GMP–PHARMA CONGRESS

#sharing challenges and solutions in practice

8/9 April 2025, WIESBADEN
RheinMain CongressCenter

8 Conferences | **100** Speakers | **120** Exhibitors

- Aseptic Technologies & Annex 1 Conference
- Digitalisation & Artificial Intelligence
- Trends in Barrier Systems & Robotics
- Cleanroom Challenges
- Sustainability/Green GMP
- Single-Use Systems
- ATMPs
- Medical Cannabis

Please scan the code to read the **full agenda and details** of the GMP PharmaCongress or to **register directly online** – or visit www.pharma-congress.com

CONCEPT HEIDELBERG

Supported by ECA Academy *Your GMP/GDP Information Source*

OVERVIEW

The guiding theme of the GMP PharmaCongress 2025 on 8/9 April will once again be „users sharing challenges and solutions in practice“. Therefore, benefit from your colleagues‘ experience and from the direct information exchange.

The Conference Tracks

As a participant you can switch between any of the **8 conference tracks** any time and also visit the PharmaTechnica Expo with close to 120 international exhibitors.

The GMP PharmaCongress Conference Tracks	8 April 2025	9 April 2025
European Aseptic Technologies & Annex 1 Conference	✓	✓
Digitalisation & Artificial Intelligence	✓	✓
Trends in Barrier Systems & Robotics	✓	✓
Cleanroom Challenges in Ongoing Operations	✓	✓
Sustainability/Green GMP	✓	✓
Single-Use Systems in Sterile & Biomanufacturing	✓	✓
ATMPs – Hurdles & Achievements in Quality and Safety	✓	✓
Medical Cannabis – Cultivation, Processing, Systems & Technology	✓	✓
GMP PharmaTechnica Expo	✓	✓

KEYNOTE

Keynote 8 April 2025

Artificial Intelligence (AI) in Manufacturing and Quality at Sanofi

Dr Maite Durrenbach, Chief Quality Officer, SANOFI

Dr Maite Durrenbach is Chief Quality Officer at Sanofi. In her function she leads the Quality Function of the group for R&D, Industrial Affairs and Commercial Activities. She joined Sanofi in November 2001 and has worked in many management roles since then.

- Launch of the Integrated Quality System Management Platform with 80,000 users
- AI Applications in use and potential areas for AI
- Digitalisation of Quality Documentation and gradually replacing it with video SOPs, e-Forms, etc
- Key Performance Indicators: what has been achieved so far – what are the goals

Keynote 9 April 2025

Pharmaceutical Manufacturing Reinvented: The 3D Printing Process and other New Technologies

Dr Ranjita Shegokar Sahoo, Chief Pharma Innovation Officer (CPO) at DiHeSys

Dr Ranjita Shegokar Sahoo has extensive expertise in drug delivery, nanotechnology, and drug device combinations. She has authored 200+ research papers, edited 25 plus books and filed multiple patents. Recognized with several awards among them are Outstanding innovator of the year (2020), the German Innovation Award (2022) and Medical Award (2023). Read more at https://ranjitas.com/.

- 2D/3D Printing: Technology – Application and Regulatory Hurdles
- Nanoparticles in Pharma - Technical and Strategic Solutions
- Other new Technologies that will impact the Pharmaceutical and Biopharmaceutical Industry

European Aseptic Technologies & Annex 1 Conference

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Quality Risk Management in Aseptic Manufacturing: Reasonable Use
Dr Ingrid Walther, *ECA Working Group on Annex 1*

Sterile Filtration – PUPSIT and Requirements beyond
Dr Frank Sielaff, *Regional GMP Authority Darmstadt, Germany*

Practical Application of setting up an annual Contamination Control Strategy (CCS) Assessment
Ruben van der Galiën, *GE HealthCare*
Dr Prachi Sawant Raschdorf, *GE HealthCare*

"RTU + RTS Materials – GMP Requirements for the Pharmaceutical Manufacturer and Supplier Qualification"
Dr Rainer Kahlich, *Local GMP Authority of Baden-Württemberg, Germany*

