GENAP SUMMIT 2025

Munich, Germany

GENAP SUMMIT
ASEPTIC PROCESSING TECHNOLOGY | GENE & CELL THERAPY

20 — 21 February 2025

Munich Marriott Hotel

Aseptic Processing Technology | Gene & Cell Therapy: CMC Analytics & Manufacturing

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HealthcareTech OUTLOOK

LAB WORLD

BioPharma Asia

P-BIO
Portugal's Biotechnology Industry Organization
Associação Portuguesa de BioIndústria

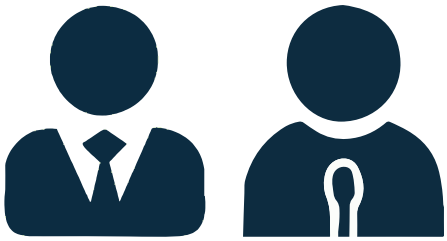
Welcome to the GENAP Summit 2025! This year, we are excited to present a streamlined, single-track format that brings together critical topics in pharmaceutical and biotech innovation, with a primary focus on aseptic production technologies and relevant aspects of gene and cell therapy. Our unified track will cover essential areas such as aseptic processing, advanced therapy medicinal products (ATMPs), fill/finish processes, Pharma 4.0, robotics, and regulatory considerations.

While the focus remains on aseptic production, we will also explore topics from gene and cell therapy that intersect with aseptic processing, including analytical development and process strategies. Our sessions will provide valuable insights into regulatory updates, implementation strategies, and best practices to ensure safe and compliant aseptic production. You'll gain knowledge on environmental monitoring systems, facility cleaning, disinfectant qualification, and cleanroom operations.

Join us in Munich to explore these vital subjects, connect with industry leaders, and gain actionable insights into the future of pharmaceutical and biotech innovation. We look forward to welcoming you to GENAP Summit 2025!

EPM Group Executive Summary

WHO You Will Meet



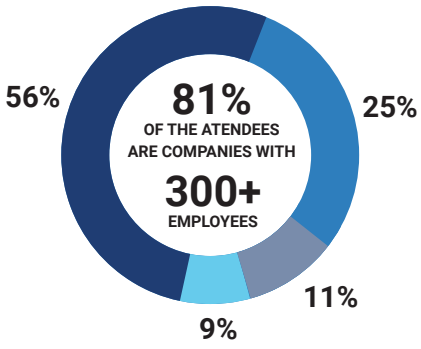
80+
Attendees

25+
Speakers

RATIO

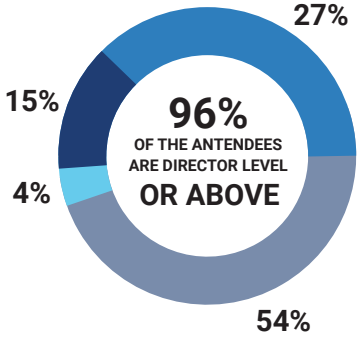
Bio/pharmaceutical manufacturing **65:35** Vendor/Solution Providers

Company Size of Attendees



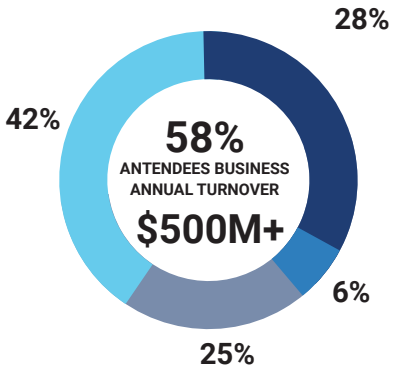
- 1000+ employees
- 300-999 employees
- 50-299 employees
- less than 49 employees

Job Title of Attendees



- C-level
- SVP/VP
- Snr Director/Director
- Snr Manager/Manager

Attendee Company Annual Turnover



- 1 Billion
- $500-999Million
- $50-499 Million
- <50 Million

HOW You Will Benefit

x1000+

Relive the conference full Acess to documentation, footages and videos.

x10+

Hours of Networking forge new professional contacts.

x20+

Case Studies Analisys

Companies Attending Our Events

FEEDBACK

94%

RATED EVENT

★★★★★

Quality of the speakers
Sharing of the best practices
Spectrum of industries
Intimate atmosphere

98%

WOULD RECOMMEND THE EVENT TO COLLEAGUES

Learn The Key Practical Points

Implementing HACCP in Contamination Control: Learn how to apply HACCP principles effectively for designing and implementing a robust Contamination Control Strategy.

