

Time	2nd International Mycoplasma qPCR Testing User Day - PharmaLab Pre-Conference Event (in Room Titus/Tiberius)	Time
12.30 h	Welcome and Introduction	12.30 h
12:45 h		12:45 h
13.00 h	Rapid Mycoplasma Testing - A revolution for Quality Control? <i>Jan-Oliver Karo, Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines</i>	13.00 h
13:15 h		13:15 h
13.30 h		13.30 h
13:45 h	MycotoOL – Method Development and Generic Validation Strategy <i>Christiana Schnitzler, Boehringer Ingelheim</i>	13:45 h
14.00 h		14.00 h
14:15 h		14:15 h
14.30 h	Coffee Break	14.30 h
14:45 h		14:45 h
15.00 h	Comparative Evaluation of 2 real-time PCR-based Mycoplasma Kits <i>Dr Christie English, Mycoplasma Experience</i>	15.00 h
15:15 h		15:15 h
15.30 h	Automatization of Mycoplasma detection using a new fast and easy to use molecular method <i>Dr Félix A. Montero Julian, bioMerieux</i>	15.30 h
15:45 h		15:45 h
16.00 h	Detection of Mycoplasma contaminations in High Cell Density Cell Cultures <i>Dr Alexandra Müller-Scholz, Sartorius Stedim Biotech</i>	16.00 h
16:15 h		16:15 h
16.30 h	Coffee Break	16.30 h
16:45 h		16:45 h
17.00 h	Mycoplasma detection system and its verification <i>Andrej Steyer, University of Ljubljana (co-author: Dr. Marjanca Blas, Sandoz, Slovenia)</i>	17.00 h
17:15 h		17:15 h
17.30 h	Summary	17.30 h
17:45 h		17:45 h
18:00h		18:00h
18:15 h		18:15 h
18:30 h		18:30 h
18:45 h		18:45 h
19:00 h		19:00 h

Time	ECA – Rapid Microbiological Methods - Apollo -	ECA – Endotoxin and Pyrogen Testing (Day 1) - Bacchus/Marks/Merkur -	ECA - Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Day 1) - Markus/Konstantin -	ECA - Bioanalytics and Bioassays - Challenges for Biological Drug Substances and Products - Titus/Tiberius -	Time				
Room					Room				
9:00 h	 <p><b>New ICH Q14 and ICH Q2 Revision – an industry view</b> Dr. Joachim Ermer, Sanofi-Aventis Deutschland, Head of QC Lifecycle Management Frankfurt Chemistry</p>				9:00 h				
9:15 h					9:15 h				
9:30 h					9:30 h				
9:45 h					9:45 h				
10:00 h	<p><b>Coffee Break</b> (Take advantage of the break to visit the exhibition)</p>				10:00 h				
10:15 h					10:15 h				
10:30 h					10:30 h				
10:45 h	<b>RMM Validation - ECA PMWG /PEI Activities</b> <i>Dr Sven M. Deutschmann, Roche</i>	<b>MAT Task Force</b> <i>Dr Oleg Krut, PEI, German Federal Agency for Vaccines and Biomedicines</i>	<b>Introduction to ECA AQCG</b> <i>Dr Christopher Burgess, Chairman of the ECA AQCG Board</i>	<b>Regulatory Requirements of analytical procedure and validation</b> <i>Dr Norbert Handler, RD&amp;C Research, Development &amp; Consulting</i>	10:45 h				
11:00 h	<b>RMM Validation Guide Food – A Look to the Neighbourhood</b> <i>Barbara Gerten, Merck</i>	<b>Validation of MAT – Regulatory Experiences</b> <i>Dr Ingo Spreitzer, PEI, German Federal Agency for Vaccines and Biomedicines</i>	<b>Overview of USP, ICH revisions &amp; APLM Guideline; Prerequisites and approaches</b> <i>Dr Christopher Burgess, Chairman of the ECA AQCG Board</i>		11:00 h				
11:15 h	<b>Evaluation and Optimization of MALDI-TOF for Identification of Filamentous Fungi</b> <i>Dr Gerold Schwarz, Bruker Daltronics</i> <i>Dr Prasanna Khot, Charles River Laboratories</i>		<b>Introduction to ATP &amp; TMU</b> <i>Phil Borman, GSK</i>		11:15 h				