Contamination Control Strategy of RTU-Packaging Systems in relation to Annex I
Horst Koller, *HK Packaging Consulting*
Katharina Golly, *Novartis Pharma*

Steam Sterilized Isolators solve indirect Product Contact Surface Dilemma (bowls/lanes)
Dr Geert Vandenbossche, *C&E Solutions*

Operational Fill & Finish Experience in Processing various „ready-to-use" Containers in an Aseptic Isolator Environment of Biologicals through to high potent Products
Stylianos Sampanis, *Sanofi-Aventis Deutschland GmbH*
Ralf Wagner, *Optima pharma*

Accelerating Pharmaceutical Manufacturing: A Case Study of entering Syringe and Cartridge Fill-Finish Production
Henning Austermann, *Siegfried Hameln*
Klaus Ullherr, *Syntegon Technology*

H2O2 Ingress Study Approach for Isolator Decontamination of the AT-Vials
Dr Maria Loos, *Johnson and Johnson*
Adrian Keller, *SKAN*

Container Closure Integrity Test
Luigi Scaffidi, *Boehringer Ingelheim Pharma*

Next Generation of Aseptic Filling: Highest Flexibility meets latest Regulations of Annex 1
Sébastien Trichot, *Sanofi*
Edgar Bauer , *Bausch+Ströbel*

Flexible Production for Parenterals, from Vision to Execution
Dr Friedrich Haefele, *formerly Boehringer Ingelheim*

Digitalisation & Artificial Intelligence

Accelerate Automation Project Implementation and Reduce Risk with a Digital Twin
Rasmus Wendelboe Jørgensen, Novo Nordisk
Vicky Athanasiou, Emerson

Live Demos
- Virtual Pharma Campus
  Pharmaplan
- Digital Assistant for Maintenance at the Shopfloor
  ZETA
- Going to Market Faster in Life Sciences, Leveraging the Emerson Digital Twin
  Emerson Automation Solutions
- Kneat Gx: Live Digital Validation Software Demonstration
  Kneat Solutions

Case Study: Design & Implementation of a new highly-automated modular OSD Production Facility at Bayer Leverkusen
Andreas Bail, *Bayer*
Anton Kopitzsch, *Glatt*

Integrating Digitalisation & Robotics in Pharmaceutical Manufacturing: Strategies, Challenges, and Compliance in the Digital Era
Maja Karovic, *F. Hoffmann-La Roche*
Yvonne Duckworth, *CRB*

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*

Continued Process Verification Using Automated Data Assessment
Dr Philip Hörsch, *Vetter Pharma-Fertigung*
Bettina Schroeder, *Vetter Pharma-Fertigung*

Digitalisation and AI from the Inspector's Point of View
Dr Arno Terhechte, *Local GMP Authority Münster, Germany*

AI (Artificial Intelligence) in Manufacturing
Dr Monika Hupfauf, *KOCH / HUPFAUF Attorneys-at-Law*
Amir Abou Elmagd, *Genome Lawyers*

Benefits and Challenges in Developing a GenAI Solution for a GxP-relevant Process
Dr Rolf Roth, *Merck Healthcare*
Stephane Guillet, *Merck Healthcare*

Artificial Intelligence (AI) for Discrepancy Management
Dr Philipp Fey, *Boehringer Ingelheim*
Jorge Gil-Hernandez, *Boehringer Ingelheim*

Application of dynamic Learning Systems to increase Efficiency Increase in Pharma Production Lines
Felix Georg Müller, *plus10*
Martin Heitmann, *d-fine*

AI in Medical Image Processing
Daniel Wolf, *Ulm University Medical Center*

Trends in Barrier Systems & Robotics

Air Velocity at Working Position and other Cleanroom (Airflow) Challenges in new Annex 1
Jörg Zimmermann, *Vetter Pharma-Fertigung*
Dr Johannes Rauschnabel, *Syntegon Technology*

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*

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*

Studies and Future Trends for Zero Human Interactions in Aseptic Filling
Dr Arne Schröder, *Vetter Pharma-Fertigung*
Tobias Resch, *Stäubli Tec-Systems*

