GMP PharmaCongress 2025 – Agenda 8 April 2025

8/9 April 2025, RheinMain CongressCenter, Wiesbaden

GMP–PHARMA CONGRESS

Time	Aseptic Technologies & Annex 1 Conference	Digitalisation & Artificial Intelligence	Single-Use Systems in Sterile & Biomanufacturing	Cleanroom Challenges in Ongoing Operations	Trends in Barrier Systems & Robotics	Sustainability/Green GMP	ATMPs – Hurdles & Achievements	Medical Cannabis	Time
Room	Forum 1.1	Studio 1.3	Studio 1.5	Studio 1.2	Forum 1.2	Studio 1.1	Forum 1.3	Studio 1.4	Room
9:00 h	**Artificial Intelligence (AI) in Manufacturing and Quality at Sanofi** Dr Maite Durrenbach, Chief Quality Officer, Sanofi								9:00 h
9:15 h									9:15 h
9:30 h	**Wallhäußer Innovation Award Ceremony**								9:30 h
9:45 h	Coffee Break				Coffee Break				9:45 h
10:00 h									10:00 h
10:15 h									10:15 h
10:30 h	Quality Risk Management in Aseptic Manufacturing: Reasonable Use *Dr Ingrid Walther, Pharma Consulting Walther*	Accelerate Automation Project Implementation and Reduce Risk with a Digital Twin *Rasmus Wendelboe Jørgensen, Novo Nordisk* *Vicky Athanasiou, Emerson*	Single-Use Systems - GMP Inspector's View *Dr Daniel Müller, Local GMP Authority of Baden-Württemberg Germany*	Cleanroom Garments - Clothing Basics, Barrier Functions and More *Jörg Mesenich, Consultant* *Gabriele Schmeer-Lioe, Deutsche Institute für Textil- und Faserforschung (DITF)*	Air Velocity at Working Position and other Cleanroom (Airflow) Challenges in new Annex 1 *Jörg Zimmermann, Vetter Pharma-Fertigung* *Dr Johannes Rauschnabel, Syntegon Technology*	How can Sustainability be integrated into a Pharmaceutical Quality Management System? ... or is it already included? *Dr Andrea Bauer, ABC&Q*	Navigating the EMA Process: Key Insights from Filing for a TEMP *Dr Katja Aschermann, Astator*	Challenges and Experiences from current GMP Inspections *Dr Rainer Gnibl, District Government of Upper Bavaria, Germany*	10:30 h
10:45 h									10:45 h
11:00 h									11:00 h
11:15 h	Sterile Filtration - PUPSIT and Requirements beyond *Dr Frank Sielaff, Regional Authority Darmstadt, Germany*	**Live Demos** PHARMAPLAN AG ZETA GmbH Emerson Automation Solutions Kneat Solutions		Qualification Study for Cleanroom Garments *Carsten Moschner, CMC3*	GMP Risk Assessment for Performing the Test for Sterility in an Isolator *Dr Bettina Rietz-Wolf, Local GMP Authority of Baden-Württemberg, Germany* *Dr Timo Krebsbach, SKAN*	Circular Economy Opportunities for the Pharmaceutical Industry *Susana Lima Santos, Bial*	Challenges and Special Requirements for GMP Inspections of ATMPs *Alexander Kammerlocher, Local GMP Authority of Baden-Württemberg, Germany*		11:15 h
11:30 h									11:30 h
11:45 h									11:45 h
12:00 h					Upgrade of integrated H2O2 Bio-Decontamination System for Production of Vial Filling Line with oRABS – Part II *Pasquale Cataldo, Roche Diagnostics* *Kenan Kanmaz, Optima Pharma containment*	The new F-Gas Regulation and its Impact on pharmaceutical Freeze-Drying *Thomas Beutler GEA*	Quality Assurance of mRNA Vaccines for human use: the Role of the European Pharmacopoeia *Prof Dr Gerrit Borchard, University Geneva & Member of the EDQM expert group*	The Intersection between GMP and GACP *Luis Meirinhos Soares, formerly INFARMED & Member of ECA's Cannabis Working Group*	12:00 h
12:15 h									12:15 h
12:30 h									12:30 h
12:45 h	Lunch Break				Lunch Break				12:45 h
13:00 h									13:00 h
13:15 h									13:15 h
13:30 h	Practical Application of setting up an annual Contamination Control Strategy (CCS) Assessment *Ruben van der Galiën, GE HealthCare* *Dr Prachi Sawant Raschdorf, GE HealthCare*	Case Study: Design & Implementation of a new highly-automated modular OSD Production Facility at Bayer Leverkusen *Andreas Bail, Bayer* *Anton Kopitzsch, Glatt*	Single-Use Technology: An overview from USP to Fill&Finish technologies *Prof Dr Regine Eibl, Zurich University of Applied Sciences*	Consumables and Cleanroom - Expectations and Experiences of an Inspector *Dr Daniel Müller, Local GMP Authority of Baden-Württemberg Germany*					13:30 h
