2nd International Mycoplasma qPCR Testing User Day - PharmaLab Pre-Konferenz-Veranstaltung

Zeit		Zeit
12.30 h	Welcome and Introduction	12.30 h
12:45 h	Rapid Mycoplasma Testing - A revolution for Quality Control? *Jan-Oliver Karo, Paul-Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines*	12:45 h
13.00 h		13.00 h
13:15 h		13:15 h
13.30 h	MycoTOOL – Method Development and Generic Validation Strategy *Christiana Schnitzler, Boehringer Ingelheim*	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		14.30 h
14:45 h	Comparative Evaluation of 2 real-time PCR-based Mycoplasma Kits *Dr Christie English, Mycoplasma Experience*	14:45 h
15.00 h		15.00 h
15:15 h	Automatization of Mycoplasma detection using a new fast and easy to use molecular method *Dr Félix A. Montero Julian, bioMerieux*	15:15 h
15.30 h		15.30 h
15:45 h	Comparability Study of a Real-time PCR-based Mycoplasma detection kit with the culture method according to EP 2.6.7 *Aurore de Lavareille, Celyad*	15:45 h
16.00 h		16.00 h
16:15 h	Coffee Break	16:15 h
16.30 h		16.30 h
16:45 h	Mycoplasma detection system and its verification *Andrej Steyer, University of Ljubljana (co-author: Dr. Marjanca Blas, Sandoz, Slovenia)*	16:45 h
17.00 h		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

PharmaLab 2019 Programm 12. November 2019

Track 1: QC Analytics | Track 2: Endoxtin and Pyrogen Testing | Track 3: QC Microbiology | Track 4: QC Bioanalytic/Biotech | Track 5: QK Trends