"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*

Implementation of RABS Systems in Small Volume Manufacturing
Marta Rodríguez Vélez, *Letipharma*

Aseptic Transfers in Small Batch Filling – Industry Standards and new Approaches to meet Annex 1
Thorsten Haefner, *PSM*
Sebastian Hillbrand, *SKAN*

A Case Study highlighting the Validation of a closed gloveless Aseptic Filling Workcell
Joachim Vereecke, *White Raven* | Brent Lieffers, *Cytiva*

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*

Benefits of Digitalisation in Sterile Testing
Katharina Schlereth, *Labor LS* | Harald Kiesel, *SKAN*

Compliance of Annex 1 Requirements for Glove Integrity Testing
Jason Creek, *Roche Diagnostics*
Kenan Kanmaz, *Optima Pharma containment*

Barrier Systems – Current GMP Requirements
Dr Daniel Müller, *Local GMP Authority of Baden Württemberg, Germany*

Cleanroom Challenges in Ongoing Operations

Cleanroom Garments – Clothing Basics, Barrier Functions and More
Jörg Mesenich, *Consultant*
Gabriele Schmeer-Lioe, *DITF – Deutsches Institut für Textil- und Faserforschung*

Qualification Study for Cleanroom Garments
Carsten Moschner, *CMC3*

Consumables and Cleanroom – Expectations and Experiences of an Inspector
Dr Daniel Müller, *Local GMP Authority Baden-Württemberg, Tübingen, Germany*

Disposables – Face Masks and the Like – what Protection do they really provide?
Monika Lamprecht, *Lamprecht Consulting & Coaching*

Cleanroom Wipes – What is Cleanroom-Compatible really?
Carsten Moschner, *CMC3*

Mopping Systems and the Associated Systems
Margarete Witt-Mäckel, *Witt Hygienemanagement*

Cleanroom Gloves – the Balancing Act between Cleanroom Suitability and Personnel Protection
Monika Lamprecht, *Lamprecht Consulting & Coaching*

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 Systems*

Pitfalls in microbiological Cleanroom Monitoring: Common Sources of Error in Qualification and Ongoing Monitoring
Melanie Braun, *Labor LS*

Live Demos

- Facility Monitoring Systems
  Particle Measuring Systems
- Continuous and rapid Monitoring of Bacteria in pharmaceutical Grade Water
  BWT Pharma & Biotech
- Surface Properities of Stainless Steel – how the Adhesion Behavior of Products can be influenced by modifying Stainless Steel Surfaces
  Bolz Intec

Case Study: Disinfectants and their Effectiveness on various Surfaces
Dr Hans-Joachim Anders, *Novartis Pharma*

Navigating the Challenges of Implementing new Annex 1 in Non-Sterile Manufacturing
Martina Gjorgjevska, *The Force CT* | Apostol Todorovski, *Sinceritas*

Sustainability/Green GMP

How can Sustainability be integrated into a pharmaceutical Quality Management System? ... or is it already included?
Dr Andrea Bauer, *ABC&Q*

Circular Economy Opportunities for the Pharmaceutical Industry
Susana Lima Santos, *BIAL*

The new F-Gas Regulation and its Impact on Pharmaceutical Freeze-Drying
Thomas Beutler, *GEA*

The EU Green Deal – Supply Chain Due Diligence Directive (CS3D) and the German Supply Chain Act (LkSG)
Leonie Evans, *Meisterernst Attorneys*

From Compliance to Sustainability: The Green GMP Journey
Ana Cláudia Pinho, *BIAL*

Quantifying the present and future environmental Sustainability of Cleanrooms
Justin Z. Lian, *University of Leiden*

Process Load Profiles as a Basis for a Cost Efficient and Sustainable Design of Utility Supply Systems
Bianca Bohrer, *PSM Saar* | Peter Gross, *PGC*

Sustainability Strategy for successful Reduction of GHG-Emissions in a SME
Dr Marius Beyersdorff, *Pekana*
Gabriele Brutscher, *Pekana*