Navigating Annex 1 Regulatory Updates: Understand the challenges of Annex 1 implementation, including real-world inspector findings, validation of cleanroom garments, and facility compliance strategies.

Enhancing CCS Compliance: Gain insights into compliant yet practical approaches for Contamination Control Strategies through real-world case studies.

Optimizing Aseptic Fill/Finish Solutions: Explore flexible solutions for small batches, from classic to gloveless systems, and their potential in decentralized manufacturing.

Adapting to Pharma 4.0 in Aseptic Manufacturing: Discover the role of robotics, automation, and digitalization in transforming aseptic manufacturing processes.

Addressing Challenges in Aseptic Obesity Care Applications: Learn about the unique challenges and innovative solutions in aseptic manufacturing for obesity care products.

Strengthening Technical Capabilities in Parenteral Manufacturing: Examine strategies for enhancing technical infrastructure and process capabilities in parenteral manufacturing.

Streamlining CMC for Gene Therapy: Learn how to align CMC and regulatory strategies to accelerate gene therapy development while navigating FDA requirements.

Advancing Cell Line Development: Discover cutting-edge innovations driving efficiency and quality in cell line development for biomanufacturing.

Connecting GMP Compliance to Advanced Therapies: Understand how to integrate GMP compliance into the manufacturing of cell and gene therapies.

Insights into Pre-fill Syringes in Fill/Finish Facilities: Explore the opportunities and challenges of pre-fill syringes and their impact on modern fill/finish operations.

Maximizing Efficiency in Gloveless Fill/ Finish: Investigate the benefits of gloveless systems in scaling out decentralized manufacturing solutions.

Leveraging AI and Pharma 4.0 in Regulatory Compliance: Examine how artificial intelligence and Pharma 4.0 concepts can enhance compliance, productivity, and innovation in aseptic processing.

Strategies for Future-proofing Aseptic Manufacturing: Gain forward-looking perspectives on balancing compliance, innovation, and operational efficiency in aseptic and ATMP manufacturing.

Meet
The Speakers

Alberto Gonzalez

Global Sterility Assurance and Microbiology at Takeda

Alan Kelly

Subject Matter Expert (Aseptic Fill Finish) at PM Group

James Drinkwater

Head of GMP Compliance at Franz Ziel

Christiane Niederlaender

Vice President Technical CMC at Parexel

Klaus Ullherr

Senior Product Manager at Syntegon Technology

Felix Müller

Co-Founder & CEO at plus10 – a Fraunhofer AI Research spinoff

Miriam Haak

Director Cell Line Development and Site Head at Cytiva

Faye Litherland

Director of Process Technology at FPC Life Sciences

Rolf Lenhardt

Founder and Managing Director at Teclen GmbH

Thomas Meindl

Head of Department at Labor LS Se & Co. KG

Gerald Dallmann

Division Manager at SGS

Petra Merker

Expert Biological Quality Control at Bayer AG

Richard Denk

Senior Consultant Aseptic Processing & Containment at SKAN AG

Ruben Van Der Galiën

Qualified Person/ QA Specialist at GE HealthCare

Steve Marnach

EMEA training manager & critical environments specialist at DuPont

Varadharaj Vijayakumar

Senior Subject Matter Expert- Aseptic Fill Finish at WuXi Biologics

Robert Kibele

Business Development Manager at groninger & co. gmbh

Pranvera Apostoli

Manager of Regulatory Affairs and Quality Assurance at Profarma

Matthias Angelmaier

Global Technology Partner and Senior SME for Fill-Finish and Isolator Technology at Pharmaplan

Mauro Giusti

Senior Director, Parenteral Technical Knowledge at Eli Lilly and Company & President, PDA Italy Chapter

Anilkumar Kangokar

Director of Process Engineering at Repligen Corporation

Scientific Agenda

DAY 0 WEDNESDAY, FEB 19

18:00 - 20:00	GENAP Pre-Conference Cocktail Reception Munich Marriott Hotel, Berliner Str. 93, 80805 München, Germany

DAY 1 THURSDAY, FEB 20

8:00 - 8:30	GENAP Summit: Registration

Morning Chairperson:

James Drinkwater, Franz Ziel

Session 1: Exploring Next-Gen Bioprocessing

8:30 - 9:00	Optimizing CMC and Regulatory Pathways for Gene Therapy Success: Lessons from EU and FDA Engagements **Christiane Niederlaender, Vice President Technical CMC at Parexel**
9:00 - 09:30	Advancing AAV production through innovative cell line development **Miriam Haak, Director Cell Line Development and Site Head at Cytiva**
09:30 - 10:00	Scalability and reproducibility of the AAV9 capture step using KRM™ Chromatography System **Anilkumar Kangokar, Director of Process Engineering at Repligen Corporation**
10:00 - 10:30	Speed Networking
10:30 - 11:00	Morning Coffee Break **10:50** Sponsor Presentation: Cytiva

Session 2: Pharma 4.0 and Digital Validation

11:00 - 11:30	Intelligent Efficiency increase in pharma production lines through GMP-compliant AI software tools – Examples from Primary and secondary packaging lines and Auto-Injectors **Felix Georg Müller, Co-Founder & CEO of plus10 – a Fraunhofer AI Research spinoff.**
11:30 - 12:00	Robotics Technology - Addressing challenges in Annex 1 **Alan Kelly, Subject Matter Expert (Aseptic Fill Finish) at PM Group**

Session 3: Technical Innovations for Aseptic

12:00 - 12:30	Designing a Steam Free Aseptic Facility in a World Built for Steam - Are We Ready? **Faye Litherland, Director of Process Technology at FPC Life Sciences**

12:30 - 13:00	How Gloveless Fill & Finish Can Enable a Scale-Out Approach for Decentralized Manufacturing **Robert Kibele, Business Development Manager at groninger & co. gmbh**
13:00 - 14:00	Lunch Break

Afternoon Chairperson:

Christiane Niederlaender, Parexel

Session 4: Innovations in Fill/Finish and Parenteral Manufacturing

14:00 - 14:30	Development of Technical Capabilities for Parenteral Manufacturing **Mauro Giusti, Senior Director, Parenteral Technical Knowledge at Eli Lilly and Company & President, PDA Italy Chapter**
14:30 - 15:00	Key Opportunities and Challenges for Pre-Fill Syringes in Fill Finish Facilities **Varadharaj Vijayakumar, Senior Subject Matter Expert-Aseptic Fill Finish at WuXi Biologics**
15:00 - 15:30	Flexible Fill/Finish Solutions for Small Batches – From Classic to Gloveless **Klaus Ullherr, Senior Product Manager at Syntegon Technology**
15:30 - 16:00	Aseptic Lyophilization with the Help of Protective Membrane Products **Rolf Lenhardt, Managing Director at Teclen GmbH, Germany**
16:00 - 16:30	Afternoon Coffee Break
16:30 - 17:30	**Panel Discussion:** Accelerating ATMP Development: Regulatory and Technical Considerations • Strategies for efficient CMC development • The future of cell and gene therapies in a regulated environment • Collaborating with regulators for smoother approval pathways • Balancing Innovation and Compliance: Exploring sustainable facility designs and their impact on regulatory and technical frameworks for ATMP manufacturing Panelists: • Mauro Giusti, Eli Lilly and Company • Christiane Niederlaender, Parexel • Miriam Haak, Cytiva • Faye Litherland, FPC Life Sciences Moderated by: James Drinkwater, Franz Ziel
17:30	**End of GENAP Summit 1st day**
20:00 - 22:00	GENAP Summit: Gala Dinner Munich Marriott Hotel, Berliner Str. 93, 80805 München, Germany

DAY 2 FRIDAY, FEB 21

Morning Chairperson:

Richard Denk, SKAN

8:00 - 8:30	Opening of the GENAP Summit 2nd day registration

Session 5: Ensuring Aseptic Compliance and Quality

8:30 - 9:00	Connecting GMP Compliance to Gene and Cell Therapeutic Product Manufacturing **James Drinkwater, Head of GMP Compliance at Franz Ziel**