11:30 h	<b>Development of the Monocyte Activation Test on vaccines containing inherently pyrogenic components</b> <i>Stéphanie Richard, Sanofi Pasteur</i>	<b>How to overcome some of the challenges when analysing Biological Drug Substances and Products</b> <i>Thomas Fechner, Agilent</i>			11:30 h				
11:45 h	<p><b>Lunch Break</b> (Take advantage of the break to visit the exhibition)</p>				11:45 h				
12:00 h					12:00 h				
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13:15 h	<p><b>Coffee Break</b> (Take advantage of the break to visit the exhibition)</p>				13:15 h				
13:30 h					13:30 h				
13:45 h					<b>Validation of the Celsis-based Alternative Sterility Test</b> <i>Jonas van den Berg, Roche Diagnostics</i>	<b>Comparison of a Monocyte Activation Test based on fetal bovine serum and on human AB serum</b> <i>Dr Eelo Gitz, Sanquin Reagents</i>	<b>Data integrity over the Analytical Procedure Lifecycle</b> <i>Dr Bob McDowall, R.D. McDowall Limited</i>	<b>Analytical Quality by Design Through the Lifecycle</b> <i>Patrick Jackson, GSK</i>	13:45 h
14:00 h					<b>Different Products require different Methods - Overview of three rapid Sterility Test Methods</b> <i>Stefan Gärtner, Labor LS</i>	<b>Pyrogenicity associated with heat-inactivated microorganisms isolated in our laboratory from actual samples</b> <i>Dr Anja Fritsch, Confarma</i>	<b>Stage 1: Procedure Design &amp; Development</b> <i>Margarita Sabater, LEO Pharma</i>	<b>State-of-the-Art evaluation of potency &amp; cell-based bioassays</b> <i>Thomas Ludwig, VelaLabs – A Tentamus Company</i>	14:00 h
14:15 h	<b>A Practical Guide on how to demonstrate a significant return of investment when implementing Real-Time RMMs</b> <i>Dr Michael Miller, Microbiology Consultants</i>	<b>Proficiency Test Program for MAT</b> <i>Dr Ruth Röder, Microcoat Biotechnologie</i>	<b>Process for automatization of a Bioassay</b> <i>Dr Marcus Gutmann, Microcoat Biotechnologie</i>	14:15 h					
14:30 h	<p><b>Coffee Break</b> (Take advantage of the break to visit the exhibition)</p>				14:30 h				
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15:15 h	<p><b>Coffee Break</b> (Take advantage of the break to visit the exhibition)</p>				15:15 h				
15:30 h					15:30 h				
15:45 h					15:45 h				
16:00 h					<b>PCR - Rodent Parvo Virus Testing</b> <i>Dr Alexander Bartes, Roche Diagnostics</i>	<b>MAT implementation: from validation to use in routine in a GMP QC Lab</b> <i>Chiara Celli, Merck</i>	<b>Stage 1 in Practice</b> <i>Phil Borman, GSK</i>	<b>Application of fast and non-destructive analysis techniques in quality and in-process control</b> <i>Prof. Dr. Hartwig Schulz, formerly Julius Kühn-Institut (JKI)</i>	16:00 h
16:15 h	<b>Rapid detection of bacteria and fungi in ATMP prior treatment - Validation of a Real-time PCR-based test</b> <i>Kai Neseemann, Sartorius Labs Instruments</i>	<b>MAT - Ready for GMP Routine?</b> <i>Stefan Gärtner, Labor LS</i>	<b>Analytical Control Strategy Workshop</b> <i>Dr Gerd Jilge, Boehringer Ingelheim</i> <i>Margarita Sabater, LEO Pharma</i>	<b>Lectin Array – a novel technology for investigation of pharmaceutical products</b> <i>Markus Roucka, VelaLabs – A Tentamus Company</i>	16:15 h				