Cleanroom Garments and Recycling – State of the Art
Carsten Moschner, *CMC3*

Sustainable Refrigeration Technologies: Overview and Implementation of innovative Air-Cooling Technology for Freeze-Drying Processes
Fabian Plaum, *Hof* | Christian Sonntag, *Roche*

Sustainable Heat and Cooling Systems – the LUnA Project
Michael Eberhard, *Abbvie* | Thomas Frank, *Refolution*

3R Initiative Within Roche's Global QC Network
Dr Sven M. Deutschmann, *Roche*

Single-Use Systems in Sterile & Biomanufacturing

Single-Use Systems – GMP Inspector's View
Dr Daniel Müller, *Local GMP Authority Baden-Württemberg, Tübingen, Germany*

Single-Use Technology in biopharmaceutical Production: An Overview from USP to Fill&Finish Technologies
Prof Dr Regine Eibl, *Zurich University of Applied Sciences*

Live Demos

- NEW Shadow Board for sterile Filtration of Drug Product (optimized for PUPSIT)
  Cytiva
- Simplifying the Qualification Journey of Single-Use Systems
  Merck

Quality Approach in Manufacturing of Single-Use Systems: How to assure Performance, Robustness, and Sterility of Single-Use Systems
Dr Marco Klatte, *Merck*

Case Study Roche: Exploring Alternative Media for Filter Flushing: Implications for Protein Concentration and Product Quality
Julia Mathy, *Roche Diagnostics*

Case Study Merck: Single-Use Technology in Aseptic Drug Product Manufacturing
Nicola Rutigliani, *Merck*

Case Study BioNTech: CCS for Processing Frozen Sterile Drug Products in a Single-Use Assembly
Dr Yuan-An (Angus) Liu

Case Study: Manufacturing of a Monoclonal Antibody with SUT
Jyotsna Agnihotry, *Flavine Europe*

Case Study Sanofi: Optimization of Single-Use Systems for Fill-Finish Manufacturing Operations to the new Requirements
Dr Rebecca Geyer, *Sanofi*

Particle Cleanliness Assessment of SUS
Gerald Dallmann, *SGS INSTITUT FRESENIUS*

E&L Testing of Process Materials used in Bioproduction – Case Studies on Study Design and showing the practical Hurdles when performing E&L Studies
Dr Koen Smets, *Nelson Labs*

ATMPs – Hurdles & Achievements in Quality and Safety

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Navigating the EMA Process: Key Insights from Filing for a TEMP
Dr Katja Aschermann, *Astator*

Challenges and Special Requirements for GMP Inspections of ATMPs
Alexander Kammerlocher, *Local GMP Authority Baden-Württemberg, Germany*

Quality Assurance of mRNA Vaccines for Human Use: the Role of the European Pharmacopoeia
Prof Dr Gerrit Borchard, *University in Geneva & member of the EDQM expert group*

Challenges on the Way to becoming a Contract Manufacturer
Dr Carolin Klemm, *DKMS Stem Cell Bank*

Industrial Scale in Vitro Expression of Bacteriophages and other Proteins
Matthias Steiger, *Invitris*
Tomaz Kasunic, *Jafra*

The Challenge of GMP Manufacturing of innovative Exosome-based Therapies
Sandrine Mores, *ExoBiologics*

From personalized Medicine to flexible Machine Solutions
Vilma Methner, *Optima*

Visible and Subvisible Particle Control for Cell Therapy from Development to Commercialisation
Dr Roman Mathaes, *Clear Solutions Laboratories*

Process Validation Sterile Drug Products: Strategy, Execution and maintaining the validated State
Dr Anne Orillo, *Novartis Pharma*

Vector Safety Assessment in Cell and Gene Therapy by NGS/TGS Sequencing
Dr Richard Gabriel, *ProtaGene*

Viral Clearance ATMPs – What if the Product is a Virus?
Sandra Zucchet, *Charles River Laboratories*

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*

Medical Cannabis – Cultivation, Processing, Systems & Technology

Challenges and Experiences from current GMP Inspections
Dr Rainer Gnibl, *District Government of Upper Bavaria, Germany*

