Sven M. Deutschmann, Roche Diagnostics, Chairman ECA Pharmaceutical Microbiology Group</i>				9:15 h
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10.00 h	Coffee Break <i>(Take advantage of the break to visit the exhibition)</i>				10.00 h	Coffee Break <i>(Take advantage of the break to visit the exhibition)</i>				10.00 h
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10:45 h	Regulatory Requirements Update (EU and US) <i>Peter J. Boogaard, Industrial Lab Automation</i>	Module 1: General Part Introduction	FDA's current Thinking on Endotoxin Testing and LER <i>Dr. Patricia Hughes, FDA</i>	Validation of a Rapid Hybrid Mycoplasma Method <i>Marleen Hoozemans, MSD</i>	10:45 h	Current Experiences from GMP Inspections in QC Labs <i>Leo Leineweber, Technical Auditor / Inspector</i>	Module 3: Development (USP<1032>) Assay design & criteria I	Safety & quality aspects of bioburden contaminations of non-sterile process intermediates <i>Dr. Friedrich von Wintzigerode, Roche</i>	Overview of Current USP Activities <i>Radhakrishna Tirumalai, USP</i>	10:45 h
11.00 h					11.00 h					
11:15 h	Audit Trail Review <i>Niek Janssen, ALTRAN Netherlands</i>	Guidelines	Data Integrity and Human Error Risk Reduction in Endotoxin Testing <i>Matthew Paquette, Charles River Laboratories</i>	Validation of Mycoplasma Testing based on PCR in cellular products <i>Dr. Klára Sochorová, Sotio a.s</i>	11:15 h	Forced Compliance: Turning the FDA Quality Metrics Initiative into Value for Your Lab <i>Dr. Wolf-Christian Gerstner, Geniu</i>	Assay design & criteria II	Latest challenges in the field of endotoxin and pyrogen testing <i>Dr. Johannes Reich, MicroCoat</i>	Overview of revised microbiology related EP chapters <i>Dr. Sébastien Jouette, EDQM</i>	11:15 h
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12.00 h	Lunch Break <i>(Take advantage of the break to visit the exhibition)</i>				12.00 h	Lunch Break <i>(Take advantage of the break to visit the exhibition)</i>				12.00 h
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14:15 h	Competing in a Data-driven World: Transforming Scientific Information into Actionable Insights <i>Peter J. Boogaard, Industrial Lab Automation</i>	Statistics	LER Strategy during endotoxin hold studies <i>Dr. Ruth Daniels, Janssen</i>	Successful implementation of a RMM for mycoplasma testing as release test in Europe <i>Marine Marius, Sanofi Pasteur</i>	14:15 h	Risk-based Approach to Sampling <i>Ulla Bondegaard, Novo Nordisk</i>	Module 4: Validation (USP<1033>) Precision & Accuracy	Regulatory view on MAT <i>Dr. Ingo Spreitzer, PEI – German Federal Institute for Vaccines and Biomedicines</i>	Revisions to <1211> and <1222> Sterility Assurance and Parametric Release <i>Don Singer, GSK/ USP</i>	14:15 h
14.30 h					14.30 h					
14:45 h	Case Study: Entering the Paperless and Digital Era @ UCB BioPharma <i>Eric De Maesschalck, UCB</i>	Module 2: Bioactivity (USP<111>, <1034>, EP 5.3) Calculation I	LER effect shown at a multi-vitamin solution <i>Dr. Michael Rieth, Merck</i>	Implementation of MycoTOOL as Early Warning System and for Lot-Release Testing <i>Dr. Carl-Ulrich Zimmermann, Mycoplasma Biosafety Services GmbH</i>	14:45 h	Case Study: Handling OOT Results <i>Dr. Lars Lueersen, CSL Behring Recombinant Facility AG</i>	Linearity & Range & Specificity	Detection of pyrogens with MAT Cell Set, a highly sensitive MAT based on pooled PBMC <i>Dr. Astrid Visser, Sanquin</i>	The revised EP chapter 5.1.6 related to alternative methods for microbiological QC <i>Dr. Sébastien Jouette, EDQM</i>	14:45 h
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15:15 h	Coffee Break <i>(Take advantage of the break to visit the exhibition)</i>				15:15 h	Coffee Break <i>(Take advantage of the break to visit the exhibition)</i>				15:15 h
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16.00 h	Case Study: Validation of a global Lab Execution System <i>Christophe Girardey, wega Informatik</i>	Calculation II	Microbial Contamination Control that includes an Immunological Context <i>Kevin Williams, BioMerieux</i>	Current Regulatory Expectations for the Microbiological Safety of ATMPs - A Roadmap to Approval <i>Jan-Oliver Karo, PEI – German Federal Institute for Vaccines and Biomedicines</i>	16:00 h	ALCOA Metrics for Data Integrity <i>Dr. Danilo Neri, PQE</i>		Evaluation of the MAT for the safety testing of meningococcal B vaccine Bexsero <i>Dr. Karin Nordgren, NIBSC</i>	Current USP Perspectives on a Rapid Sterility Test <i>Dr. David Roesti, Novartis/USP</i>	16:00 h
16:15 h					16:15 h					
16:30 h	How Informatics will enable better Quality - One Process, One Record, One Solution <i>Robert Lutskus, Lonza</i>	Similarity	Influence of origine and culturing method of Natural Occuring Endotoxins on Endotoxin Masking <i>Peter Cornelis, Toxikon</i>	Validation of a qPCR-based test for Gram positive and Gram negative bacteria <i>Kai Neseemann, Sartorius Lab Instruments GmbH</i>	16:30 h	Update 2017: New challenging ANVI-SA Requirements to Method Validation and Method Transfer (Brazil) <i>Ulla Bondegaard, Novo Nordisk</i>		The Monocyte activation test in routine quality control <i>Dr. Anja Fritsch, Conforma</i>	Current USP perspectives on Objectionable Organisms <i>Dr. Radhakrishna Tirumalai, USP</i>	16:30 h
16:45 h					16:45 h					
17.00 h	Final Discussion	Wrap Up	Final Discussion	Phylogenetic analysis based on 16S rRNA gene sequence for bacterial identification <i>Dr. Sunhee Hong, Charles River Microbial Solutions</i>	17:00 h	Final Discussion		Importance Of Data Integrity When Testing For Endotoxin <i>Robert Porzio, Lonza</i>	Implementation of USP <1115> in the Non-Sterile Pharma Manufacturing Environment <i>Rick Jakober, Perritt Laboratories Inc.</i>	17:00 h
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