PharmaLab 2018 Programme 19 November 2018

Zeit	1st International Mycoplasma qPCR Testing User Day - PharmaLab Pre-Conference Event			Zeit
12.30 h	Welcome and Introduction			12.30 h
12:45 h 13.00 h 13:15 h	Rapid Mycoplasma Testing - A revolution for Quality Control? *Prof. Renate Rosengarten, University of Veterinary Medicine Vienna*			12:45 h 13.00 h 13:15 h
13.30 h 13:45 h 14.00 h 14:15 h	qPCR Mycoplasma Testing at Roche Pharma - method development, validation, and global roll out *Dr Alexander Bartes, Roche Diagnostics*			13.30 h 13:45 h 14.00 h 14:15 h
14.30 h 14:45 h	Coffee Break			14.30 h 14:45 h
15.00 h 15:15 h	External quality assessment of Mycoplasma NATs: regulatory implications? *Dr Micha Nübling, PEI – German Federal Institute for Vaccines and Biomedicines*			15.00 h 15:15 h
15.30 h 15:45 h	Case Study - Implementation of MycoTOOL as a Release Test *Damian Derincovsky, Novartis*			15.30 h 15:45 h
16.00 h 16:15 h	Case Study - Approval of MycoTool Roche qPCR assay by FDA, FAMHP and MHRA, accelerating QC release of an autologous cell therapeutic product *Aurore de Lavareille, Celyad*			16.00 h 16:15 h
16.30 h	Coffee Break			16.30 h
16:45 h 17.00 h 17:15 h	**Parallel Round Table Discussion I** External quality assessment of Mycoplasma NATs: regulatory implications? *Dr Micha Nübling, PEI – German Federal Institute for Vaccines and Biomedicines*	**Parallel Round Table Discussion II** Rapid Mycoplasma Testing for ATMPs *Jessica Wynendale and Kim Baert, Anacura* *Aurore de Lavareille, Celyad*	**Parallel Round Table Discussion III** Implement MycoTOOL on non-validated instrumentation (e.g. other PCR cycler) *Dr Manuela Natoli, Cancer Research UK* *Dr Giusy Canino, Roche Diagnostics*	16:45 h 17.00 h 17:15 h
17.30 h	Summary			17.30 h
17:45 h 18:00h 18:15 h 18:30 h 18:45 h				17:45 h 18:00h 18:15 h 18:30 h 18:45 h
19:00 h	Networking Dinner			19:00 h

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Zeit	ECA - Analytical Procedure Lifecycle Management	ECA - Computerised Systems in Analytical Laboratories	ECA – Endotoxin and Pyrogen Testing (Day 1)	ECA – Rapid Microbiological Methods and Mycoplasma Testing	ECA – Pest Control – from classic trap to digital control
9.00 h	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction
9:15 h 9.30 h 9:45 h	Congress Key Note Alternative Microbiological Methods: AstraZeneca's, MSD's, Johnson&Johnson's and Roche's Global Implementation Roadmap *Miriam Guest, AstraZeneca / Philip Breugelmann, JnJ / Marja Claasen, MSD / Dr Sven M. Deutschmann, Roche*				
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	Overview of the new APLM Guideline and the Workshop *Dr Christopher Burgess, Chairman of the ECA AQCG Board*	Regulatory Requirements *Dr Frank Sielaff, Regional Authority Darmstadt*	Current US Regulation and FDAs Thinking *Jessica Hankins, FDA*	Microbial test automation to support plate incubation and enumeration *Dr Lucile Plourde Owobi, Sanofi Pasteur*	Regulatory Expectations *Dr Rainer Gnibl, Government of Upper Bavaria*
11.30 h 11:45 h 12.00 h	Stage 1: Procedure Design and Developmen *Margarita Sabater, ECA AQCG Board*	The Real Problem - Integration of Existing Instruments to Lab Systems *Andreas Steinle, Roche Diagnostics*	PDA LER Technical Report Scope, Overview, Impact on Industry *Dr Friedrich von Wintzingerode, Roche*	Present and Future of Molecular Microbial Identification – Bridging of Scientific Progress and Practical Application in Regulated Environments *Dr Jörg Peplies, Ribocon*	Pest Elimination – Outside to inside *Petra Barth, formerly AbbVie*