The Intersection between GACP and GMP – View on the Inspection of Cannabis GACP and its Relation to GMP
Luis Meirinhos Soares, *Auditor and Consultant*

Case Study 1 – Cannabis Cultivation under GACP
Natalie Thurner, *Chemgineering*
Dr Michał Wójcicki, *Cannerald*

Drying of Medical Cannabis – Challenges for Process Validation
Tina Cacanoska, *PharmaRolly*

Update from the German Cannabis Agency
Dr Anne Wolf, *German Cannabis Agency (BfArM)*

Validation /Qualification – Experiences & Lessons learned
Dr Ingrid Walther, *ECA Cannabis Working Group*

Regulatory Status and Quality Standards of Cannabinoids Manufacture
Dr Giorgia Tossi, *Linnea*

Challenges in Microbiological Decontamination of Medicinal Cannabis
Dr David Surjo, *GOC NEXUS*

Contamination Control Strategy in Cannabis Manufacturing
Martina Gjorgjevska, *The Force CT*
Apostol Todorovski, *Sinceritas*

Case Study 2 – Pharmaceutical Cannabinoid Extractions: Balancing Efficiency and Quality
Dr Nikos Xynos, *Nomad Labs Scientific*

Digitalisation in Cannabis Production
Hannes Schubert, *Ness Online*

Israel Medical Cannabis Regulation
Dr Viviana Braude, *Cronos*

Medical Cannabis Manufacturing & Compounding: Regulatory Issues to be aware of upfront
Dr Hanneke Later-Nijland, *Genome Lawyers*
Dr Monika Hupfauf, *KOCH / HUPFAUF Attorneys-at-Law*

The following close to 100 speakers from industry and authorities already have confirmed their participation (constantly updated):

Jyotsna Agnihotry
Flavine Europe, Germany, *Head of QA and Regulatory Affairs*

Dr Hans-Joachim Anders
Novartis Pharma, *Teamlead Analytical Science and Technology*

Dr Katja Aschermann
Astator, Germany, *Consultant*

Vicky Athanasiou
Emerson, Netherlands, *Director Process Simulation Europe*

Henning Austermann
Siegfried Hameln, Germany, *Head of Engineering*

Andreas Bail
Bayer, Germany, *PCT Lead Engineer*

Dr Andrea Bauer
ABC&Q, *Owner*

Edgar Bauer
Bausch+Ströbel, *Regional Sales & Business Development Director Europe, Global Key Account Manager*

Thomas Beutler
GEA, *Senior Director Lyophilization Technology Management*

Dr Marius Beyersdorff
Pekana, *General Manager*

Bianca Bohrer
PSM Saar, *CEO*

Prof Dr Gerrit Borchard
University in Geneva, *Chair of the mRNA Vaccines for Human Use Working Party at the European Pharmacopoeia*

Dr Viviana Braude
Cronos, Israel, *VP Quality and Regulations & Member of ECA's Cannabis Working Group*

Melanie Braun
Labor LS, *Lead Microbiological Services*

Tina Cacanoska
PharmaRolly, North Macedonia, *Chief Quality Officer and QP & Member of ECA's Cannabis Working Group*

Pasquale Cataldo
Roche Diagnostics, Germany, *Innovation Project & Lab Lead*

Jason Creek
Roche Diagnostics, Germany, *Expert for sterile manufacturing and lab lead*

Gerald Dallmann
SGS INSTITUT FRESENIUS GmbH, *Division Manager*

Christoph Dechow
Boehringer Ingelheim Pharma, Germany, *Head of Digital Transformation Management*

Yvonne Duckworth
CRB, USA, *Fellow of Digital Technology*

Prof Dr Regine Eibl
Zurich University of Applied Science, *Professor at the Zürich University and the platform leader for "Single-use technology" of the Swiss Biotechnet*

Leonie Evans
Meisterernst Attorneys, *Attorney and Partner*

Dr Philipp Fey
Boehringer Ingelheim, *Responsible for process and validation management for the global quality management system*

