Zeit	1st International Mycoplasma qPCR Testing User Day - PharmaLab Pre-Konferenz-Veranstaltung			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	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	Coffee Break			14:15 h 14.30 h
14:45 h 15.00 h	External quality assessment of Mycoplasma NATs: regulatory implications? *Dr Micha Nübling, PEI – German Federal Institute for Vaccines and Biomedicines*			14:45 h 15.00 h
15:15 h 15.30 h	Case Study - Implementation of MycoTOOL as a Release Test *Damian Derincovsky, Novartis*			15:15 h 15.30 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 *Aurore de Lavareille, Celyad*			15:45 h 16.00 h
16:15 h 16.30 h	Coffee Break			16:15 h 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 *Jessika Wynendaele 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

PharmaLab 2018 Programm 20. November 2018

Analytik | Bioanalytik | Mikrobiologie

Zeit	Methodenvalidierung bei Wirk- und Hilfsstoffen	Mikrobiologische Nährmedien – von der Auswahl bis zur Qualifizierung	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
9.00 h 9:15 h 9.30 h 9:45 h	Congress Key Note Alternative Microbiological Methods: AstraZeneca's, GSK's, Johnson&Johnson's, MSD's and Roche's Global Implementation Roadmap *Miriam Guest, AstraZeneca / Philip Breugelmann, JnJ / Dr Sven M. Deutschmann, Roche*							9.00 h 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	Regulatorische Anforderungen an die Validierung analytischer Methoden *Julia Eichhorn, HHAC Labor Dr. Heusler*	Regulatorische Vorgaben zu den Nährmedien: Eine Übersicht *Barbara Gerten, Merck*	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*	10:45 h 11.00 h 11:15 h
11.30 h 11:45 h 12.00 h	„Case Studies“ aus der Analytik: Chloranisole in Glibenclamid / Flüchtige Verunreinigungen in Ethanol / Gehalt und Reinheit von Xylitol *Dr. Michael Bertz, Berlin Chemie*	Die Tücken bei der Eigenherstellung von Nährmedien *Dr. Juliane Hornung, Labor LS*	Stage 1: Procedure Design and Development *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*	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	SO analysiert man heute! Neue Ansätze der Rohstoff-, Prozess- und Endproduktkontrolle mit modernster NIR- und Raman-Technologie *Dr. Sebastian Ziewer-Arndts, analyticon instruments*	Die Tücken des Wachstumstests *Dr. Marcel Goverde, MGP*	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*	13:45 h 14.00 h 14:15 h
14.30 h 14:45 h 15.00 h	Methodenvalidierung – welche Daten erwartet die FDA? *Dr. Heinz Sarter, Waldbrunn*	Nährmediumherstellung für Media Fills *Hartmut Schmidt, CSL*	Stage 3: Procedure Performance Verification *Silviya Dimitrova, ECA AQCG Board*	Data Integrity for “Dummies” OR Practical Data Integrity *Rob Hahnraths, Bayer*	Data-based decision-making in Endotoxin Testing *Nicola Reid, Charles River Laboratories*	Rapid detection of bacteria in ATMP prior treatment - validation of a qPCR-based test *Dr Karl Pflanz, Sartorius*	The Pest Management Standard in Pharma - Non-Toxic, zero tolerance and IoT Solutions *Tini Grauwet, SGS*	14:15 h 14.30 h 14:45 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)*		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*	15.00 h 15:15 h 15.30 h 15:45 h
16.00 h 16:15 h 16.30 h	Stichprobenpläne für Wirk- und Hilfsstoffe *Philip Lienbacher, Shire*	Wie definiere ich meine Hausisolate & wie kann ich diese Standardisieren für den GPT *Dr. Hans Joachim Anders, Novartis*	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 Thomas Meindl, Labor LS*	16.00 h 16:15 h 16.30 h
16:45 h 17.00 h 17:15 h	Quantifizierung von Polysorbaten und deren Abbauprodukten in proteinhaltigen Lösungen *Alexander Doppelreiter, Vela Labs*	Enthemmer in Abklatschplatten - Anspruch und Wirklichkeit *Dr. Ulrich Eikmanns, PMM*	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*	16:45 h 17.00 h 17:15 h
17.30 h 17:45 h 18:00 h	Abschlussdiskussion	How far the human eye is accurate in small events detection into Environmental Monitoring culture media? *Laurent Leblanc, bioMerieux* Abschlussdiskussion	ICH Concept Paper for Revision of Q2(R2) & Q14 *Dr Christopher Burgess, Chairman of the ECA AQCG Board* Interactive discussion of the ICH implications and Questions *All members of the ECA AQCG Board* Final Discussion	Integrating Devices and Systems in QC (and Production) to enable Data Driven Decisions *Sinead Cowman, Lonza* Final Discussion	Evaluation of new solutions for endotoxin testing for water samples *Marine Marius, Sanofi Pasteur* (1->3)-ß-D-Glucan: A biological response modifier found as a contaminant in pharmaceuticals *Veronika Wills, ACC Europe*	Using an alternative gene sequence for species-level identification for members of the Burkholderia cepacia complex (Bcc) *Dr Sunhee Hong, Charles River Laboratories* Pulse Light Decontamination - Robotic Tub Decontaminating System *Christophe Riedel, Clearanor* *Larissa Ebeling, EbeTech*	Final Discussion	17:15 h 17.30 h 17:45 h 18:00 h
18.30 h	Social Event für Kongress-Teilnehmer, Referenten und Aussteller							18.30 h