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	Stage 2: Procedure Performance Qualification (PPQ) *Dr Gerd Jilge, ECA AQCG Board*	Case Study: Paperless Laboratory *Florian Göhner, Vetter Pharma Fertigung*	The Evolution of Endotoxin Test *Kevin Williams, bioMerieux*	Bringing Innovation into quality control: How a novel Isothermal mycoplasma assay changes the race *Samuel Zürcher, Certus Molecular Diagnostics*	Possibilities and Limits of Monitoring Systems *Gerhard Karg, B.U.G.S*
14.30 h 14:45 h 15.00 h	Stage 3: Procedure Performance Verification *Silviya Dimitrova, ECA AQCG Board*	Data Integrity for "Dummies" OR Practical Data Integrity *Rob Hahnraths, Bayer*	LER – An alternative Explanation *John Dubczak, Charles River Laboratories*	Rapid detection of bacteria in ATMP prior treatment - validation of a qPCR-based test *Kai Nesemann, Sartorius*	The Pest Management Standard in Pharma - Non-Toxic, zero tolerance and IoT Solutions *Tini Grauwet, SGS*
15:15 h 15.30 h 15:45 h	Coffee Break *(Take advantage of the break to visit the exhibition)*		Pyrogenicity of Food Supplements - Comperative Study of MAT, BET and rFC *Stefan Gärtner, Labor LS*	Understanding the Revised Ph. Eur. Chapter 5.1.6 & how it compares with USP <1223>, PDA Technical Report 33 and Industry Best Practices *Dr Michael Miller, Microbiology Consultants*	GxP compliant Pest Control in Pharmaceutical Laboratories *Martin Tabak, Xendo*
16.00 h 16:15 h	APLM Questionnaire *Dr Christopher Burgess, Chairman of the ECA AQCG Board*	Audit Trail Review *Tejs Kyhl, ALK*	From First Evaluation to a Representative Endotoxin Test: a Story about Masking *Dr Jan Erik Rau, Lonza*	Strategies for Rapid Sterility Testing of Gene and Cell Therapy Products *Dr Michael Miller, Microbiology Consultants*	Case Study: Pest Control Strategy for a New Laboratory Building *Dr Jürgen Balles, Labor LS*
16.30 h 16:45 h	Workshop Critique of a SWOT Analysis of the APLM *All members of the ECA AQCG Board*	Ensuring Data Integrity throughout the Supply Chain *Dr Danilo Neri, PQE*	An approach to LER (Low Endotoxin Recovery) & Update of EP chapter 5.1.10 *Hans Noordergraaf, Abbott*	Modern alternative viable air monitoring in light of the new Annex 1 draft *Dr Frank Panofen, PMS*	Pest Control Strategies for Phytopharmaceutical Manufacturing *Dr Cornelia Bodinet, Schaper & Brümmer*
17.00 h 17:15 h	ICH Concept Paper for Revision of Q2(R2) & Q14 *Dr Christopher Burgess, Chairman of the ECA AQCG Board*	Integrating Devices and Systems in QC (and Production) to enable Data Driven Decisions *Sinead Cowman, Lonza*	Evaluation of new solutions for endotoxin testing for water samples *Evaluation of new solutions for endotoxin testing for water samples*	Using an alternative gene sequence for species-level identification for members of the Burkholderia cepacia complex (Bcc) *Dr Sunhee Hong, Charles River Laboratories*	