9:00 - 9:30	Application of the HACCP-Methodology for the Setup of a Contamination Control Strategy **Ruben van der Galiën, Qualified Person/QA Specialist at GE Healthcare**
9:30 - 10:00	Annex 1 - Challenges Facing an Actual Facility to Fulfill the Regulatory Requirements of the New Guidelines **Pranvera Apostoli, Manager of Regulatory Affairs and Quality Assurance at Profarma**
10:00 - 10:30	Analysis of surface contamination and particles for quality assurance **Gerald Dallmann, Division Manager at SGS**
10:30 - 11:00	Morning Coffee Break
11:00 - 11:30	2022 GMP Annex 1 – How to Validate Protective Cleanroom Garments? **Steve Marnach, EMEA training manager & critical environments specialist at DuPont**
11:30 - 12:00	Annex 1 Implementation and First Inspector Findings **Richard Denk, Senior Consultant Aseptic Processing & Containment at SKAN AG**
12:00 - 13:00	**Panel Discussion:** Strategies to Navigate Annex 1 Compliance and Aseptic Production Innovations • Balancing regulatory compliance with operational efficiency • Overcoming Annex 1 implementation challenges • The role of emerging technologies in aseptic manufacturing Panelists: • Pranvera Apostoli, Profarma • Robert Kibele, groninger & co. • Klaus Ullherr, Syntegon • Steve Marnach, DuPont Moderated by: Richard Denk, SKAN AG
13:00 - 14:00	Lunch Break

Session 6: Innovative Approaches to Aseptic Manufacturing and Contamination Control

Afternoon Chairperson:

Alberto González, Takeda

14:00 - 14:30	Continuous Real-time Environmental Monitoring for Aseptic Filling / CGT **Petra Merker, Expert Biological Quality Control at Bayer AG**
14:30 - 15:00	CCS case study: a compliant (yet practical and pragmatic) approach **Alberto González, Global Sterility Assurance and Microbiology at Takeda**
15:00 - 15:30	Insights into challenges and solutions for aseptic obesity care applications **Matthias Angelmaier, Global Technology Partner and Senior SME for Fill-Finish and Isolator Technology at PharmaPlan**
15:30 - 16:00	Specific challenges for Microbiological Quality Control for ATMPs **Thomas Meindl, Head of Department at Labor LS**
16:00	Closing remarks & End of GENAP Summit 2025

Biographies

Alan Kelly Subject Matter Expert (Aseptic Fill Finish) at PM Group

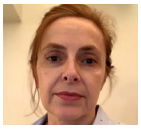
Alan is a seasoned, self-driven, and passionate Process Engineer with over 25 years of experience in various engineering roles within the Biopharmaceutical industry. His expertise includes serving as Project Lead, Process Engineering Manager for aseptic process start-up, Process/Technical Lead, and Program Lead in Fill Finish operations. Alan thrives in fast-paced, demanding environments, successfully leading teams to deliver Biopharmaceutical manufacturing processes and programs. His experience encompasses Fill Finish isolated filling lines with freeze dryers, syringe and cartridge inspection systems (both manual and automatic), high-speed packaging lines, and the management of product transfers to site.

Alberto Gonzalez Global Sterility Assurance and Microbiology at Takeda

Alberto is currently rolling out a Contamination Control Strategy program across Takeda's global network. Together with his team, Global Sterility Assurance and Microbiology, he has developed a practical CCS approach in collaboration with other global functions and has tested it at different sites prior to the implementation phase. Alberto is a pharmacist with 15 years of multinational experience in the pharma and biotech industries, and throughout his career he has been responsible for Quality Assurance, Quality Systems and Quality Compliance for sterile products. He is a regular speaker at conferences and is active in industry collaborations for topics related with Aseptic Process Simulations and Quality Risk Management.

Anilkumar Kangokar Director of Process Engineering at Repligen Corporation

Anilkumar Kangokar is an accomplished professional in the field of bioprocess technology, with over 20 years of experience in various aspects of bioprocessing, including development, optimization, scale-up, technology transfer, and manufacturing. Currently, Anilkumar serves as the Director of Process Engineering at Repligen Corporation, a position he has held since July 2024. Anilkumar held several key roles at various global organizations like Lonza, Stelis Biopharma, Merck Life Sciences and Biocon. Anilkumar holds a Master of Science in Biotechnology and a Master of Business Administration.



Christiane Niederlaender Vice President Technical CMC at Parexel

Christiane has spent 18 years in biological medicines, tissue, cell and gene therapy regulation, 12 years of this in governmental regulatory agencies, including over 9 years at the UK medicines regulator MHRA. Christiane has experience in CMC and regulatory strategy for all types of biological products, with a particular focus on gene and cell therapies, novel biotherapeutics, biosimilars and vectored vaccines. While at MHRA, she was the principal quality/CMC assessor for 10 centralized MAAs, including two full dossier applications for ATMPs as sole UK quality assessor (including CAR-T, cells). Christiane joined Parexel in January 2021 as Vice President Technical for CMC and now works with developers to accelerate the journey of advanced therapies into the clinic and to market.

