

Time	Non-Sterile Products	GMP – Green or Good Manufacturing Practice?	European Aseptic Conference	Trends in Barrier Systems & Robotics	Modern Cleanroom Technology	Digitalisation & Artificial Intelligence	GMP for Pre-Filled Syringes (PFS)	Time	
Room	Studio 1.3 CD	Loge 1.1	Forum 1.2	Studio 1.1	Forum 1.3	Forum 1.1	Studio 1.4	Room	
9:00 h	Manufacturing of Pandemic Vaccines – Manufacturing & Supply Solutions Enabling the Delivery of Large Numbers of Vaccine Doses							9:00 h	
9:15 h	Dr Guido Dietrich, CEPI							9:15 h	
9:30 h	Wallhäußer Innovation Award Ceremony							9:30 h	
9:45 h	Break			Break				9:45 h	
10:00 h	Live Demos Ellab boTec			Live Demos Ellab boTec				10:00 h	
10:15 h	Fully Automated and DoE-Based Development of an Oral Solid Dosage Form <i>Dr Thomas Brinz, Syntegon</i>			Compliance in Aseptic Production from a QP-Perspective <i>Dr Rita Jacobs-Haage, Vetter Pharma-Fertigung</i>	Isolator / RABS: What is really new in Annex 1 <i>Dr Florian Witte, Boehringer Ingelheim Pharma</i>	Current Zoning Concepts for special Requirements <i>Andreas Nuhn, D&B Pharmadesign</i>	An overview on AI/ML in GxP Environments <i>Stefan Münch, Körber Pharma Consulting</i> <i>Yves Samson, Kereon</i>	Regulatory Overview, Annex 1 Impact and Inspection Experience <i>Dr Daniel Müller, Local GMP Authority of Baden-Württemberg</i>	10:30 h
10:30 h	Use and Implementation of SIX sigma and SPC (Statistical Process Control) Cp and Cpk to improve our Routine Production Process throughout finding the Problems <i>Pranvera Apostoli, Profarma</i>	Sustainability and GMP – Contradictive or supportive? How can Sustainability Aspects been built in GMP Requirements <i>Dr Andrea Bauer, ABC&Q</i>	Reading the EU-GMP Guide with green Glasses <i>Dr Jean-Denis Mallet, PharmaPlan</i>	Live Demos Bausch+Ströbel Merck Cytiva	Tackling Annex 1 Requirements by Robotics: On the Way to Zero Human Interaction in Lyo Vial Filling <i>Dr Arne Schröder, Vetter Pharma-Fertigung</i>	Case Study Stulln Pharma – Design of a new Facility for Sterile Production <i>Nikolaus Ferstl, Facility Engineering Services</i>	Regulatory Requirements and Inspector's View on Artificial Intelligence <i>Ib Alstrup, Danish Medicines Agency</i>	Contamination Control Strategy <i>Marsha Steed, Steed MicroBio</i>	11:15 h
11:15 h	Break							11:15 h	
11:30 h	Live Demos MK Versuchsanlagen Innerspace MBV			Live Demos MK Versuchsanlagen Innerspace MBV				11:30 h	
11:45 h	Break							11:45 h	
12:00 h	Break							12:00 h	
12:15 h	Break							12:15 h	
12:30 h	Live Demos MK Versuchsanlagen Innerspace MBV			Live Demos MK Versuchsanlagen Innerspace MBV				12:30 h	
12:45 h	Break							12:45 h	
13:00 h	Break							13:00 h	
13:15 h	Break							13:15 h	
13:30 h	EU-GMP Inspection: Inspector's hot Topics <i>Dr Rainer Gnibl, Government of Upper Bavaria</i>	Does Sustainability stand only for green GMP? <i>Ana Cláudia Pinho, Bial Portela</i> <i>Susana Lima, Bial Portela</i>	Industry asks – Annex 1 unfortunately does not answer! – What to do? <i>Dr Ingrid Walther, Pharma Consulting Walther</i>	Robotics and Automation – The Enabler for a higher Quality and Annex 1 CCS Compliance <i>Robert Kibele, groninger & co</i>	New Cleanroom / Barrier System Requirements from Annex 1 <i>Dr Jean Denis Mallet, Former head of the French Inspection Department AFSSAPS, Pharmaplan</i>	Use of AI in daily Deviation and CAPA Management <i>Dr Sven Alexander Moritz, Sanofi-Aventis Deutschland</i>	MDR – Understanding the Impact and ensuring Compliance for Syringe-based Combination Products <i>Christa Jansen-Otten, West</i>	13:30 h	