Thomas Frank
Refolution, *CEO*

Dr Richard Gabriel
ProtaGene, *Vice President R&D*

Ruben van der Galiën
GE HealthCare, Netherlands, *Qualified Person / Pharmacist*

Dr Rebecca Geyer
Sanofi, *Head of Implementation Management, Drug Product*

Jorge Gil-Hernandez
Boehringer Ingelheim, *Senior QA Manager for CSA*

Martina Gjorgjevska
The Force CT, *Quality Manager*

Dr Rainer Gnibl
District Government of Upper Bavaria, Germany, *GMP Inspector*

Katharina Golly
Novartis Pharma, Switzerland, *Senior Expert Engineering*

Peter Gross
PGC, *CEO*

Giacomo Guidi
IMA Life, *R&D Isolation Technologies*

Stephane Guillet
Merck HealthCare, *Quality Compliance Project Lead, Healthcare Quality, Global Healthcare Operations*

Dr Friedrich Haefele
Formerly Boehringer Ingelheim, *Pharma Congress Steering Committee*

Thorsten Häfner
PSM, Germany, *VP Business Development*

Martin Heitmann
d-fine GmbH, Germany, *Senior Manager*

Sebastian Hillbrand
SKAN, Switzerland, *Strategic Product Manager*

Dr Philip Hörsch
Vetter Pharma-Fertigung, Germany, *Director QA - Validation/ Risk Management/Trending*

Marcus Hoppe
Pfizer, *Technology Owner Engineering (Filling)*

Manfred Holzer
SKAN, *Strategic Product Manager ebeam Technology*

Dr Monika Hupfauf
KOCH / HUPFAUF Attorneys-at-Law, *Owner*

Dr Rainer Kahlich
Local GMP Authority Baden-Württemberg, Tübingen, Germany, *GMP Inspector*

Alexander Kammerlocher
Local GMP Authority Baden-Württemberg, Tübingen, Germany, *Surveillance of medical devices*

Kenan Kanmaz
Optima pharma containment, Germany, *Technical Sales Manager*

Maja Karovic
F. Hoffmann-La Roche, Switzerland, *Network Technology Lead Robotics*