Felix Müller Co-Founder & CEO at plus10 – a Fraunhofer AI Research spinoff

Felix Georg Müller is CEO and Co-founder of plus10 GmbH, which he founded in 2019 together with Pablo Mayer and Thomas Hilzbrich as a high-tech spin-off of Fraunhofer IPA (Fraunhofer is Europe's largest applied research association with more than 72 institutes) . He holds a diploma degree in production engineering from RWTH Aachen and Ecole Centrale Paris and additional data Science certifications. The spinoff plus10 develops, delivers and implements AI-based continuously learning software tools for the automated optimization of complex production lines and machines especially in regulated environment such as Pharma and Medtech production. At Fraunhofer, Felix Georg Müller developed new methods for production optimization, patented, evaluated and industrialized them. At the same time, he built up a Fraunhofer research group for autonomous production optimization, which granted for example the first place in the Hans-Jürgen Warnecke award for innovation.

Gerald Dallmann Division Manager at SGS

Gerald is working as division manager at SGS INSTITUT FRESENIUS GmbH in Dresden, proving since many years analytical services to pharmaceutical companies, producers of medical devices and microelectronic/ electronic products. He has more than 40 years of experience in application of surface and particles analysis methods for R/D, quality control and production monitoring. Gerald is active as a speaker on these topics in conferences, webinars and technical publications.

James Drinkwater Head of GMP Compliance at Franz Ziel

James Drinkwater is the Head of GMP Compliance at Franz Ziel Germany and lead of the PHSS: Pharmaceutical and Healthcare Sciences Society Aseptic processing special interest group. Franz Ziel are the largest barrier and cleanroom technology manufacturer in Germany with international projects that include filling lines (with partners) and Gene & Cell Therapy manufacturing platforms. James engages at a consultancy level through facility and process design then oversees and supports GMP compliance through project execution. James co-leads the PHSS Annex 1 focus with the PHSS as one of the European Commission appointed EU GMP Annex 1 complementing platforms through the targeted consultation process into the final publication.

Klaus Ullherr Senior Product Manager at Syntegon Technology

Klaus Ullherr (Senior Product Manager) has a degree in engineering. In March 2000 he joined Bosch Packaging Technology (which is Syntegon Technology since 2020) as project manager. Since 2002 he is product manager for the business field syringes/RTU with global product responsibility. His focused on market analysis, initiating new product developments, business development and is an expert for syringe/nested container processing. He is member of the PDA and trainer at the PDA syringe training course. He also works as an expert in the DIN/ISO group for primary packaging as well as in the APV, focus group packaging. Klaus is also member of ISPE and member of the program committee of the yearly ISPE Aseptic Conference.

Matthias Angelmaier Global Technology Partner and Senior SME for Fill-Finish and Isolator Technology at Pharmaplan

Matthias Angelmaier is a Global Technology Partner and Senior SME for Fill-Finish and Isolator Technology at Pharmaplan. He joined the company in 2022. His previous positions were at a multinational processing and packaging technology solutions provider where he started in 2009 as a project manager for handling complex customer projects. Since 2012 he was global responsible product manager for aseptic fill-finish, barrier and Isolator systems as well as process technology. His expertise includes process engineering, sterilization, biodecontamination, aseptic and high-potent Isolator applications, GMP and HSE-related fill-finish applications as well as topics related to advanced aseptic processing. He has a bachelor's degree in industrial and mechanical engineering as well as a master's degree in business development.

Mauro Giusti Senior Director, Parenteral Technical Knowledge at Eli Lilly and Company & President, PDA Italy Chapter

Dr. Mauro Giusti holds a Master Degree in Chemistry at University of Florence, he is Board Certified by National Chemist association and he is Board certified as Technical Director (Qualified Person) by the Italian Minister of Health. After serving as Army Officer, he joined Eli Lilly at the Italy manufacturing plant site in 1988. Over the 34 years with Eli Lilly, Dr. Giusti has covered several positions within the Lilly Manufacturing organization (Regulatory, Technical Services, Project Management, QC, QA, Operations, Technical Director/Qualified Person, Six Sigma Champion, Science and Technology, Procurement), dealing both with Lilly manufacturing plants as well as with Contract manufacturing in the Europe/Africa/Asia.