Zeit	Qualitätskontrolle - Aktuelle Trends im pharmazeutischen Labor	ECA - Rapid Microbiological Methods	ECA – Endotoxin and Pyrogen Testing (Tag 1)	ECA - Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Tag 1)	ECA - Bioanalytics and Bioassays - Challenges for Biological Drug Substances and Products	Zeit
9:15 h 9.30 h 9:45 h	**New ICH Q14 and ICH Q2 Revision – an industry view** Congress Key Note *Dr. Joachim Ermer, Sanofi-Aventis Deutschland, Head of QC Lifecycle Management Frankfurt Chemistry*					9:15 h 9.30 h 9:45 h
10.00 h 10:15 h 10.30 h	Kaffeepause *(Nutzen Sie die Pause zu einem Besuch der Fachmesse)*	Coffee Break *(Take advantage of the break to visit the exhibition)*				10.00 h 10:15 h 10.30 h
10:45 h 11.00 h 11:15 h	Erwartungen eines GMP-Inspektors an QK-Labore *Dr. Jörg Petersohn, Landesverwaltungsamt Sachsen-Anhalt*	RMM Validation - ECA PMWG /PEI Activities *Dr Sven M. Deutschmann, Roche* RMM Validation Guide Food – A Look to the Neighbourhood *Barbara Gerten, Merck*	MAT Task Force *Dr Sven Deutschmann, Roche Diagnostics* Validation of MAT – Regulatory Experiences *Dr Ingo Spreitzer, PEI, German Federal Agency for Vaccines and Biomedicines*	Introduction to ECA AQCG *Dr Christopher Burgess, Chairman of the ECA AQCG Board* Overview of USP, ICH revisions & APLM Guideline; Prerequisites and approaches *Dr Christopher Burgess, Chairman of the ECA AQCG Board*	Regulatory Requirements of analytical procedure and validation *Dr Norbert Handler, RD&C Research, Development & Consulting*	10:45 h 11.00 h 11:15 h
11.30 h 11:45 h 12.00 h	LIMS in der Mikrobiologie *Elias Michlig, Lonza*	Evaluation and Optimization of MALDI-TOF for Identification of Filamentous Fungi *Dr Gerold Schwarz, Bruker Daltronics* *Dr Prasanna Khot, Charles River Laboratories*	Development of the Monocyte Activation Test on vaccines containing inherently pyrogenic components *Stéphanie Richard, Sanofi Pasteur*	Introduction to ATP & TMU *Phil Borman, GSK*	How to overcome some of the challenges when analysing Biological Drug Substances and Products *Thomas Fechner, Agilent*	11.30 h 11:45 h 12.00 h
12:15 h 12.30 h 12:45 h 13.00 h 13:15 h 13.30 h	Mittagspause mit Anwendungsdemonstrationen *(Nutzen Sie die Pause zu einem Besuch der Fachmesse)*	Lunch Break *(Take advantage of the break to visit the exhibition)*				12:15 h 12.30 h 12:45 h 13.00 h 13:15 h 13.30 h
13:45 h 14.00 h	Gestresste Mikroorganismen für Validierungen und Verifizierungen *Barbara Gerten, Merck*	Validation of the Celsis-based Alternative Sterility Test *Jonas van den Berg, Roche Diagnostics*	Comparison of a Monocyte Activation Test based on fetal bovine serum and on human AB serum *Dr Eelo Gitz, Sanquin Reagents*	Data integrity over the Analytical Procedure Lifecycle *Bob McDowall, R.D. McDowall Limited*	Analytical Quality by Design Through the Lifecycle *Patrick Jackson, GSK*	13:45 h 14.00 h
14:15 h 14.30 h	Moderne mikrobiologische Methoden und Testkonzepte – Trends & Erwartungen für ATMPs *Jan-Oliver Karo, Paul-Ehrlich Institut (PEI)*	Rapid Micro instruments: secure implementation to LIMS for data security *Kham Nguyen, Rapid Micro Biosystems*	Pyrogenicity associated with heat-inactivated microorganisms isolated in our laboratory from actual samples *Dr Anja Fritsch, Confarma*		State-of-the-Art evaluation of potency & cell-based bioassays *Thomas Ludwig, VelaLabs – A Tentamus Company*	14:15 h 14.30 h
14:45 h 15.00 h	Der risikobasierte Ansatz erlaubt den Herstellern von ATMPs mehr Flexibilität und fordert gleichzeitig vermehrte Qualitätskontrollen *Dr. Hans-Georg Eckert, Valicare*	A Practical Guide on how to demonstrate a significant return of investement when implementing Real-Time RMMs *Dr Michael Miller, Microbiology Consultants*	Proficiency Test Program for MAT *Dr Ruth Röder, Microcoat Biotechnologie*	Stage 1: Procedure Design & Development *Margarita Sabater, Dako Denmark, an Agilent Technologies Company*	Process for automatization of a Bioassay *Dr Marcus Gutmann, Microcoat Biotechnologie*	14:45 h 15.00 h
15:15 h 15.30 h 15:45 h	Kaffeepause mit Anwendungsdemonstrationen *(Nutzen Sie die Pause zu einem Besuch der Fachmesse)*	Coffee Break *(Take advantage of the break to visit the exhibition)*				15:15 h 15.30 h 15:45 h
16.00 h 16:15 h 16.30 h	Neue Standorte und Technologie Transfers - Ein Praxisbeispiel (anhand der QC-Laboratorien) *Dr. Lars Lueersen, CSL*	PCR - Rodent Parvo Virus Testing *Dr Alexander Bartes, Roche Diagnostics*	MAT implementation: from validation to use in routine in a GMP QC Lab *Chiara Celli, Merck* MAT - Ready for GMP Routine? *Stefan Gärtner, Labor LS*	Stage 1 in Practice *Phil Borman, GSK*	Application of fast and non-destructive analysis techniques in quality and in-process control *Prof. Dr. Hartwig Schulz, formerly Julius Kühn-Institut (JKI)*	16.00 h 16:15 h 16.30 h
16:45 h 17.00 h 17:15 h	Digitalisierung im Labor: Industrie 4.0-Trends die das Labor verändern können *Dr. Christian Gerstner, Geniu*	Rapid detection of bacteria and fungi in ATMP prior treatment - Validation of a Real-time PCR-based test *Kai Nesemann, Sartorius Labs Instruments*	The Monocyte Activation Test: Validation & Analysis *Katrin Pauls, Lonza*	Analytical Control Strategy Workshop *Dr Gerd Jilge, Boehringer Ingelheim* *Margarita Sabater, Dako Denmark, an Agilent Technologies Company*	Lectin Array – a novel technology for investigation of pharmaceutical products *Markus Roucka, VelaLabs – A Tentamus Company*	16:45 h 17.00 h 17:15 h
17.30 h 17:45 h 18:00 h	Diskussion	Discussion	Endotoxin, ten misconceptions around detection and control *Kevin Williams, bioMérieux*	Discussion	Discussion	17.30 h 17:45 h 18:00 h
18.30 h	Social Event für Kongress-Teilnehmer, Referenten und Aussteller					18.30 h

