PharmaLab 2017

Programme 7 November 2017

Programme 8 November 2017

Analytics | Bioanalytics | Microbiology

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
9.00 h	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction
9:15 h 9.30 h 9:45 h	Congress Key Note A Risk-Driven Approach to Data Integrity *Niek Janssen, ALTRAN Netherlands*			
10.00 h 10:15 h 10.30 h	Coffee Break *(Take advantage of the break to visit the exhibition)*			
10:45 h 11.00 h 11:15 h	Regulatory Requirements Update (EU and US) *Peter J. Boogaard, Industrial Lab Automation*	Module 1: General Part Introduction	FDA's current Thinking on Endotoxin Testing and LER *Dr. Patricia Hughes, FDA*	Validation of a Rapid Hybrid Mycoplasma Method *Marleen Hoozemans, MSD*
11.30 h 11:45 h 12.00 h	Audit Trail Review *Niek Janssen, ALTRAN Netherlands*	Guidelines	Data Integrity and Human Error Risk Reduction in Endotoxin Testing *Matthew Paquette, Charles River Laboratories*	Validation of Mycoplasma Testing based on PCR in cellular products *Dr. Klára Sochorová, Sotio a.s*
12:15 h 12.30 h 12:45 h 13.00 h 13:15 h 13.30 h	Lunch Break *(Take advantage of the break to visit the exhibition)*			
13:45 h 14.00 h 14:15 h	Competing in a Data-driven World: Transforming Scientific Information into Actionable Insights *Peter J. Boogaard, Industrial Lab Automation*	Statistics	LER Strategy during endotoxin hold studies *Dr. Ruth Daniels, Janssen*	Successful implementation of a RMM for mycoplasma testing as release test in Europe *Marine Marius, Sanofi Pasteur*
14.30 h 14:45 h 15.00 h	Case Study: Entering the Paperless and Digital Era @ UCB BioPharma *Eric De Maesschalck, UCB*	Module 2: Bioactivity (USP<111>, <1034>, EP 5.3) Calculation I	LER effect shown at a multi-vitamin solution *Dr. Michael Rieth, Merck*	Implementation of MycoTOOL as Early Warning System and for Lot-Release Testing *Dr. Carl-Ulrich Zimmermann, Mycoplasma Biosafety Services GmbH*
15:15 h 15.30 h 15:45 h	Coffee Break *(Take advantage of the break to visit the exhibition)*			MODA EM Solution and its integration with the Growth Direct system for EM testing *Robert Lutskus, Lonza* *Kham Nguyen, Rapid Micro Biosystems* Coffee Break *(Take advantage of the break to visit the exhibition)*
16.00 h 16:15 h 16.30 h	Case Study: Paperless Lab Project at Vetter *Dr. Margit Braunschläger, Vetter Pharma-Fertigung*	Statistics	Microbial Contamination Control that includes an Immunological Context *Kevin Williams, BioMerieux* Influence of origine and culturing method of Natural Occuring Endotoxins on Endotoxin Masking *Peter Cornelis, Toxikon*	Current Regulatory Expectations for the Microbiological Safety of ATMPs - A Roadmap to Approval *Jan-Oliver Karo, PEI – German Federal Institute for Vaccines and Biomedicines*
16:45 h 17.00 h 17:15 h	From Sample to Decision: Role of Informatics in Laboratory Workflows *Dr: Ruud Vervoort, Waters*	Module 2: Bioactivity (USP<111>, <1034>, EP 5.3) Calculation I	Case Studies on LER from a CMO *Dr. Jan Erik Rau, Lonza*	Validation of a qPCR-based test for Gram positive and Gram negative bacteria *Kai Nesemann, Sartorius-Stedim-Biotech* Phylogenetic analysis based on 16S rRNA gene sequence for bacterial identification *Dr. Sunhee Hong, Charles River Microbial Solutions*
17.30 h 17:45 h 18:00 h	Final Discussion	Wrap Up	Final Discussion	Final Discussion
18.30 h				

