



PharmaLab 2018 Programme 19 November 2018

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

Time	ECA - Analytical Procedure Lifecycle Management	ECA - Computerised Systems in Analytical Laboratories	ECA - Endotoxin and Pyrogen Testing	ECA - Rapid Microbiological Methods and Mycoplasma Testing	ECA - Pest Control - from classic trap to digital control	Zeit	ECA - QC Compliance Trends in Analytical Laboratories	ECA - Endotoxin and Pyrogen Testing	ECA - Analytical Challenges for Biological Drug Substances and Products	Time
9:00 h	 Alternative Microbiological Methods: AstraZeneca's, GSK's, MSD's, Johnson&Johnson's and Roche's Global Implementation Roadmap <i>Miriam Guest, AstraZeneca / Philip Breugelmann, JNJ / Dr Sven M. Deutschmann, Roche</i>					9:00 h	 ECA Analytical Quality Control Group; Aims, Achievements and Activities <i>Dr Christopher Burgess, Burgess Analytical Consultancy Chairman of the ECA QC Group</i>			9:00 h
9:15 h						9:15 h				9:15 h
9:30 h						9:30 h				9:30 h
9:45 h						9:45 h				9:45 h
10:00 h						10:00 h				10:00 h
10:15 h	Coffee Break <i>(Take advantage of the break to visit the exhibition)</i>					10:15 h	Coffee Break <i>(Take advantage of the break to visit the exhibition)</i>			10:15 h
10:30 h						10:30 h				10:30 h
10:45 h	Overview of the new APLM Guideline and the Workshop <i>Dr Christopher Burgess, Chairman of the ECA AQCG Board</i>	Regulatory Requirements <i>Dr Frank Sielaff, Regional Authority Darmstadt</i>	Current US Regulation and FDAs Thinking <i>Jessica Hankins, FDA</i>	Microbial test automation to support plate incubation and enumeration <i>Dr Lucile Plourde Owobi, Sanofi Pasteur</i>	Regulatory Expectations <i>Dr Rainer Gnibl, Government of Upper Bavaria</i>	10:45 h	Current Experiences from GMP Inspections in QC Labs <i>Dr Frank Sielaff, Regional Authority Darmstadt</i>	Requirements of JP <i>Yutaka Kikuchi, National Institute of Health Sciences</i>	The Revised FDA Guidance on the validation of analytical methods <i>Dr Markus Fido, VelaLabs</i>	10:45 h
11:00 h						11:00 h				11:00 h
11:15 h						11:15 h				11:15 h
11:30 h	Stage 1: Procedure Design and Developmen <i>Margarita Sabater, ECA AQCG Board</i>	The Real Problem - Integration of Existing Instruments to Lab Systems <i>Andreas Steinle, Roche Diagnostics</i>	PDA LER Technical Report Scope, Overview, Impact on Industry <i>Dr Friedrich von Wintzingerode, Roche</i>	Present and Future of Molecular Microbial Identification - Bridging of Scientific Progress and Practical Application in Regulated Environments <i>Dr Jörg Peplies, Ribocoon</i>	Pest Elimination - Outside to inside <i>Petra Barth, formerly AbbVie</i>	11:30 h	Cleaning Validation of Analytical Equipment <i>Dieter Brillert, Wiewelhove</i>	LPS Structure <i>Martine Caroff, LPS Bioscience</i>	What do we need of information from a potency assay? <i>Dr Jan Amstrup, Novo Nordisk</i>	11:30 h
11:45 h						11:45 h				11:45 h
12:00 h						12:00 h				12:00 h
12:15 h	Lunch Break <i>(Take advantage of the break to visit the exhibition)</i>					12:15 h	Lunch Break <i>(Take advantage of the break to visit the exhibition)</i>			12:15 h
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13:45 h	Stage 2: Procedure Performance Qualification (PPQ) <i>Dr Gerd Jilge, ECAAQCG Board</i>	Case Study: Paperless Laboratory <i>Florian Göhner, Vetter Pharma Fertigung</i>	The Evolution of Endotoxin Test <i>Kevin Williams, bioMerieux</i>	Bringing Innovation into quality control: How a novel Isothermal mycoplasma assay changes the race <i>Samuel Zürcher, Certus Molecular Diagnostics</i>	Possibilities and Limits of Monitoring Systems <i>Gerhard Karg, B.U.G.S</i>	13:45 h	cGMP Compliance Trends in Analytical Labs <i>Dr Hiltrud Horn, Horn Pharmaceutical Consulting</i>	Pyrogen and Endotoxin Testing - Where do we go? <i>Dr. Ingo Spreitzer, PEI - German Federal Institute for Vaccines and Biomedicines</i>	The interdependence of Bioassays and Structural characterisation <i>Klemens Weithenthaler, VelaLabs</i>	13:45 h
14:00 h						14:00 h				14:00 h
14:15 h						14:15 h				14:15 h
