PharmaCongress 2023 – Agenda 28 March 2023

28/29 March 2023, RheinMain CongressCenter, Wiesbaden

GMP–PHARMA CONGRESS

Time	European Aseptic Conference – Technology	European Aseptic Conference – Compliance	New Developments in Barrier Systems & Robotics	PUPSIT: Complying with the Main Annex 1 Changes	GMP for Pre-filled Syringes (PFS)	Pharma 4.0 & Digitalisation	Handling of Highly Active Products	ATMP – Manufacturing, Quality & Safety	Time
	Studio 1.2	Studio 1.3 CD	Studio 1.3 AB	Forum 1.2	Studio 1.5	Studio 1.4	Studio 1.1	Forum 1.3	
9:00 h 9:15 h 9:30 h	Keynote: Comprehensive Transformation of DR. KADE's Sites and Supply Chain *Dr Norbert Marquardt, Dr Kade Health Care*								9:00 h 9:15 h 9:30 h
9:45 h 10:00 h 10:15 h	Break								9:45 h 10:00 h 10:15 h
10:30 h 10:45 h 11:00 h	Implementing of PAT Tool for Lyophilization *Dr Patricia Desmaris, Merck Serono* *Anton Mangold, Tempris*	Inspection Readiness in View of Annex 1 *Dr Stephan Heck,Bipso* *Dr Ralf Aubeck,gempex*	Retrofitting RABS - Upgrade to V-CRT *Dr Ute Schleyer,* *Vetter Pharma-Fertigung*	Introduction of the Annex 1 PUPSIT Requirement *Dr Simone Biel, Merck*	Regulatory overview, Annex 1 Impact and Inspection Experience *Dr Daniel Müller, Local Government, Germany*	Introduction: Digitalisation in GxP environment: Between Mantra and Reality *Yves Samson, Kereon* *Stefan Münch, Körber Pharma Consulting*	Principles of Assessing and Managing Occupational Health Risks in Potent Compound Handling *Dr Andreas Flückiger,* *formerly F. Hoffmann-La Roche*	Vectors for ATMPs – Stabilization by Formulation Development *Dr Sabine Hauck, Leukocare*	10:30 h 10:45 h 11:00 h
11:15 h 11:30 h 11:45 h 12:00 h	**Live Demos** *ZETA* *Tempris* *Alfa Laval Mid Europe* *VITRONIC*	Getting the Basics right *Owen Prichard, Consultant*	Process Automation in a Small Scale Aseptic Manu-facturing Site for Clinical Trial Products *Dr Tim Stöveken, Merz Therapeutics* *Martin Glättli, ProSys Group*	Practical Aspects of PUPSIT Implementation *Guillaume Lesage, Merck*	PFS made from Glass or Polymer *Horst Koller, HK Packaging*	Digitalisation from the Inspector's Point of View *Dr Arno Terhechte, Bezirksregierung Münster, Germany*		Cellular Starting Material for ATMP *Lisa Meyer, Minaris Regenerative Medicine*	11:15 h 11:30 h 11:45 h 12:00 h
12:15 h 12:30 h	Break								12:15 h 12:30 h
12:45 h 13:00 h	**Live Demos** *IWT / Tecniplast* *Innerspace*								12:45 h 13:00 h
13:15 h	Break								13:15 h
13:30 h 13:45 h 14:00 h	Continuous Freeze Drying *Dr Friedrich Haefele, formerly Boehringer Ingelheim Pharma*	Cross-contamination: Other Aspects than Cleaning Validation *Jean-Denis Mallet, ECA*	Replacement of H_2O_2 Generator from Existing Vial Filling Line *Dr Simone Bläsi, F. Hoffmann-La Roche* *Kenan Kanmaz, Metall+Plastic*	Case Study Boehringer Ingelheim Pharma: PUPSIT Risk Assessment: The Impact of Equipment Design *Dr Florian Witte, Boehringer Ingelheim Pharma*	PFS and Needle Safety Systems *Horst Koller, HK Packaging*	Influence of Digitalisation on the Future Work of Quality Depart-ments *Jürgen Schmitz, GSK Biologicals*	Review of Technical Requirements for contained Product Handling *Dr Andreas Flückiger,* *formerly F. Hoffmann-La Roche*	ATMP: Market, Manufacturing and Challenges *Dr Mohamad Toutounji, Molgenium*	13:30 h 13:45 h 14:00 h