16:30 h		<b>The Monocyte Activation Test: Validation &amp; Analysis</b> <i>Katrin Pauls, Lonza</i>			16:30 h				
16:45 h	<p><b>Discussion</b></p>				16:45 h				
17:00 h					<b>Endotoxin, ten misconceptions around detection and control</b> <i>Kevin Williams, bioMérieux</i>	<b>Discussion</b>	<b>Discussion</b>	17:00 h	
17:15 h					17:15 h				
17:30 h	<p><b>Social Event for Congress Delegates, Speakers and Exhibitors</b></p>				17:30 h				
17:45 h					17:45 h				
18:00 h					18:00 h				
18:30 h					18:30 h				

Time	ECA – Microbiological Real Time Counting and Testing - Apollo -	ECA – Endotoxin and Pyrogen Testing (Day 2) - Bacchus/Marks/Merkur -	ECA - Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Day 2) - Markus/Konstantin -	ECA - Testing and Analytics of Cells, Tissues and ATMP - Titus/Tiberius -	Time
Room					Room
9:00 h	<div style="text-align: center;">  <p><b>Laboratory Services - from Outsourcing to a strategic partnership</b> <i>Dr Jürgen Balles, Dr Thomas Meindl and Ingo Grimm, Labor LS</i></p> </div>				9:00 h
9:15 h					9:15 h
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9:45 h					9:45 h
10:00 h	<div style="text-align: center;"> <p><b>Coffee Break</b> <i>(Take advantage of the break to visit the exhibition)</i></p> </div>				10:00 h
10:15 h					10:15 h
10:30 h					10:30 h
10:45 h	Different Measurement Methods/Systems - Pros and Cons <i>Annette Kunz, CSL</i>	Current development in Endotoxin and Pyrogen Testing – FDA Point of View <i>Dr Jessica Hankins, U.S. Food and Drug Administration</i>	<div style="text-align: center;"> <p><b>Stage 2: Procedure Performance Qualification: Problems and issues?</b> <i>Dr Gerd Jilge, Boehringer Ingelheim</i></p> </div>	Suitability of the test method for the test 'Microbiological Examination of cell-based Preparations' according to EP 2.6.27 <i>Dr Jörg Degen, Eurofins</i>	10:45 h
11:00 h	11:00 h				
11:15 h	11:15 h				
11:30 h	Implementation of a Microbial Detection Analyzer For Real-Time Monitoring of Microbial Contamination for Purified Water <i>Natascha Staub, Mibelle</i>	Putting Patient Safety First, View from the other side <i>Milanka Setina, Medicines and Medical Devices Agency of Serbia</i>	<div style="text-align: center;"> <p><b>Stage 3: Procedure Performance Verification</b> <i>Silviya Dimitrova, Teva</i></p> </div>	RMM for sterility testing of an oncology cell therapy product using ATP bioluminescence <i>Dr Michael Miller, Microbiology Consultants LLC</i>	11:30 h
11:45 h	11:45 h				
12:00 h	Biofluorescent Particle Counting (BFPC) for continuous monitoring in aseptic manufacturing <i>Dr Marja Claassen-Willemse, MSD</i>	LER Hold-Time studies <i>Anders Thorn, Novo Nordisk</i>			12:00 h
12:15 h	<div style="text-align: center;"> <p><b>Lunch Break</b> <i>(Take advantage of the break to visit the exhibition)</i></p> </div>				12:15 h
12:30 h					12:30 h
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13:30 h					13:30 h