13:45 h									13:45 h
14:00 h									14:00 h
14:15 h	"RTU + RTS materials - GMP Requirements for the Pharmaceutical Manufacturer and Supplier Qualification" *Dr Rainer Kahlich, Authority of Baden-Württemberg, Germany*	Integrating Digitalization & Robotics in Pharmaceutical Manufacturing: Strategies, Challenges, and Compliance in the Digital Era *Maja Karovic, F. Hoffmann-La Roche* *Yvonne Duckworth, CRB*	**Live Demos** Cytiva Merck MK Versuchsanlagen Innerspace	Disposables - Face Masks and the Like - what Protection do they Really Provide? *Monika Lamprecht, Lamprecht Consulting and Coaching*	Case Studies and future Trends for Zero Human Interactions in Aseptic Filling *Dr Arne Schröder, Vetter Pharma-Fertigung* *Tobias Resch, Stäubli Tec-Systems*	The EU Green Deal – Supply Chain Due Diligence Directive (CS3D) and the German Supply Chain Act (LkSG) *Leonie Evans, Meisterernst Attorneys*	Challenges on the Way to becoming a Contract Manufacturer *Dr Carolin Klemm, DKMS Stem Cell*	Case Study 1 Cannabis Cultivation under GACP *Natalie Thurner, Chemgineering* *Dr Michal Wojcicki, Cannerald*	14:15 h
14:30 h									14:30 h
14:45 h									14:45 h
15:00 h					"Case study: E-Beam used as transfer technology for RTU Pre-filled Syringes at Pfizer Puurs on multiple filling lines" *Marcus Hoppe, Pfizer* *Manfred Holzer, SKAN*	From Compliance to Sustainability: The Green GMP Journey *Ana Cláudia Pinho, Bial*	Industrial Scale in Vitro Expression of Bacteriophages and other Proteins *Dr Matthias Steiger, Invitris* *Dr Frenk Smrekar, Jafral*	Drying of Medical Cannabis – Challenges for Process Validation *Tina Cacanoska, PharmaRolly*	15:00 h
15:15 h	Coffee Break								15:15 h
15:30 h									15:30 h
15:45 h	Contamination Control Strategy of RTU-Packaging Systems in relation to Annex I *Horst Koller, HK Packaging Consulting* *Katharina Golly, Novartis*	Smart Panel – The future of the pharmaceutical production process *Christoph Dechow, Boehringer Ingelheim Pharma* *Dr Sebastian Wibbeling, Fraunhofer-Institut for Material Flow and Logistics IML*	Quality Approach in Manufacturing of SUS: performance, robustness & sterility *Dr Marco Klatte, Merck Healthcare*	Cleanroom Wipes - What is Cleanroom-Compatible really? *Carsten Moschner, CMC3*	Coffee Break				15:45 h
16:00 h									16:00 h
16:15 h									16:15 h
16:30 h	Steam Sterilized Isolators solve indirect Product Contact Surface Dilemma (bowls/lanes) *Dr Geert Vandenbossche, C&E Solutions BV*	Continued Process Verification Using Automated Data Assessment *Dr Philip Hörsch, Vetter Pharma-Fertigung* *Bettina Schroeder, Vetter Pharma-Fertigung*	Pharma QA/QC when using Single-Use Equipment *Dr Alicja Sobantka, Octapharma*	Mopping Systems and the Associated Systems *Margarete Witt-Mäckel, Witt Hygienemanagement*	Implementation of RABS systems in Small Volume Manufacturing *Marta Rodríguez-Vélez, Letipharma*	3R Initiative Within Roche's Global QC Network *Dr Sven M. Deutschmann, Roche*	The Challenge of GMP Manufacturing of innova-tive Exosome-based Therapies *Sandrine Mores, ExoBiologics*	Update from the German Cannabis Agency *Dr Anne Wolf, German Cannabis Agency (BfArM)*	16:30 h
16:45 h									16:45 h
17:00 h									17:00 h
17:15 h	Discussion	Discussion	Discussion	Discussion	Discussion	Discussion	Discussion	Validation /Qualification - Experiences & Lessons learned *Dr Ingrid Walther, Walther Pharma Consulting*	17:15 h
17:30 h									17:30 h
18:00 h	Social Event				Social Event				