14:15 h 14:30 h 14:45 h	Energy Saving in Class C Clean-rooms Through Reduced Air Change Rates – a Case Study From a Biotech Company *Dr Detlef Behrens, University of Applied Sciences / Philips University*	Airflow Visualization According to New Annex 1 *Luigi Scaffidi, Boehringer Ingelheim Pharma*	Barrier Systems and Automation – the Needs and the Potential considering Contamination Control Strategy (CCS) *Robert G. Schwarz, FH Campus Wien*	PUPSIT – Annex 1 – Application of Risk Management *Dr Philip Hörsch,* *Vetter Pharma-Fertigung*	Tubs and Nests *Iwan Tresch, FischerSöhne*	**Live Demos** *Pharmaplan* *Ellab* *Bausch+Ströbel*	Case Study Pfizer: Constructional and regulatory Challenges of an OEB 4 Manufacturing Site (online) *Dr Gunther Bechmann, Pfizer*	GMP for ATMP *Dr Rainer Gnibl, Local Government of Upper Bavaria*	14:15 h 14:30 h 14:45 h
15:00 h 15:15 h 15:30 h	Break								15:00 h 15:15 h 15:30 h
15:45 h 16:00 h 16:15 h	Critical Thinking and Risk Management in Construction Projects as a Means to Maximize Value – a Template for New CR Site in Kaarst *Carsten Jasper, Charles River Laboratories*	Sustainable Way of flexible Filling – prepared for Future Demands *Martin Frei, Lonza* *Patrick Wieland, Bausch+Ströbel*	Benefits of Robotics in a CDMO Environment – A Case Study at the German CDMO PSM about using gloveless robotic filling System... *Julian Petersen, groninger & co* *Thorsten Häfner, PSM*	Case Study Novartis Pharma: PUPSIT – YES or NO? *Matthias Schaar, Novartis Pharma Stein*	Fill-Finish Processes for Prefilled Syringes *Markus Busch, Vetter Pharma-Fertigung*	Case Study – Digitalisation for Construction Management of Large Biopharmaceutical Plant *Marick Paris-Cadet, Technip Energies*	GMP Inspection Experience of Products containing hazardous Substances & Introduction to WHO's Prequalification Program *Vimal Sachdeva, WHO*	From Process Transfer to clinical / commercial Manufacturing of Cell and Gene Therapy Products – Experiences of a CDMO *Kati Kebbel, Fraunhofer Institute for Cell Therapy and Immunology*	15:45 h 16:00 h 16:15 h
16:30 h 16:45 h 17:00 h	What if Final Product Filtration is Not Possible? Challenges and Opportunities of Aseptic Manufac-turing for Large Viruses *Margarida Rosa,* *Genlbet Biopharmaceuticals*	Annex 1 and the Related Improve-ments Out of Machine Vendor Perspective *Dr Friedrich Haefele, formerly Boehringer Ingelheim Pharma* *Jill Dietrich, Bausch+Ströbel*	Barriers & Robotic Isolators in New Annex 1 (2022 version) *Dr Daniel Müller, Local Government, Germany*	Case Study GSK: PUPSIT – From Design to Implementation *Vincent Delferriere, GSK*	Sterile Secondary Packaging *Peter Huonker, Lonza*	Automated Validation – Enabling Better Data Reliability and Integrity in Life Sciences *Eva Kelly, ERA Sciences*	Case Study Hovione: Spray Drying and Continuous Tableting of highly active Materials in a GMP Environment *Dr Filipe Gaspar, Hovione*	Cell based ATMPs: A Success Story *Dr Katja Aschermann, TETEC*	16:30 h 16:45 h 17:00 h
17:15 h	Discussion	Discussion	Discussion	Discussion	Discussion	Discussion	Discussion	Discussion	17:15 h
17:30 h	Social Event				Social Event				17:30 h