PharmaLab 2018 Programm 21. November 2018

Analytik | Bioanalytik | Mikrobiologie

Zeit	Optimierung von Laborprozessen	Anforderungen an ATMP/ Neuartige Therapien	ECA – QC Compliance Trends in Analytical Laboratories	ECA – Endotoxin and Pyrogen Testing	ECA - Analytical Challenges for Biological Drug Substances and Products	Zeit
9.00 h 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*					9.00 h 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	Der Weg zum Lean Management in der Qualitätskontrolle: Erfahrungsbericht eines Change Prozesses *Sabrina Killat, Biologische Heilmittel Heel*	Regulatorische Anforderungen für Neuartige Therapien (ATMP) *Dr. Christoph Mück, AGES*	Current Experiences from GMP Inspections in QC Labs *Dr. Frank Sielaff, Regional Authority Darmstadt*	Requirements of JP *Yutaka Kikuchi, National Institute of Health Sciences* LPS Structure *Martine Caroff, LPS Bioscience*	The Revised FDA Guidance on the validation of analytical methods *Dr Markus Fido, VelaLabs* What do we need of information from a potency assay? *Dr Jan Amstrup, Novo Nordisk*	10:45 h 11.00 h 11:15 h
11.30 h 11:45 h 12.00 h	Optimierung von Laborprozessen durch effektive und effiziente Projektarbeit im Dienstleistungssektor *Jennifer Mayrhofer, VelaLabs*	GMP Leitfaden für ATMP *Dr. Gabriele Wanninger, Regierung von Oberbayern*	Cleaning Validation of Analytical Equipment *Dieter Brillert, Wiewelhove*	Biophysical interpretation of a systematic comparison of MAT and BET for LER understanding *Wilmar Correa, Research Center Borstel*	Challenges in Bioactivity Determination *Dr Ulrike Herbrand, Charles River Laboratories*	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 *(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	Digitalisierung im Labor - Industrie 4.0 - Trends die das Labor verändern können *Dr. Christian Gerstner, Geniu*	Fallstudie: Herstellung von ATMP für Klinische Phase I/II im Universitären Maßstab *Dr Andrea Hauser, José CarrerasZentrum für somatische Zelltherapie, Chair ECA ATMP Working Group*	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*	13:45 h 14.00 h 14:15 h
14.30 h 14:45 h 15.00 h	Nutzen von Knowledge Management für Ihr Labor *Dr Lars Luerssen, CSL Behring Recombinant*	QK-Testprofile und Freigabe-Strategien für "extremporale ATMP" *Stéphane Gumy, PMS Process Management System*	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*	14.30 h 14:45 h 15.00 h
15:15 h 15.30 h 15:45 h	Kaffeepause *(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	Datenintegrität (DI) anders betrachtet - Wird durch die Anforderungen der DI die Effizienz bei Laborgeräten gesteigert? – Keine Angst vor den Anforderungen *Eberhard Kwiatkowski, PharmAdvantageIT*	ATMP manufacturing as CMO: Challenges *Christoph Prinz, Apceth*	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* Pyrogen detection with the MM6 cell-line: implementation as a routine test *Mathilde Arnault/Dr Anja Fritsch, Merck/Confarma*	Getting Host Cell DNA analysis up to speed with an automated System *Kyrillos Kyriosoglou, Roche*	16.00 h 16:15 h 16.30 h
16:45 h 17.00 h 17:15 h	Effizientes Managen von Referenz-/Retention-Samples unter Einhaltung der behördlichen Anforderungen *Philip Lienbacher, Shire*	Sterilitätsprüfung von ATMPs *Caroline Fromm, Labor LS*	Training in QC *Ulla Bondegaard, Novo Nordisk*	Healthy human immune cells as pyrogen detection source and advancement of drug release testing *Shabnam Solati, CTL-MAT*	Development and Validation of an Excel workbook for automated sample information management in the analytical lab *Dr Sonja Molinaro, Microcoat Biotechnologie*	16:45 h 17.00 h 17:15 h
17.30 h 17:45 h 18:00 h	Abschlussdiskussion	Abschlussdiskussion	Final Discussion	Final Discussion	Final Discussion	17.30 h 17:45 h 18:00 h