13:45 h	Evaluation of the Scanstation 100 system for the automated incubation and analysis of pharmaceutical environmental monitoring samples using standard Petri plates <i>Diarmaid O'Riordan, Pfizer</i>	Endotoxin and Pyrogen detection of LER Samples <i>Paul Negwer, PEI, German Federal Agency for Vaccines and Biomedicines</i>	<div style="text-align: center;"> <p><b>Approaches to the transfer of Analytical Procedures</b> <i>Ulla Bondegaard, Novo Nordisk</i></p> </div>	Validation of a flow cytometry based quantitative lymphocyte immunophenotyping method to qualify cellular products for immune effector cells processing <i>Dr Claude Lemarié, Center for Cell Therapy Marseille</i>	13:45 h
14:00 h		14:00 h			
14:15 h	Case Study: Using continuous Real-Time intrinsic Fluorescence Techniques for EM in Isolators <i>Dr Michael Miller, Microbiology Consultants</i>	Endotoxins – Requirements of CP <i>Dr Qing He, Chinese National Institutes for Food and Drug Control</i>	<div style="text-align: center;"> <p><b>Stage 3: Procedure Performance Verification</b> <i>Silviya Dimitrova, Teva</i></p> </div>	Microbiological testing of Cell Based Medicinal Products using automated growth based methods <i>Dr Antonio Rodríguez Acosta, Andalusian Initiative for Advanced Therapies-Biomedicines Institute (IBIMA)</i>	14:15 h
14:30 h		14:30 h			
14:45 h		14:45 h			
15:00 h		Practical Insights in BET <i>Dr Jelena Novakovic, Galenika</i>		Challenges for cell-based medicinal products <i>Dr Markus Fido, VelaLabs - A Tentamus Company</i>	15:00 h
15:15 h	<div style="text-align: center;"> <p><b>Coffee Break</b> <i>(Take advantage of the break to visit the exhibition)</i></p> </div>				15:15 h
15:30 h					15:30 h
15:45 h					15:45 h
16:00 h					16:00 h
16:15 h	IMD-W "In-line system for purified water systems" and other devices for rapid water bioburden analyses <i>Dr Sven Deutschmann, Roche Diagnostics</i>	A Global Perspective for Quantifying All Endotoxins within Pharmaceutical Water Systems <i>Nicola Reid, CRL</i>	<div style="text-align: center;"> <p><b>Experiences in the ongoing verification of Analytical Procedures</b> <i>Ulla Bondegaard, Novo Nordisk</i></p> </div>	Filling the gap – from bench to bedside <i>Dr Claudia Papewalis, Valicare</i>	16:15 h
16:30 h	16:30 h				
16:45 h	Calculating alert levels and trending of microbiological data <i>Dr David Roesti, Novartis Stein Pharma</i>	Evaluation of rFC for product testing <i>Marine Marius, Sanofi Pasteur</i>	<div style="text-align: center;"> <p><b>"What happens with Legacy Products?" Workshop</b> <i>Silviya Dimitrova, Teva</i> <i>Dr Christopher Burgess, Chairman of the ECA AQCG Board</i></p> </div>	Cell Based Potency Assays: Analytical Considerations from a Regulatory Perspective <i>Dr Sigrid Roosendaal, Quality RA</i>	16:45 h
17:00 h	17:00 h				
17:15 h	17:15 h				
17:30 h	New Generation of Solid Phase Cytometry for Rapid Detection of Microbiological Contaminants in Water Samples <i>Joseph Pierquin, Redberry</i>	Application of a recombinant three-factor chromogenic reagent, PyroSmart, for bacterial endotoxins test <i>Dr Hikaru Mizumura, Seikagaku</i> <i>Veronika Wills, ACC</i>	<div style="text-align: center;"> <p><b>Discussion</b></p> </div>	Discussion	17:30 h
17:45 h	17:45 h				
18:00 h	18:00 h				
17:45 h	Discussion	4 Factors affecting the recovery of endotoxin <i>Dr Michael Kracklauer, Microcoat</i> <i>Peter Kitschmann, Bausch &amp; Stroebel</i>			17:45 h
18:00 h					18:00 h