Adrian Keller
SKAN, Switzerland, *Strategic Product Manager*

Harald Kiesel
SKAN, Switzerland, *Strategic Product Manager*

SPEAKERS

Dr Marco Klatte
Merck, *Technical Application Consultant - Single-Use Technologies*
Dr Carolin Klemm
DKMS Stem Cells, *Head of Production*
Horst Koller
HK Packaging Consulting, Switzerland, *CEO*
Anton Kopitzsch
Glatt, Germany, *Team Lead Automation Engineering*
Dr Timo Krebsbach
SKAN, Switzerland, *Strategic Product Manager*
Monika Lamprecht
Lamprecht C&C
Dr Hanneke Later-Nijland
Genome Lawyers, *Partner*
Justin Z. Lian
University of Leiden
Brent Lieffers
Cytiva, Canada, Senior Director, *Innovation Advocacy*
Dr Yuan-An (Angus) Liu
BioNTech, *Associate Director CMC*
Dr Maria Loos
Johnson and Johnson, *MSAT Senior Associate Scientist*
Dr Roman Mathaes
Clear Solutions Laboratories, *CEO*
Julia Mathy
Roche Diagnostics, Primary Packaging and Product Process Lead for Robotic Filling Line
Dr Christian Matz
Formerly F. Hoffmann-La Roche, *Aseptic Manufacturing & Single Use Technology Expert*
Jörg Mesenich
Mesenich Consulting, *Owner*
Vilma Methner
PTIMA pharma GmbH, *Sr. Market Development Manager ATMP*
Sandrine Mores
ExoBiologics, *COO*
Carsten Moschner
CMC3, *Founder*
Dr Daniel Müller
Local GMP Authority Baden-Württemberg, Tübingen, Germany, *Head of GMP Inspectorate*
Felix Georg Müller
plus10 GmbH, Germany, *CEO and Co-founder*
Dr Thomas Müller
Recipharm, *Sterility Assurance Manager*
Dr Anne Orillo
Novartis Pharma, *Senior Validation Lead*
Ana Cláudia Pinho
BIAL Portela &C^a, S.A, *Senior Manager, Sustainability*
Fabian Plaum
Hof, *Freeze-Drying and Freeze-Thaw applications*
Dr Johannes Rauschnabel
Syntegon Technology, Germany, *Head of the process development department*
Tobias Resch
Stäubli Tec-Systems, *Key Account Manager*
Dr Bettina Rietz-Wolf
Local GMP Authority Baden-Württemberg, Tübingen, Germany, *Inspector*
Marta Rodríguez Vélez
Letipharma, Spain, *Quality Assurance*
Dr Rolf Roth
Merck HealthCare, *Head of Data Science and AI for Global Healthcare Operations and Principal Technical AI Lead*
Nicola Rutigliani
Merck, *Aseptic Production Associate Director*
Stylianos Sampanis
Sanofi-Aventis Deutschland GmbH, Germany
Yves Samson
Kereon AG, Switzerland, *Founder and Chairman*
Susana Lima Santos
BIAL Portela &C^a, S.A, *Environment Specialist*
Dr Prachi Sawant Raschdorf
GE HealthCare, Netherlands, *Qualified Person / Pharmacist*
Luigi Scaffidi
Boehringer Ingelheim Pharma, Germany
Katharina Schlereth
Labor LS, *Head of Test for Sterillity*
Gabriele Schmeer-Lioe
DITF - German Institutes for Textile and Fiber Research Denkendorf, *Scientist; Head of the Cleanroom Textiles and Electrostatics Laboratory*
Dr Arne Schröder
Vetter Pharma-Fertigung, Germany, *Head of Production in the area of manufacturing and filling of sterile drug products*
Hannes Schubert
Ness Online, *CEO*
Dr Frank Sielaff
Regional GMP Authority, Darmstadt, Germany, *GMP Inspector*
Dr Koen Smets
Nelson Labs, *Scientific Expert E&L*
Dr Frenk Smrekar
Jafral Ltd., *CEO and Co-Founder*
Luis Meirinhos Soares
Auditor and Consultant, former GMP Inspector at INFARMED, Portugal, *Head of Compliance and Regulatory Affairs & Member of ECA's Cannabis Working Group*
Christian Sonntag
Roche, *Senior Project Manager*
Ivan Spiro
Particle Measuring Systems, *Sales Manager*
Matthias Steiger
Invitris, *Research Scientist*
Dr David Surjo
GOC NEXUS GMBH, Germany, *CEO*
Dr Arno Terhechte
Local GMP Authority Münster, Germany, *Medicines Inspector*
Apostol Todorovski
Sinceritas, *Head of Quality Control*
Dr Giorgia Tossi
Linnea, Switzerland, *Chief Quality Officer & Member of ECA's Cannabis Working Group*
Natalie Thurner
Chemgineering, *Senior Consultant Pharma Compliance*
Sébastien Trichot
Sanofi, *FF&P Equipment Leader – Design Team, Global Engineering*

Vaccines
Klaus Ullherr
Syntegon Technology, Germany, *Senior Product Manager*
Dr Geert Vandenbossche
C&E Solutions BV, *Owner*
Joachim Vereecke
White Raven, Belgium, *COO and Co-Founder*
Ralf Wagner
Optima pharma, Germany, *Director Sales D/A/CH, Spain, Portugal*
Dr Ingrid Walther
Chairman of the ECA Working Group on Annex 1,
Leader of the ECA Cannabis Working Group, Consultant
Rasmus Wendelboe Jørgensen
Novo Nordisk, Denmark, *Automation Lead*
Patrick Wieland
Bausch+Ströbel, *Global Lead Business Development*
Dr Anne Wolf
German Cannabis Agency (BfArM), *Scientiest*
Dr Michał Wójcicki
Cannerald, *Chief Sales and Medical Officer*
Dr Sebastian Wibbeling
Fraunhofer-Institut for Material Flow and Logistics IML, Germany, *Head of Health Care Logistics*
Margarete Witt-Mäckel
Witt Hygienemanagement, *Founder*
Daniel Wolf
Ulm University Medical Center
Dr Nikos Xynos
Nomad Labs Scientific, *Founder, Managing Director*
Jörg Zimmermann
Vetter Pharma-Fertigung, *Vice President Vetter Development Service, External Affairs*
Sandra Zucchet
CRL, *R&D Scientist for Viral Clearance*