13:45 h	Cleaning Validation in Pharmaceutical Manufacturing Industry <i>Eni Bushi, Profarma</i>	Sustainable and Energy-Efficient Planning and Construction of a Laboratory and Production Facility <i>Dr Johannes Reich, Microcoat Biotechnologie</i>	Aseptic Production in the Light of the new Annex 1 <i>Dr Frank Sielaff, Hessian State Office of Health and Care</i>	Aseptic Process Simulation in a Robotic Filling Line <i>Dennis Dürr, Roche Diagnostics</i>	Implementation of the new Requirements of EU GMP Annex 1 from Boehringer Ingelheim's Perspective <i>Dr Lars Kreye, Boehringer Ingelheim Pharma</i>	Validation of AI/ML in the GxP Environment <i>Dr Ulrich Köllisch, GxP-CC</i>	PFS made from Glass or Polymer <i>Katharina Golly, Novartis</i>	14:00 h	
14:00 h	Break							14:00 h	
14:15 h	Live Demos ZETA Friedrich Sailer Particle Measuring Systems			Live Demos ZETA Friedrich Sailer Particle Measuring Systems				14:15 h	
14:30 h	Modern Approach for Identifying Sampling Points in the Non-Sterile Area (grid-line Approach) <i>Dr Marcel Goverde, MGP Consulting</i>	Sustainability – HVAC Optimization Program at Merck Healthcare KGaA with significant Energy Savings <i>Lenz Kunath, Merck Healthcare</i>	Advancing Aseptic Manufacturing: Insights and Best Practices from a Chief Quality Assurance Officer <i>Dr Hiva Hossein Tehrani, CinnaGen</i>	Pre-Validation Steps of a fully gloveless Aseptic Isolator – A Case Study at the German CDMO PSM <i>Bianca Bohrer, PSM</i>	Modern Cleanroom Garment Systems <i>Carsten Moschner, CMC3</i>	When Data runs wild – Data Integrity as a Control Tool for AI <i>Galit Lisaey, Gal.IT Data Integrity Consulting</i>	PFS and Needle Safety Systems <i>Katharina Golly, Novartis</i> <i>Jinesh Sadalge, Novartis</i>	14:30 h	
14:45 h	USP chapter <1115> – Industrial Implementation <i>Dr Marcel Goverde, MGP Consulting</i>	How to reduce Carbon & Water Footprint in clean Utility Systems <i>Alistair Wotherspoon, CRB</i>	Small Volume sterile Manufacturing – Challenges derived from new GMP Annex 1 <i>Marta Rodriguez-Vélez, Letipharma</i>	Barrier Systems – Current GMP Requirements <i>Dr Daniel Müller, Local GMP Authority of Baden-Württemberg</i>	Green GMP in Cleanrooms – Contradiction or Opportunity <i>Dr Johannes Krämer, CSL Behring</i>	Simplified Extractables and Leachables Assessment using prior Knowledge and IT Solutions <i>Dr Armin Hauk, Sartorius Stedim Biotech</i>	Validation of a Steam Sterilization Process for a Pre-Filled Syringe <i>Maria Luisa Bernuzzi, MesaLabs</i>	14:45 h	
15:00 h	Break							15:00 h	
15:15 h	Live Demos ZETA Friedrich Sailer Particle Measuring Systems			Live Demos ZETA Friedrich Sailer Particle Measuring Systems				15:15 h	
15:30 h	Break							15:30 h	
15:45 h	A Case of <i>Burkholderia cepacia</i> Complex in Non-Sterile Manufacturing; <i>Rashid Kihwelo, Kairuki</i>	Sustainability in Pharma – how a Company can achieve CO ₂ net zero Goal; <i>Henning Austermann, Siegfried</i> <i>Markus Burkert, Syntegon</i>	Discussion	Discussion	Discussion	Discussion	Discussion	15:45 h	
16:00 h	Social Event							16:00 h	
16:15 h	Social Event							16:15 h	
16:30 h	Social Event							16:30 h	
16:45 h	Social Event							16:45 h	
17:00 h	Social Event							17:00 h	
17:15 h	Social Event							17:15 h	
17:30 h	Social Event							17:30 h	



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Time	Lyophilization	ATMPs	Vaccines
Room	Studio 1.5	Studio 1.2	Studio 1.3 AB