PharmaLab 2019 Programm 13. November 2019

Track 1: QC Analytics | Track 2: Endoxtin and Pyrogen Testing | Track 3: QC Microbiology | Track 4: QC Bioanalytic/Biotech | Track 5: QK Trends

Zeit	Qualitätskontrolle - Aktuelle Trends im pharmazeutischen Labor (Tag 2)	ECA – Microbiological Real Time Counting and Testing	ECA – Endotoxin and Pyrogen Testing (Tag 2)	ECA - Analytical Procedure Lifecycle Management / Revisions to ICH Q2 & the proposed Q14 (Tag 2)	ECA - Testing and Analytics of Cells, Tissues and ATMP	Zeit
9:15 h 9.30 h 9:45 h	Congress Key Note **Laboratory Services - from Outsourcing to a strategic partnership** *Dr Jürgen Balles, Dr Thomas Meindl and Ingo Grimm, Labor LS*					9:15 h 9.30 h 9:45 h
10.00 h 10:15 h 10.30 h	Kaffeepause *(Nutzen Sie die Pause zu einem Besuch der Fachmesse)*	Coffee Break *(Take advantage of the break to visit the exhibition)*				10.00 h 10:15 h 10.30 h
10:45 h 11.00 h 11:15 h	GMP Inspektionen im analytischen Labor - die richtige Vorbereitung *Dr. Christina Jann-Gröllert, VelaLabs - A Tentamus Company*	Different Measurement Methods/Systems - Pros and Cons *Annette Kunz, CSL*	Current development in Endotoxin and Pyrogen Testing – FDA Point of View *Dr Jessica Hankins, U.S. Food and Drug Administration*	Stage 2: Procedure Performance Qualification: Problems and issues? *Dr Gerd Jilge, Boehringer Ingelheim*	Suitability of the test method for the test 'Microbiological Examination of cell-based Preparations' according to EP 2.6.27 *Dr Jörg Degen, Eurofins*	10:45 h 11.00 h 11:15 h
11.30 h 11:45 h 12.00 h	Data Integrity und Audit Trail *Dr. Serap Acikgöz, Diapharm*	Implementation of a Microbial Detection Analyzer For Real-Time Monitoring of Microbial Contamination for Purified Water *Natascha Staub, Mibelle* Biofluorescent Particle Counting (BFPC) for continuousmo-nitoring in aseptic manufacturing *Dr Marja Claassen-Willemse, MSD*	Putting Patient Safety First, View from the other side *Milanka Setina, Medicines and Medical Devices Agency of Serbia* LER Hold-Time studies *Anders Thorn, Novo Nordisk*		RMM for sterility testing of an oncology cell therapy product using ATP bioluminescence *Dr Michael Miller, Microbiology Consultants LLC*	11.30 h 11:45 h 12.00 h
12:15 h 12.30 h 12:45 h 13.00 h 13:15 h 13.30 h	Mittagspause mit Anwendungsdemonstrationen *(Nutzen Sie die Pause zu einem Besuch der Fachmesse)*	Lunch Break *(Take advantage of the break to visit the exhibition)*				12:15 h 12.30 h 12:45 h 13.00 h 13:15 h 13.30 h
13:45 h 14.00 h 14:15 h 14.30 h 14:45 h 15.00 h	Die Mikro-LC - eine nachhaltige Methode in der Routineana-lytik *Dr. Kerstin Hermuth-Kleinschmidt, NIUB* *Lars Reinders, IUTA* Erweiterung / Neubau eins GMP-Labor mit Fokus Auftrags-analytik *Dr. Jochen Kolb, BLS* Laborkosten - optimieren statt reduzieren *Dr. Jörg Neumann, JNB*	Evaluation of the Scanstation 100 system for the automated incubation and analysis of pharmaceutical environmental monitoring samples using standard Petri plates *Diarmaid