ORGANISATIONAL ISSUES

Fees
€ 790,- for the one day ticket plus VAT. These one day tickets allow you to follow any track offered that day (you can also switch between the tracks any time). They include a lunch and beverages during the tracks and in breaks as well as the free visit of the PharmaTechnica Expo and the social event on the evening of the first congress day. Charges are payable after receipt of invoice. Please note that due to the special fees for the congress, ECA membership discounts are not applicable.

PharmaTechnica Expo
Parallel to the tracks there will be the PharmaTechnica Expo. Take advantage of this opportunity to get to know new technologies, products and services at the stands of the close to 120 international exhibitors.

Location
RheinMain CongressCenter (rmcc)
Friedrich-Ebert-Allee 1 | 65189 Wiesbaden
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Contacts – Conference Tracks
For questions regarding the content of the tracks:
Cleanroom Challenges in Ongoing Operations | Sustainability/Green GMP
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European Aseptic Technologies & Annex 1 Conference | Trends in Barrier Systems & Robotics | Digitalisation & Artificial Intelligence
Dr Andreas Mangel (Operations Director),
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Single-Use Systems in Sterile & Biomanufacturing
Dr Robert Eicher (Operations Director),
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Organiser
CONCEPT HEIDELBERG –
On behalf of the ECA Academy
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Please note
Exhibition Visit: The PharmaTechnica Expo will also be open to visitors on both days who are not attending the Congress. Please be aware, though, that you will need to register in advance of the visit. The visit of the exhibition does not entitle you to also attend any of the tracks.

Congress Materials: Please note that there will not be any print-outs at the Congress. Instead you will receive all available presentations prior to the Congress as Downloads.

Room Reservations: There will be no room reservations via Concept Heidelberg. Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice. Charges are payable after receipt of the invoice.

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Registration Form:
(06221) 84 44 34

E-Mail:
info@concept-heidelberg.de

Internet:
www.pharma-congress.com

Congress Dates

Tuesday, 8 April 2025, 09.00 - 18.00 h
Wednesday 9 April 2025, 09.00 - 17.00 h
Registration
Tuesday & Wednesday, 8/9 April 2025, 08.00 - 09.00 h

Fees

The one day ticket is available for € 790,- plus VAT. It includes participation in any track on that day and the visit of the PharmaTechnica Expo. In addition, lunch and beverages during the tracks and in breaks as well as the social event on the evening of the first congress day, 8 April is included; please mark if you would like to attend the Social Event.

Location

RheinMain CongressCenter (rmcc)
Friedrich-Ebert-Allee 1
65189 Wiesbaden
Phone: +49 (0) 611 1729-444
E-Mail: veranstaltungsservice-rmcc@wicm.de

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Please also mark the day you plan on attending the Congress. To be able to prepare the conference rooms, we would appreciate if you also marked the track you are interested in (Please only mark one track per day).

The GMP PharmaCongress Tracks	Participation on 8 April 2025 ☐	Participation on 9 April 2025 ☐
European Aseptic Technologies & Annex 1 Conference	☐	☐
Digitalisation & Artificial Intelligence	☐	☐
Trends in Barrier Systems & Robotics	☐	☐
Cleanroom Challenges in Ongoing Operations	☐	☐
Sustainability/Green GMP	☐	☐
Single-Use Systems in Sterile & Biomanufacturing	☐	☐
ATMPs	☐	☐
Medical Cannabis	☐	☐
Participation in Social Event	☐	n.a.
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Please scan the code to read the **full agenda and details** of the GMP PharmaCongress or to **register directly online** – or visit www.pharma-congress.com

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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