9:00 h	Manufacturing of Pandemic Vaccines – Manufacturing & Supply Solutions		
9:15 h	Enabling the Delivery of Large Numbers of Vaccine Doses		
9:30 h	Dr Guido Dietrich, CEPI		
9:45 h	Wallhäußer Innovation Award Ceremony		
9:45 h	Break		
10:00 h	Live Demos		
10:15 h	Ellab boTec		
10:30 h	Regulatory Overview, Annex 1 Impact and Inspection Experience <i>Dr Frank Sielaff, Hessian State Office of Health and Care</i>	CMC Strategies for successful ATMP Commercialization <i>Alicja Fiedorowicz, Dark Horse Consulting</i>	Global Progress in Vaccine Development: Regulatory Considerations and Scientific Advances <i>Dr Mohamad Toutounji, Molgenium</i>
10:45 h	Process Validation of Lyophilized Products and ongoing Lifecycle Verification <i>Dr Andrea Weiland-Waibel, ExplicatPharma</i>	Challenges in the Bench-to-Bedside Translation of Gene and Cell Therapeutics (GCT) <i>Prof Dr Sven Stegemann, Leibniz Jointlab „First-in-Translation“</i>	Modern Vaccines – Perspective from the Regulatory Authority <i>Petra Falb, AGES - Austrian Agency for Health and Food Safety</i>
11:00 h	Break		
11:15 h	Live Demos		
11:30 h	MK Versuchsanlagen Innerspace MBV		
11:45 h	Break		
12:00 h	Break		
12:15 h	Break		
12:30 h	Live Demos		
12:45 h	MK Versuchsanlagen Innerspace MBV		
13:00 h	Break		
13:15 h	Break		
13:30 h	Lyophilized Plasma Products – Experience and Technical Challenges in Refrigeration <i>Frank Heck, CSL Behring</i>	Decentralised Manufacturing for T-Cell Therapies <i>Dr Ursula Busse, Tigen</i>	Added Value by Advanced Formulations for Vaccines <i>Dr Sabine Hauck, ECA ATMP Interest Group</i>
13:45 h	Atmospheric Spray Freeze Drying <i>Prof Alf Lamprecht, University of Bonn</i>	Digital Evolution Strategies in Manufacturing, Science and Technology (MSAT) <i>Dr Veronika Nindl, VTU Engineering</i>	Low-Energy-Electron Irradiation – a Potential Game Changer for the Development of Vaccines and Cell Therapies <i>Dr Andrea Traube, Kyoobe Tech</i>
14:00 h	Break		
14:15 h	Live Demos		
14:30 h	ZETA Friedrich Sailer Particle Measuring Systems		
14:45 h	New Automatic Format Change System for the Transportation of Freeze-Drying Vials <i>Xavier Gómez, Telstar</i>	Design Considerations for allogeneic Cell Therapies <i>Erik Steffensen, Spot-on Pharma Consulting</i>	Resolving Facility Design Conflicts between Biocontainment & Good Manufacturing Practices for Vaccines Manufacture <i>Faye Litherland, Fluor Limited</i>
15:00 h	Improving the Sustainability of Pharmaceutical Freeze Drying <i>Dr Benjamin Ledermann, GEA</i>	Challenges in allogeneic CAR-T Manufacturing using Viral Vectors and LNPs <i>Dr Juliane Heilig, CMT</i>	The Search for efficacious and Sustainable Alternatives to Triton™ X-100 in Therapeutics <i>James Humphrey, Croda Pharma</i>
15:15 h	Break		
15:30 h	Discussion		
15:45 h	Discussion		
16:00 h	Discussion		
16:15 h	Discussion		
16:30 h	Discussion		
16:45 h	Discussion		
17:00 h	Discussion		
17:15 h	Discussion		
17:30 h	Social Event		

Packaging / Packaging Materials	European Aseptic Conference	Trends in Barrier Systems & Robotics	Time
Studio 1.3 CD	Forum 1.2	Studio 1.1	Room
Keynote by the Wallhäußer Innovation Award Winner			9:00 h
Break			9:15 h
Live Demos			9:30 h
PHARMAPLAN Emerson Automation Solutions Yokogawa Deutschland			9:45 h
Primary and Secondary Packaging of Drug Substances <i>Jyotsna Agnihotry, Flavine Europe</i>	Single-Use Design for Small-Volume Filling <i>Julia Mathy, Roche Diagnostics</i>	Case Study on Management of indirect Products Contact Parts in an Isolator <i>Antoine Toussaint, GlaxoSmithKline Vaccines</i>	10:00 h