14:30 h	Stage 3: Procedure Performance Verification <i>Silviya Dimitrova, ECAAQCG Board</i>	Data Integrity for "Dummies" OR Practical Data Integrity <i>Rob Hahnraaths, Bayer</i>	Data-based decision-making in Endotoxin Testing <i>Nicola Reid, Charles River Laboratories</i>	Rapid detection of bacteria in ATMP prior treatment - validation of a qPCR-based test <i>Dr Karl Pflanz, Sartorius</i>	The Pest Management Standard in Pharma - Non-toxic, zero tolerance and IoT Solutions <i>Tini Grauwet, SGS</i>	14:30 h	Defining and Managing Raw Data <i>Tejs Kyhl, ALK-Abelló</i>	Monocyte Activation Test for predicting pyrogenic content in vaccines without animal models <i>Dr Barbara Capecci, GSK</i>	Single Molecular Detection - A new technology <i>Dr Alice Hellwig, Microcoat Biotechnologie</i>	14:30 h
14:45 h						14:45 h				14:45 h
15:00 h						15:00 h				15:00 h
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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15:45 h						15:45 h				15:45 h
16:00 h	APLM Questionnaire <i>Dr Christopher Burgess, Chairman of the ECA AQCG Board</i>	Audit Trail Review <i>Tejs Kyhl, ALK</i>	From First Evaluation to a Representative Endotoxin Test: a Story about Masking <i>Dr Jan Erik Rau, Lonza</i>	Strategies for Rapid Sterility Testing of Gene and Cell Therapy Products <i>Dr Michael Miller, Microbiology Consultants</i>	Case Study: Pest Control Strategy for a New Laboratory Building <i>Dr Thomas Meindl, Labor LS</i>	16:00 h	Current Trends at FDA and future of FDA Inspections (MRA) <i>Dr Hiltrud Horn, Horn Pharmaceutical Consulting</i>	Pyrogen detection with the cryopreserved PBMC-based MAT Cell Set: performance, study examples and challenges <i>Dr Eelo Gitz, Sanquin</i>	Getting Host Cell DNA analysis up to speed with an automated System <i>Kyrillos Kyriosoglou, Roche</i>	16:00 h
16:15 h						16:15 h				16:15 h
16:30 h	Workshop Critique of a SWOT Analysis of the APLM <i>All members of the ECA AQCG Board</i>	Ensuring Data Integrity throughout the Supply Chain <i>Dr Danilo Neri, PQE</i>	An approach to LER (Low Endotoxin Recovery) & Update of EP chapter 5.1.10 <i>Hans Noordergraaf, Abbott</i>	Modern alternative viable air monitoring in light of the new Annex 1 draft <i>Dr Frank Panofen, PMS</i>	Pest Control Strategies for Phytopharmaceutical Manufacturing <i>Dr Cornelia Bodinet, Schaper & Brümmer</i>	16:30 h	Training in QC <i>Ulla Bondegaard, Novo Nordisk</i>	Pyrogen detection with the MM6 cell-line: implementation as a routine test <i>Mathilde Arnault/Dr Anja Fritsch, Merck/Confarma</i>	Development and Validation of an Excel workbook for automated sample information management in the analytical lab <i>Dr Sonja Molinaro, Microcoat Biotechnologie</i>	16:30 h
16:45 h						16:45 h				16:45 h
17:00 h	ICH Concept Paper for Revision of Q2(R2) & Q14 <i>Dr Christopher Burgess, Chairman of the ECA AQCG Board</i>	Integrating Devices and Systems in QC (and Production) to enable Data Driven Decisions <i>Sinead Cowman, Lonza</i>	Evaluation of new solutions for endotoxin testing for water samples <i>Marine Marius, Sanofi Pasteur</i>	Using an alternative gene sequence for species-level identification for members of the Burkholderia cepacia complex (Bcc) <i>Dr Sunhee Hong, Charles River Laboratories</i>	Pest Control Strategies for Phytopharmaceutical Manufacturing <i>Dr Cornelia Bodinet, Schaper & Brümmer</i>	17:00 h	Final Discussion	Healthy human immune cells as pyrogen detection source and advancement of drug release testing <i>Shabnam Solati, CTL-MAT</i>	Final Discussion	17:00 h
17:15 h						17:15 h				17:15 h
17:30 h	Interactive discussion of the ICH implications and Questions <i>All members of the ECA AQCG Board</i>	Final Discussion	(1->3)-β-D-Glucan: A biological response modifier found as a contaminant in pharmaceuticals <i>Veronika Wills, ACC Europe</i>	Pulse Light Decontamination - Robotic Tub Decontaminating System <i>Christophe Riedel, Claranor Larissa Ebeling, EbeTech</i>	Final Discussion	17:30 h	Final Discussion	Final Discussion	Final Discussion	17:30 h
17:45 h						17:45 h				17:45 h
18:00 h	Social Event for Congress Delegates, Speakers and Exhibitors					18:00 h	Social Event for Congress Delegates, Speakers and Exhibitors			18:00 h
18:30 h						18:30 h				18:30 h