17.30 h 17:45 h 18:00 h	Interactive discussion of the ICH implications and Questions *All members of the ECA AQCG Board* Final Discussion	Final Discussion	(1->3)-ß-D-Glucan: A biological response modifier found as a contaminant in pharmaceuticals *Veronika Wills, ACC Europe*	Pulse Light Decontamination - Robotic Tub Decontaminating System *Christophe Riedel, Clearanor* *Mario Fusi, Steriline*	Final Discussion
18.30 h	Social Event for Congress Delegates, Speakers and Exhibitors				

Programme 21 November 2018

Zeit	ECA – QC Compliance Trends in Analytical Laboratories	ECA – Endotoxin and Pyrogen Testing (Day 2)	ECA - Analytical Challenges for Biological Drug Substances and Products
9.00 h	Welcome and Introduction	Welcome and Introduction	Welcome and Introduction
9:15 h 9.30 h 9:45 h	Congress Key Note ECA Analytical Quality Control Group; Aims, Achievements and Activities *Dr Christopher Burgess, Burgess Analytical Consultancy* *Chairman of the ECA QC 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 *Dr. Frank Sielaff, Regional Authority Darmstadt*	Requirements of JP *Yutaka Kikuchi, National Institute of Health Sciences*	The Revised FDA Guidance on the validation of analytical methods *Dr Markus Fido, VelaLabs*
11.30 h 11:45 h 12.00 h	Cleaning Validation of Analytical Equipment *Dieter Brillert, Wiewelhove*	LPS Structure *Martine Caroff, LPS Bioscience* Biophysical interpretation of a systematic comparison of MAT and BET for LER understanding *Wilmar Correa, Research Center Borstel*	What do we need of information from a potency assay? *Dr Jan Amstrup, Novo Nordisk* Challenges in Bioactivity Determination *Dr Ulrike Herbrand, Charles River Laboratories*
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	cGMP Compliance Trends in Analytical Labs *Dr Hiltrud Horn, Horn Pharmaceutical Consulting*	Pyrogen and Endotoxin Testing – Where do we go? *Dr. Ingo Spreitzer, PEI – German Federal Institute for Vaccines and Biomedicines* Monocyte Activation Test for predicting pyrogenic content in vaccines without animal models *Dr Barabara Capecchi, GSK*	The interdependence of Bioassays and Structural characterisation *Klemens Weitenthaler, VelaLabs*
14.30 h 14:45 h 15.00 h	Defining and Managing Raw Data *Tejs Kyhl, ALK-Abelló*	Challenges in applying the Monocyte Activation Test for routine testing in the QC environment *Dr Ruth Röder, Microcoat Biotechnologie*	Single Molecular Detection – A new technology *Dr Alice Hellwig, Microcoat Biotechnologie*
15:15 h 15.30 h 15:45 h	Coffee Break *(Take advantage of the break to visit the exhibition)*		
16.00 h 16:15 h	Current Trends at FDA and future of FDA Inspections (MRA) *Dr Hiltrud Horn, Horn Pharmaceutical Consulting*	Pyrogen detection with the cryopreserved PBMC-based MAT Cell Set: performance, study examples and challenges *Dr Eelo Gitz, Sanquin*	Getting Host Cell DNA analysis up to speed with an automated System *Kyrillos Kyriosoglou, Roche*
16.30 h 16:45 h		Pyrogen detection with the MM6 cell-line: implementation as a routine test *Mathilde Arnault/Dr Anja Fritsch, Merck/ Confarma*	
17.00 h 17:15 h	Training in QC *Ulla Bondegaard, Novo Nordisk*	Healthy human immune cells as pyrogen detection source and advancement of drug release testing *Shabnam Solati, MAT Biotech*	Development and Validation of an Excel workbook for automated sample information management in the analytical lab *Dr Michael Habert, Microcoat Biotechnologie*
17.30 h 17:45 h 18:00 h	Final Discussion	Final Discussion	Final Discussion
18.30 h			