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
9.00 h	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction
9:15 h 9.30 h 9:45 h	Congress Key Note Challenges for QC Network *Dr Sven M. Deutschmann, Roche Diagnostics,* *Chairman ECA Pharmaceutical Microbiology Group*			
10.00 h 10:15 h 10.30 h	Coffee Break *(Take advantage of the break to visit the exhibition)*			
10:45 h 11.00 h 11:15 h	Current Experiences from GMP Inspections in QC Labs *Leo Leineweber, Technical Auditor / Inspector*	Module 3: Development (USP<1032>) Assay design & criteria I	Safety & quality aspects of bioburden contaminations of non-sterile process intermediates *Dr. Friedrich von Wintzigerode, Roche*	Overview of Current USP Activities *Radhakrishna Tirumalai, USP* Overview of revised microbiology related EP chapters *Dr. Sébastien Jouette, EDQM*
11.30 h 11:45 h 12.00 h	Forced Compliance: Turning the FDA Quality Metrics Initiative into Value for Your Lab *Dr. Wolf-Christian Gerstner, Geniu*	Assay design & criteria II	Latest challenges in the field of endotoxin and pyrogen testing *Dr. Johannes Reich, MicroCoat*	<1229.x> Series of Sterilization Chapters *Don Singer, GSK/ USP*
12:15 h 12.30 h 12:45 h 13.00 h 13:15 h 13.30 h	Lunch Break *(Take advantage of the break to visit the exhibition)*			
13:45 h 14.00 h 14:15 h	Risk-based Approach to Sampling *Ulla Bondegaard, Novo Nordisk*	Module 4: Validation (USP<1033>) Precision & Accuracy	Regulatory view on MAT *Dr. Ingo Spreitzer, PEI – German Federal Institute for Vaccines and Biomedicines* Comparing key performance aspects of different MAT technologies *Shabnam Solati, MAT Research*	Revisions to <1211> and <1222> Sterility Assurance and Parametric Release *Don Singer,GSK/ USP*
14.30 h 14:45 h 15.00 h	Case Study: Handling OOT Results *Dr. Lars Lueersen, CSL Behring Recombinant Facility AG*	Linearity & Range & Specificity Summary	Detection of pyrogens with MAT Cell Set, a highly sensitive MAT based on pooled PBMC *Dr Astrid Visser, Sanquin*	The revised EP chapter 5.1.6 related to alternative methods for microbiological QC *Dr. Sébastien Jouette, EDQM*
15:15 h 15.30 h 15:45 h	Coffee Break *(Take advantage of the break to visit the exhibition)*	End of Workshop and Coffee Break *(Take advantage of the break to visit the exhibition)*	Coffee Break *(Take advantage of the break to visit the exhibition)*	
16.00 h 16:15 h 16.30 h	ALCOA Metrics for Data Integrity *Dr. Danilo Neri, PQE*		Evaluation of the MAT for the safety testing of meningococcal B vaccine Bexsero *Dr. Karin Nordgren, NIBSC* The Monocyte activation test in routine quality control *Dr. Anja Fritsch, Confarma*	Current USP Perspectives on a Rapid Sterility Test *Dr. David Roesti, Novartis/USP* Current USP perspectives on Objectionable Organisms *Dr. Radhakrishna Tirumalai, USP*
16:45 h 17.00 h 17:15 h	Update 2017: New challenging ANVISA Requirements to Method Validation and Method Transfer (Brazil) *Ulla Bondegaard, Novo Nordisk*		Importance Of Data Integrity When Testing For Endotoxin *Robert Porzio, Lonza*	Implementation of USP <1115> in the Non-Sterile Pharma Manufacturing Environment *Rick Jakober, Perritt Laboratories Inc.*
17.30 h 17:45 h 18:00 h	Final Discussion		Final Discussion	Final Discussion
18.30 h				