Miriam Haak Director Cell Line Development and Site Head at Cytiva

Miriam is leading the client services team, who develops custom stable producer cell lines for large scale adeno-associated virus (AAV) manufacturing. With Rep, Helper, Cap and the gene of interest incorporated into the genome, these cell lines allow enhanced scalability and reproducibility. The site focuses on cell line development to improve both AAV production robustness but also quality by reducing encapsidated host cell DNA using cell line engineering. Miriam joined Cytiva in 2024. Prior to that, she was heading the Cell and Gene Therapy site at ProtaGene CGT GmbH, who offers vector integration site analysis services for preclinical and clinical evaluations. Before that time, she worked at Miltenyi Biotec B.V. & Co. KG in the evaluation and establishment of partnership programs in the context of Miltenyi Biotec's BioIndistry CDMO services.

Petra Merker Expert Biological Quality Control at Bayer AG

Petra is holding a PhD with emphasis on Molecular Biology and Microbiology and is currently working as a "Biological Quality Control Expert" at Bayer in Berlin. She is supporting aseptic production processes as well as new technologies and filling lines. She has been a group leader of several QC laboratories within Biological QC at Bayer, like Sterility testing, Monitoring, and the Identification of germs. Petra is a member of different industry working groups, who aim to support the implementation of Rapid Microbiological Methods, esp. Alternative Monitoring Methods, like Biofluorescent Particle Counting (BFPCs)

Pranvera Apostoli Manager of Regulatory Affairs and Quality Assurance at Profarma

Pranvera received a MsC in Pharmacy primary from Faculty of Pharmacy, University of Tirana, Albania in 2012 and secondly nostrified from Charles University, Czechia in 2020. After two years as community pharmacist, she joined Profarma in 2015, as a part of the Drug Regulatory Affairs and PhV department. Following she joined the QA Department, mainly dealing with the managing of Annual Product Review and Validations. Additionally she was involved in upgrading the production processes until it reaching the EU GMP level. Also she is actually involved in managing the project of building a new production site for the production of small volume parenterals and large volume parenterals with EU standards, starting from conceptual design up to the end poing in their production site in Tirana.

Richard Denk Senior Consultant Aseptic Processing & Containment at SKAN AG

Richard Denk is working at the company SKAN AG, headquartered in Allschwil Switzerland in the position Senior Consultant Aseptic Processing & Containment. Richard is Member of the PDA ATMP Advisory Board and chair of the PtC of the Manufacturing of ATMPs. Richard is member of the PDA Isolator Expert Group and publisher of the PDA Paper “Isolator Surfaces and Contamination Risk to Personnel and Patient”. Furthermore, Richard is member of the ISPE Annex 1 and PIC/s Annex 2A commenting group, Founded the ISPE CoP Containment and SIG Future Robotics. Richard is Member of the ISPE European Leadership Team and Member of the ISPE CoP Sterile Product Processing. Richard is a global recognized subject matter expert on Aseptic Processing, ATMPs and Containment and has developed the containment pyramid.

Robert Kibele Business Development Manager at groninger & co. gmbh

Robert Kibele is business development manager for groninger’s fill & finish equipment for ready-to-use containers with a strong focus on robotic solutions. He has been with groninger for 3.5 years and holds degrees in packaging technology and industrial management. His main responsibilities are conducting market and trend analyses, product portfolio management, business development and partnerships. He is an active member of the PDA, the ISPE and the PHSS and works as an expert in the DIN/ISO group for pharmaceutical primary packaging.

Rolf Lenhardt Founder and Managing Director at Teclen GmbH

Rolf is a Process-Engineer by education (Dipl.-Ing. Univ.) and has 17 years of experience in the pharmaceutical industry. He is Founder and Managing Director of Teclen GmbH with deep knowledge in protective membrane for lyophilization.

Ruben Van Der Galiën Qualified Person / QA Specialist at GE HealthCare

Ruben van der Galiën is a pharmacist with over 5 years of experience within the pharmaceutical industry. In 2016, he graduated as a pharmacist at the University of Groningen and received his MSc-degree. After working for several years in hospital pharmacies, he started to work as a QA specialist / pharmacist at GE HealthCare in 2019. As of 2021, he became Qualified Person at GE HealthCare Eindhoven, The Netherlands. Currently, he is responsible for amongst others batch release activities, complaint handling and audits. Together with a multidisciplinary team, he was also responsible for setting up the Contamination Control Strategy together (CCS) and keeping it up-to-date. In 2023, he published a scientific article in PDA Journal on the set-up of a CCS applying the HACCP methodology.