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Room	Forum 1.1	Studio 1.3	Studio 1.5	Studio 1.2	Forum 1.2	Studio 1.1	Forum 1.3	Studio 1.4	Room
9:00 h	**Pharmaceutical Manufacturing Reinvented: The 3D Printing Process and other New Technologies** Dr Ranjita Shegokar Sahoo, Chief Pharma Innovation Officer (CPO), DiHeSys								9:00 h
9:15 h									9:15 h
9:30 h									9:30 h
9:45 h	Coffee Break				Coffee Break				9:45 h
10:00 h									10:00 h
10:15 h									10:15 h
10:30 h	Fill & Finish of various Ready-to-Use Containers from clinical late Stage until commercial Launch of Biologicals through to high-potent Products; *Stylianos Sampanis, Sanofi Ralf Wagner, Optima Pharma*	Digitalisation and AI from the Inspector's Point of View *Dr Arno Terhechte, GMP Inspectorate Münster, Germany*	Case Study Merck: Single-Use Technology in Aseptic Drug Product Manufacturing *Nicola Rutigliani, Merck Healthcare*	Cleanroom Gloves - the Balancing Act Between Cleanroom Suitability and Personnel Protection *Monika Lamprecht, Lamprecht Consulting and Coaching*	Aseptic Transfers in Small Batch Filling - Industry standards and new approaches to meet Annex 1 *Thorsten Haefner, PSM* *Sebastian Hillbrand, SKAN*	Process Load Profiles as a Basis for a Cost efficient and sustainable Design of Utility Supply Systems *Bianca Bohrer PSM Saar* *Peter Gross, Consulting*	From personalized medicine to flexible machine solutions *Vilma Methner, Optima*	Regulatory Status and Quality Standards of Cannabinoids Manufacture *Dr Giorgia Tossi, Linnea*	10:30 h
10:45 h									10:45 h
11:00 h									11:00 h
11:15 h	Accelerating Pharmaceutical Manufacturing: A Case Study of entering Syringe and Cartridge Fill-Finish Production *Henning Austermann, Siegfried Hameln* *Klaus Ullherr, Syntegon Technology*	AI (Artificial Intelligence) in Manufacturing *Dr Monika Hupfauf, KOCH/HUPFAUF Attorneys* *Amir Abou Elmagd, Genome Lawyers*	Case Study BioNTech: CCS for Processing Frozen Sterile Drug Products in a Single-Use Assembly *Dr Yuan-An (Angus) Liu, BioNTech*	Facility Monitoring with Single-Use Active Viable Sampling in the Daily Practice of a Contract Developer and Manufacturer - Complete and Simple Solution; *Dr Thomas Müller, Recipharm* *Ivan Spiro, Particle Measuring System*	A Case Study highlighting the Validation of a closed gloveless Aseptic Filling Workcell *Joachim Vereecke, White Raven* *Brent Lieffers, Cytiva*	Sustainability Strategies at Pekana *Dr Marius Beyersdorff, Pekana* *Gabriele Brutscher, Pekana*	Visible and Subvisible Particle Control for Cell Therapy From Development to Commercialization *Dr Roman Mathaes, Clear Solutions Laboratories*	Challenges in Microbiological Decontamination of Medicinal Cannabis *Dr David Surjo, GOC NEXUS*	11:15 h
11:30 h									11:30 h
11:45 h									11:45 h
12:00 h	**Live Demos** Tempris GmbH Bausch+Ströbel REA Elektonik Yokogawa Deutschland GmbH				Challenges and benefits for modern and state-of-the art fill & finish equipment to reduce glove interventions; *Dr Christian Matz, Formerly F. Hoffmann-La Roche,* *Patrick Wieland, Bausch + Ströbel*	Recycling and Cleanroom Garments *Carsten Moschner, CMC3*	Process Validation Sterile Drug Products: Strategy, execution and maintaining the validated state *Dr Anne Orillo, Novartis*	Contamination Control Strategy in Cannabis Manufacturing *Martina Gjorgjevska, The Force CT* *Apostol Todorovski, Sinceritas*	12:00 h
12:15 h									12:15 h
12:30 h									12:30 h
12:45 h									12:45 h
13:00 h	Lunch Break				Lunch Break				13:00 h
13:15 h									13:15 h