Regulatory demands / Challenges in CCS of Injections <i>Pirkko Lahti, Orion</i>	Container Closure Integrity Testing (CCIT) and Biologics – Some Case Studies <i>Dr Constantin Hozsa, Siegfried</i>	Meeting EU GMP Annex 1 Requirements: Sterilization of indirect Product Contact Parts in Filling Lines using Sterilization Container <i>Dr Annika Bernsdorf, GlaxoSmithKline Biologicals</i>	10:15 h
Live Demos			10:30 h
REA Elektronik IWT / Tecniplast Quascenta Pte Kneat Solutions			10:45 h
Break			11:00 h
Packaging Materials Challenges in Aseptic / Sterile Manufacturing <i>Sergio Cuevas Luján, Boehringer Ingelheim</i>	Particle Life Cycle Concept <i>Dr Philip Hörsch, Vetter Pharma-Fertigung</i>	Upgrade of H ₂ O ₂ Decontamination System for Production oRABS Vial Filling Line <i>Pasquale Cataldo, Roche Diagnostics</i> <i>Kenan Kanmaz, Optima pharma containment</i>	11:15 h
Microbiological Control of Packaging Materials <i>Dr Marcel Goverde, MGP Consulting</i>	Implementation and Execution of an active microbial Air Monitoring System into a sterile, radiopharmaceutical Environment <i>Stephanie Ziesche / Dr Emad Albarouki</i>	Case Study Janssen: Flexible Fill & Finish Equipment for Multi-Product Manufacturing Processes <i>Dr Göran Crucius, Cilag / Janssen</i> <i>Patrick Wieland, Bausch+Ströbel</i>	11:30 h
Break			11:45 h
Break			12:00 h
Break			12:15 h
Break			12:30 h
Break			12:45 h
Break			13:00 h
Break			13:15 h
Development and Validation of a Cloud-based System for Automated Text Verification <i>Dr Carsten Börger, Valicare</i> <i>Frank Hessler, Schlafender Hase</i>	Case Study: Critical Process Parameters for Filling of Sterile Products with BFS Technology <i>Dr Martin Haerer, Rommelag CMO</i>	Modern Sterile Test Isolators – Safe, Compliant, Efficient, Versatile <i>Katharina Schlereth, Labor LS</i> <i>Harald Kiesel, Skan</i>	13:30 h
Distribution Testing: How to make sure, the Product makes it to the Destination <i>Dr Jan Oberländer, GfPS</i>	GMP compliant Environmental Monitoring <i>Dr Anne-Grit Klees, Merck</i>	Case Study: E-Beam – A validated Transfer Method for RTU into Grade A in Compliance with Annex 1 <i>Anette Mörbel-Witte, Sanofi-Aventis Deutschland</i> <i>Manfred Holzer, Skan</i>	13:45 h
Break			14:00 h
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Break			17:15 h
Break			17:30 h



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Time	Modern Cleanroom Technology	Digitalisation & Artificial Intelligence	GMP for Pre-Filled Syringes (PFS)	Lyophilization	ATMPs	Vaccines	Time
Room	Forum 1.3	Forum 1.1	Studio 1.4	Studio 1.5	Studio 1.2	Studio 1.3 AB	Room
9:00 h	Keynote by the Wallhäußer Innovation Award Winner						9:00 h
9:15 h							9:15 h
9:30 h							9:30 h
9:45 h							9:45 h
10:00 h	Break Live Demos PHARMAPLAN Emerson Automation Solutions Yokogawa Deutschland		Break Live Demos PHARMAPLAN Emerson Automation Solutions Yokogawa Deutschland				10:00 h
10:15 h							10:15 h
10:30 h	HVAC-System Design for a High Potent Facility <i>Nikolaus Ferstl, Facility Engineering Services</i>	Applying Industry 4.0 – What are the Use Cases and how can they be successfully implemented <i>Dr Andreas Aemissegger, Bachem</i> <i>Yvonne Duckworth, CRB</i>	Container Closure Integrity <i>Jean-François Decoster, UCB</i>	Vials and Stoppers for Lyophilization <i>Francis Carroll, West</i>	Contamination Control Strategy (CCS) for ATMP <i>Marsha Steed, Steed MicroBio</i>	Micro Array Patches for Vaccination <i>Sebastian Scherr, LTS Lohmann Therapie-Systeme</i>	10:30 h