Steve Marnach EMEA training manager & critical environments specialist at DuPont

Steve has a Masters' degree in Business Administration and has joined DuPont in 1995. After having held various positions within the company, he is currently the EMEA Training Manager and critical environments specialist for DuPont Personal Protection, the chemical protective & cleanroom garments business that Steve has been working for since 2003. A specialist in cleanroom & chemical protective garments, his articles were published in several specialised magazines (such as Salles Propres, Cleanroom Technologies, FarmaEspaña Industrial, Ascca News, Clean Air & Containment Review, C2 MGZN, SifaPlus or IOSH Magazine) and he has spoken at various events (such as Tema Renrum (Sweden), Pharmaceutical Cleanroom Technology Europe (UK), ContaminExpert (France), A3P International Congress (France), R3 Nordics (Finland), Reinraum Lounges (Germany), PHSS Annual conference (UK), PharmaForum 2023 (USA), SMi's 2nd Annual Next Generation Pharmaceutical Cleanroom (UK), 4th Annual HPAPI Summit or Cleanroom Expo (DK) or Cleanroom Forum (South Africa).

Thomas Meindl Head of Department at Labor LS Se & Co. KG

Dr. Meindl is a biologist and received his doctorate from the University of Basel at Novartis. He began his career at Sympore GmbH in Tübingen, where he was involved in the development of novel pharmaceuticals in the field of inflammation and immunosuppression. From there he moved to SKM Oncology, where he worked in clinical research for oncology studies. He has been working for Labor LS for 20 years as head of various departments (biological assays, endotoxins, molecular biology, disinfectant testing, validation officer, LIMS project manager, R&D, implementation of new molecular methods). He is a member of the ECA Microbiology Board and the FAH Board.

Varadharaj Vijayakumar Senior Subject Matter Expert-Aseptic Fill Finish at WuXi Biologics

Varadharaj Vijayakumar is an experienced Pharma/ BioPharma professional (16 ~Years), diligent in his core functional area (pharmaceutical technical operations) and committed to the profession. His main area of expertise is aseptic processing & areas of interests are sterility assurance, manufacturing technology, process validation, failure investigations, troubleshooting, continuous improvement, Lyophilization Technology, Isolators with VHP cycle developments and resolution of complex technical/ regulatory/ GMP issues. Additionally, he has experience in facing GMP inspections /audits and responding to the Inspectional observations of various regulatory agencies, such as WHO,USFDA, UK-MHRA, ANVISA, INVIMA, Russia, Romania, Germany, CDSCO etc. Varad has worked with medium to large, well-respected pharmaceutical/Biological products manufacturing like Franz Ziel GmbH Germany, Pfizer India ,Dr. Reddy's Laboratories Ltd, Emcure Pharmaceuticals (Oncology Division), Biocon Biologics (India) Ltd and Caplin steriles.

Faye Litherland Director of Process Technology at FPC Life Sciences

Faye Litherland is a Chartered Engineer, Chartered Scientist, and Fellow of the Institution of Chemical Engineers. She has over 25 years' experience of contributing to the successful delivery of projects in the Pharmaceutical, Biotech, and Life Sciences industries. Faye has experience working for consultancies, design houses, manufacturing companies, equipment vendors, private equity funds and as an expert witness. This broad experience and knowledge across the whole industry allows her to advise clients on business master planning and market trends in addition to her core skills in process and facility design. Although Faye has broad experience within the pharmaceutical and life sciences sector, her primary areas of interest are biological containment, biotechnology and clean utilities.