O'Riordan, Pfizer* Case Study: Using continuous Real-Time intrinsic Fluores-cence Techniques for EM in Isolators *Dr Michael Miller, Microbiology Consultants*	Endotoxin and Pyrogen detection of LER Samples *Paul Negwer, PEI, German Federal Agency for Vaccines and Biomedicines* Endotoxins – Requirements of CP *Dr Qing He, Chinese National Institutes for Food and Drug Control* Practical Insights in BET *Dr Jelena Novakovic, Galenika*	Approaches to the transfer of Analytical Procedures *Ulla Bondegaard, Novo Nordisk* Stage 3: Procedure Performance Verification *Silviya Dimitrova, Teva*	Validation of a flow cytometry based quantitative lympho-cyte immunophenotyping method to qualify cellular products for immune effector cells processing *Dr Claude Lemarié, Center for Cell Therapy Marseille* Microbiological testing of Cell Based Medicinal Products using automated growth based methods *Dr Antonio Rodríguez Acosta, Andalusian Initiative for Advanced Therapies* Challenges for cell-based medicinal products *Dr Ilona Kalaszczyska, Medical University of Warsaw*	13:45 h 14.00 h 14:15 h 14.30 h 14:45 h 15.00 h
15:15 h 15.30 h 15:45 h	Kaffeepause mit Anwendungsdemonstrationen *(Nutzen Sie die Pause zu einem Besuch der Fachmesse)*	Coffee Break *(Take advantage of the break to visit the exhibition)*				15:15 h 15.30 h 15:45 h
16.00 h 16:15 h 16.30 h	Bestimmung elementarer Verunreinigungen in pharmazeu-tischen Rohstoffen gemäß ICH Q3D *Franz Keller, Labor LS*	IMD-W "In-line system for purified water systems" and other decvices for rapid water bioburden analyses *Dr Sven Deutschmann, Roche Diagnostics*	A Global Perspective for Quantifying All Endotoxins within Pharmaceutical Water Systems *Nicola Reid, CRL*	Experiences in the ongoing verification of Analytical Proceduresn *Ulla Bondegaard, Novo Nordisk*	Filling the gap – from bench to bedside *Dr Claudia Papewalis, Valicare*	16.00 h 16:15 h 16.30 h
16:45 h 17.00 h 17:15 h	Neubau eines GMP Labors - Konzeption, Planung, Umset-zung sowie GMP-konformer Umzug *Dr Christian Flügge, Eurofins BioPharma Product Testing*	Calculating alert levels and trending of microbiological data *Dr David Roesti, Novartis Stein Pharma* New Generation of Solid Phase Cytometry for Rapid Detection of Microbiological Contaminants in Water Samples *Joseph Pierquin, Redberry*	Evaluation of rFC for product testing *Marine Marius, Sanofi Pasteur* Application of a recombinant three-factor chromogenic reagent, PyroSmart, for bacterial endotoxins test *Dr Hikaru Mizumura, Seikagak* *Veronika Wills, ACC*	"What happens with Legacy Products?" Workshop *Silviya Dimitrova, Teva* *Dr Christopher Burgess, Burgess Analytical Consultancy*	Cell Based Potency Assays: Analytical Considerations from a Regulatory Perspective *Dr Sigrid Roosendaal, Quality RA*	16:45 h 17.00 h 17:15 h
17.30 h 17:45 h 18:00 h	Diskussion	Discussion	4 Factors affecting the recovery of endotoxin *Dr Johannes Reich, Microcoat*	Discussion	Discussion	17.30 h 17:45 h 18:00 h