10:45 h							10:45 h
11:00 h	Setup of a Contamination Control Strategy Using the HACCP Methodology <i>Ruben van der Galiën, GE HealthCare</i>	How the Digital Transformation could really improve Inspections & Audits Effectiveness and Efficiency <i>Dr Jean Denis Mallet, Former head of the French Inspection Department AFSSAPS, Pharmaplan</i>	Process Simulation / Media Fill <i>Dr Helen Sauter, Vetter Pharma-Fertigung</i>	Container Closure Integrity <i>Matthias Schaar, Novartis</i>	Increase Risk Awareness: QRM for ATMPs <i>Dr Rainer Gnihl, Government of Upper Bavaria</i>	Batch Release of Vaccines <i>Dr Alexander Bachmann, Pharmaceutical Consultancy Dr Bachmann</i>	11:00 h
11:15 h							11:15 h
11:30 h							11:30 h
11:45 h	Break Live Demos REA Elektronik IWT / Tecniplast Quascenta Pte Kneat Solutions						11:45 h
12:00 h							12:00 h
12:15 h							12:15 h
12:30 h							12:30 h
12:45 h	Break						12:45 h
13:00 h							13:00 h
13:15 h	Airflow Visualization within the critical Zone of Cleanrooms and Barrier Systems <i>Luigi Scaffidi, Boehringer Ingelheim Pharma</i>	Quality Contracts in the Era of Digitalisation and AI <i>Ioannis Tsiagkas, Pharmathen</i>	Visual Inspection <i>Jean-François Decoster, UCB</i>	Process Simulation / Media Fill <i>Heide Nagel, Novartis Pharma Stein</i>	Viral Clearance ATMPs – What if the Product is a Virus? <i>Sandra Meier, Charles River Laboratories</i>	Modern Vaccines - GMP Inspectors View <i>Dr Frank Sielaff, Hessian State Office Of Health and Care</i>	13:15 h
13:30 h							13:30 h
13:45 h	Break						13:45 h
14:00 h							14:00 h
14:15 h							14:15 h
14:30 h	Cleanroom Performance Test According ISO 14644 <i>André Lourenço, NNE</i>	Bridging Innovation and Compliance: Open-Sourcing Data Computation Platform (DCP) for GxP-Compliant Pharma 4.0 Advancements <i>Dr Tobias Ladner, Roche Diagnostics</i>	Automated Visual Inspection: Process and Transfer <i>Dr Max Scheible, Vetter Pharma-Fertigung</i>	Annex 1 Upgrade of Aseptic Filling and Lyophilization of Parenterals in RABS <i>Dr Tino Galgon, Lyocontract</i>	Effective Cell Culture Operations by accurate, non-invasive Determination of the critical Process Parameter pH in Roche's Drug Substance Network <i>Christian Klingler, Roche</i>	Considerations for Cleaning Lipid Nanoparticles <i>Cecilia Pierobon, STERIS Life Sciences</i>	14:30 h
14:45 h	Break						14:45 h
15:00 h							15:00 h
15:15 h	Case Study IPA Fraunhofer: Horizontal vs. vertical unidirectional Airflow Directions <i>Dr Markus Keller, IPA Fraunhofer</i>	Enabling ML Applications by a "Data Expert Team" <i>Dr Jörg Stüben, Boehringer Ingelheim International</i> <i>Martin Heitmann, d-fine</i>	Endotoxin Detection in Pre-Filled Syringes: Challenges during Method Development and Validation <i>Dr Bernhard Illes, Microcoat Biotechnologie</i>	Aseptic Lyophilization with the Help of Protective Membrane Bags <i>Rolf Lenhardt, Teclen</i>	Digital PCR for In-Process Control and Lot Release Testing of Gene Therapy Applications <i>Dr Nicole Paland, Minerva Biolabs</i>	USP Approach to mRNA and Viral Vector Vaccines <i>Nikhil Rautela, USP</i>	15:15 h
15:30 h							15:30 h
15:45 h	Discussion						15:45 h
16:00 h							16:00 h
16:15 h							16:15 h
16:30 h							16:30 h
16:45 h	Discussion	Discussion	Discussion				16:45 h
17:00 h	Assessment of microbial Contamination in a sterile Production Environment <i>Doris Laçej, Profarma</i>						Panel/Plenary Discussion