13:30 h	H2O2 Ingress Study Approach for Isolator Decontamination of the AT-Vials *Dr Maria Loos, Johnson and Johnson* *Adrian Keller, SKAN*	Benefits and Challenges in Developing a GenAI Solutio for a GxP-relevant Process *Dr Rolf Roth, Merck Healthcare* *Stephane Guillet, Merck Healthcare*	Case Study: Manufacturing of a Monoclonal Antibody with SUT *Jyotsna Agnihotry, Flavine Europe*	Pitfalls in Microbiological Cleanroom Monitoring: Common Sources of Error in Qualification and Ongoing Monitoring *Melanie Braun, Labor LS*					13:30 h
13:45 h									13:45 h
14:00 h									14:00 h
14:15 h	Container Closure Integrity Test *Luigi Scaffidi, Boehringer Ingelheim Pharma*	Artificial Intelligence (AI) for Discrepancy Management *Dr Philipp Fey, Boehringer Ingelheim Pharma* *Jorge Gil-Hernandez, Boehringer Ingelheim Pharma*	Case Study Sanofi: Optimization of Single-Use Systems for Fill-Finish Manufacturing Operations to the new Requirements *Dr Rebecca Geyer, Sanofi*	**Live Demos** Particle Measuring Systems BWT Pharma & Biotech GmbH Bolz Intec GmbH AVEVA	Benefits of Digitalization in Sterile Testing *Katharina Schlereth, Labor L+S* *Harald Kiesel, SKAN*	Quantifying the present and future environmental sustainability of cleanrooms *Justin Z. Lian, University of Leiden*	Vector Safety Assessment in Cell and Gene Therapy by NGS/TGS sequencing *Dr Richard Gabriel, ProtaGene*	Case Study 2 – Pharmaceutical Cannabinoid Extractions: Balancing Efficiency and Quality *Dr Nikos Xynos, Nomad Lab Scientific*	14:15 h
14:30 h									14:30 h
14:45 h									14:45 h
15:00 h	Coffee Break				Compliance of Annex 1 Requirements for Glove Integrity Testing *Jason Creek, Roche Diagnostics* *Kenan Kanmaz, Optima Pharma containment*	Sustainable Heat and Cooling Systems - the LUnA Projekt *Michael Eberhard, Abbvie* *Thomas Frank, Refolution*	Viral Clearance ATMPs – What if the Product is a Virus? *Sandra Zucchet, CRL*	Digitalization in Cannabis Production *Hannes Schubert, NESS*	15:00 h
15:15 h									15:15 h
15:30 h									15:30 h
15:45 h	Next Generation of Aseptic Filling: Highest Flexibility meets latest Regulations of Annex 1 *Sébastien Trichot, Sanofi* *Edgar Bauer, Bausch + Ströbel*	Application of dynamic learning systems to increase efficiency increase in pharma production lines *Felix Georg Müller, plus10* *Martin Heitmann, d-fine*	Particle Cleanliness Assessment of SUS *Gerald Dallmann, SGS Institut Fresenius*	Case Study: Disinfectants and Their Effectiveness on Various Surfaces *Dr Hans-Joachim Anders, Novartis*	Coffee Break				15:45 h
16:00 h									16:00 h
16:15 h									16:15 h
16:30 h	Flexible Production for Parenterals, from vision to execution *Dr Friedrich Haefele, Formerly Boehringer Ingelheim*	AI in Medical Image Processing *Daniel Wolf, Ulm University Medical Center*	E&L testing of process materials used in bioproduction *Dr Koen Smets, Nelson Lab*	Navigating the Challenges of Implementing New Annex 1 in Non-Sterile Manufacturing *Martina Gjorgjevska, The ForceCT* *Apostol Todorovski, Sinceritas*	Barrier Systems – Current GMP Requirements *Dr Daniel Müller, Local GMP Authority of Baden-Württemberg, Germany*	Sustainable Refrigeration Technologies: Overview and Implementation of innovative Air-Cooling Technology for Freeze-Drying Processes *Christian Sonntag, Roche* *Fabian Plaum, Hof*	Gloveless aseptic Fillers for small Batches and Cell & Gene Therapy Sectors: a novel Approach utilizing Modular Design and magnetic Levitation Conveyors *Giacomo Guidi, IMA Life*	Israel Medical Cannabis Regulation *Dr Viviana Braude, Cronos Israel*	16:30 h
16:45 h									16:45 h
17:00 h									17:00 h
17:15 h	Discussion	Discussion	Discussion	Discussion	Discussion	Discussion	Discussion	Medical Cannabis Manufacturing & Compounding: Regulatory Issues *Dr Hanneke Later-Nijland, Genome Lawyers* *Dr Monika Hupfauf, KOCH/HUPFAUF Attorneys*	17:15 h
17:30 h									17:30 h
17:45 h	End of Congress				End of Congress				18:00 h

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