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	Studio 1.2	Studio 1.3 AB	Forum 1.2	Studio 1.5	Studio 1.4	Studio 1.1	Forum 1.3	
9:00 h 9:15 h 9:30 h	**Keynote: Trends in Aseptic Manufacturing: Questions and Demands for Pharma Machine Vendors** *Dr Friedrich Haefele, formerly Boehringer Ingelheim Pharma*							9:00 h 9:15 h 9:30 h
9:45 h 10:00 h 10:15 h	Break							9:45 h 10:00 h 10:15 h
10:30 h 10:45 h 11:00 h	Preparing the Facility for Extended Global Markets – Case Study *Raquel Arenós, INBISA* *Londa Ritchey , Pharmalex*	The Use of Robotic Systems *Jörg Zimmermann, Vetter Pharma-Fertigung* Validated Technology for a Flexible Aseptic Robotic Parts *Sascha Wittig, WEISS ROBOTICS*	Case Study Roche Diagnostics: Pre-Use Post Sterilisation Integrity Testing (PUPSIT) in the Revised Annex 1 - Friend or Foe of the Pharmaceutical Entrepreneur? *Manuel Grund, Roche Diagnostics*	Container Closure Integrity *Jean-François Decoster, UCB*	Advanced Monitoring of Production Process Using IIoT System *Milos Nikolic, Galenika*	Cross Contamination Control Strategy in Light of the new Annex I *Robert G. Schwarz, FH Campus, Vienna*	Individual stringent Mini Isolators for autologous Cell Therapy *Didier Meyer, DMCompliance*	10:30 h 10:45 h 11:00 h
11:15 h 11:30 h 11:45 h	Innovative Ozone Decontamination Process Including Areas of Application and Practical Example *Bernd Geis* *Julian Ott* *Matthias Buttazoni*	Automated Thawing Process: Combining Robotic and Manual Process Steps *Maren Jahn, Vetter Pharma-Fertigung*	**Live Demos** *Merck* *Pall*	Process Simulation / Media Fill *Dr Helen Sauter, Vetter Pharma-Fertigung*	DigitaliSation and Automation: How to Avoid Losing from Day One, Preventing Successful Transformation to Fall Short *Ana Cláudia Pinho, BIAL - Portela & C.ª*	Case Study Lonza: Use of single-use equipment for the commercial production of highly potent ADCs (online) *Dr Christoph Umbricht, Lonza*	Case study: QC Test Profile and Release Strategies for ATMP *Stephane Gumy, PMS* *Dr Joaquin Urdinez, Cutiss*	11:15 h 11:30 h 11:45 h
12:00 h 12:15 h	Break							12:00 h 12:15 h
12:30 h 12:45 h 13:00 h	**Live Demos** *Yokogawa* *Emerson Automation Solutions* *WILCO*							12:30 h 12:45 h 13:00 h
13:15 h 13:30 h 13:45 h	Flexible Solutions for Different Market Requirements *Rainer Glöckler, ten23 health* *Ralf Wagner, Optima pharma*	Disposable Isolator and Robotic Input, Why Not? *Frank Pavan, GTP Nano*	To PUPSIT or not to PUPSIT? – Science-based Considerations for a risk-based Approach *Robert G. Schwarz, FH Campus, Vienna*	Visual Inspection *Jean-François Decoster, UCB*	Implementation of Pharma 4.0 at the German CDMO PSM GmbH *Thorsten Häfner, PSM* *Julian Petersen, groninger & co*	Case Study Minapharm: Design of a HPAPI Biomanufacturing Facility *Dr Marcos Loka, Minapharm*	Exceptional Provision of AT(I)MPs affected by OOS Results *Dr Rüdiger Alt, Novartis*	13:15 h 13:30 h 13:45 h
14:00 h 14:15 h 14:30 h	Relocation of a Capping Machine to an Existing Production Line and Insertion of an Automatic Vial Inspection (AVI) *Christoph Möller, Burgwedel Biotech (MSD)* *Lizar Duhoki, Chemgineering*	**Live Demos** *Optima pharma* *MK Versuchsanlagen* *Stäubli* *Steriline*	Podium Discussion on PUPSIT	Silicone-free Primary Packaging Materials in Filling & Stopper Process Development – Challenges & Opportunities *Manuel Grund, Roche Diagnostics*	Are Digitalisation and Artificial Intelligence a Double-Edged Sword in Pharma and Healthcare? *Marco Reiss, Paul-Ehrlich-Institut*	Case Study Merz: Production of sterile & highly potent Products *Fred Wulfgramm, Merz* *Julian Petersen, groninger & co* *Frank Lehman, Skan*	Metabolic Sensing and AI Control to improve Quality of Cell Therapy Manufacturing and potentially enable Release by Exception *Noam Bercovich, ADVA Biotechnology*	14:00 h 14:15 h 14:30 h
14:45 h 15:00 h			Break					14:45 h 15:00 h
15:15 h 15:30 h 15:45 h	Fast Track Tech Transfer – Experience & Best Practices: Aseptic Filling & Lyo CSL Behring Project *Steffen Mörler, CSL Behring*	New Methods to develop Pharma Automation and Robotic Solutions in Warp Speed *Milad Jami, Novo Nordisk* *Julien Lora, Stäubli*	Podium Discussion on PUPSIT	High speed Syringe Filling Line for Oncological Drugs – Challenges & Solutions *Radek Fialka, Oncomed* *Klaus Ullherr, Syntegon*	AI Supported Intervention Detection and Classification in the Aseptic Core *Christoph Köth, Fresenius Kabi Austria*	Handling of Solids with Single-Use Systems in the chemical Synthesis of highly active Substances *Dr Rainer Nicolai, F. Hoffmann-La Roche*	Establishment of Quality Management System (QMS) for Cell Therapies *Erik Steffensen, Novo Nordisk*	15:15 h 15:30 h 15:45 h
16:00 h 16:15 h 16:30 h	Discussion	Fill&Finish Machine for Cell&Gene Therapy: From Requirements to Concept and Realization *Alexandre Daune, UCB* *Matteo Tagliabue, Steriline*		Device Assembling and Control Processes for Auto Injectors *Susanne Hall, Vetter Pharma-Fertigung*	Discussion	New Approach for assessing Dust-Retention Performance of high-containment Systems *Dr Andreas Flückiger, formerly F. Hoffmann-La Roche*	The Assessment of Process Equipment Related Leachables in Cell and Gene Therapies *Dr Armin Hauk, Sartorius Stedim Biotech*	16:00 h 16:15 h 16:30 h
16:45 h		Discussion	Discussion	Discussion		Discussion	Discussion	16:45 h
17:00 h								17:00 h

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