cytiva

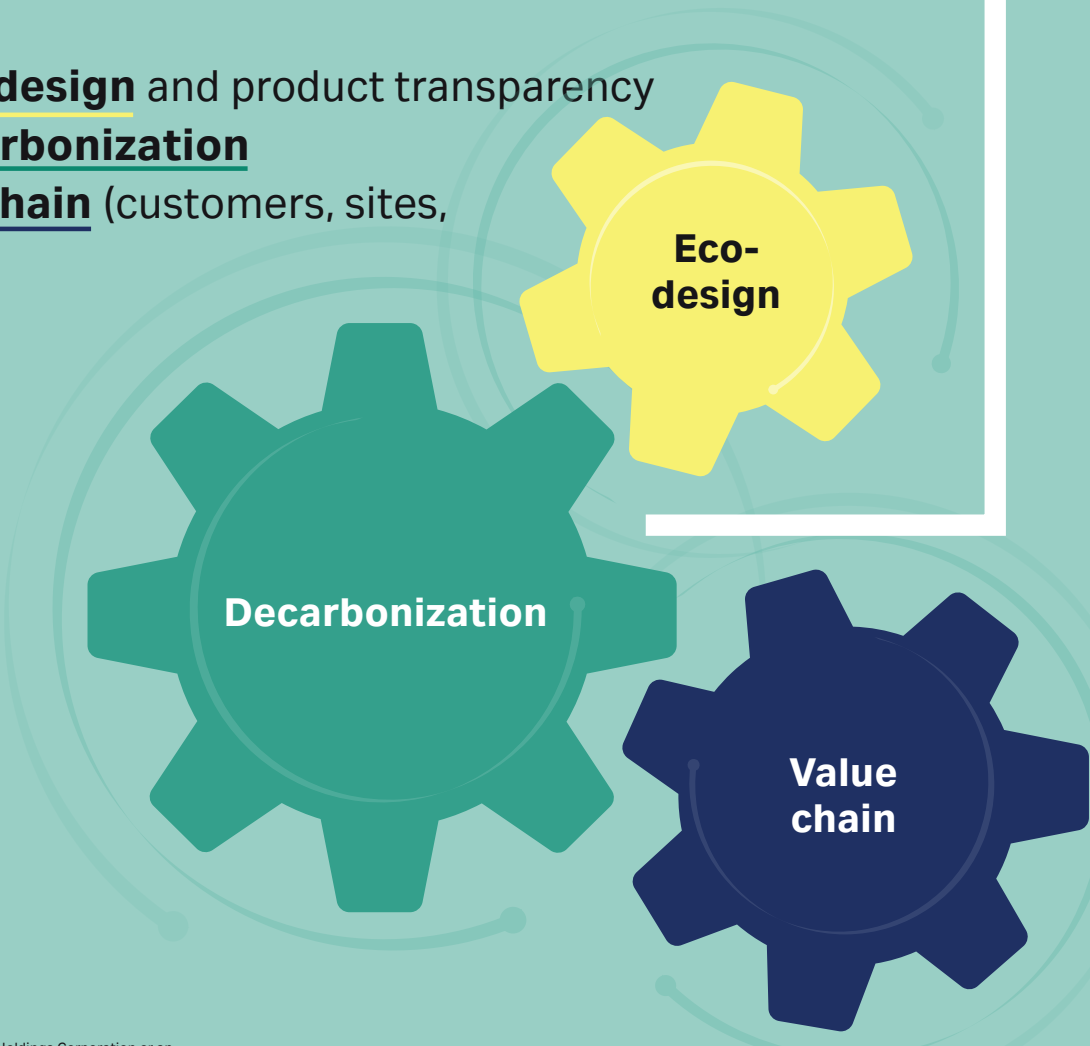
We are committed to set science-based

Net Zero

greenhouse gas (GHG) emission reduction targets.

We are

- Leading with **eco-design** and product transparency
- Accelerating **decarbonization** across the **value chain** (customers, sites, and suppliers)
- Building a culture of sustainability



cytiva.com/sustainability

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PLATINUM 2023 ecovadis Sustainability Rating

LRQA CERTIFIED ISO 14001

Science-based targets + Net Zero

WE SUPPORT UN GLOBAL COMPACT

This statement of our commitment to sustainability reflects our support of the UN Global Compact and its 10 principles on human and labor rights, environmental protection, and anti-corruption. It is echoed in relevant policies, procedures and strategic priorities across Cytiva.


Marienplatz
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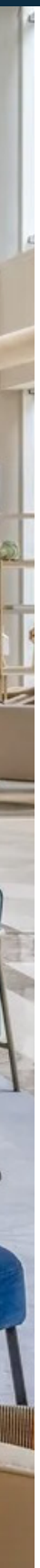
Munich Marriott Hotel



The Munich Marriott Hotel, located at Berliner Str. 93, 80805 Munich, Germany, offers a sophisticated and modern setting for the GENAP Summit 2025. Renowned for its exceptional service and state-of-the-art facilities, the hotel features versatile event spaces, including spacious meeting rooms and a stylish foyer for networking and exhibitions. Attendees will enjoy its convenient location, just a short distance from Munich's city center, with excellent transport links. The hotel also boasts comfortable accommodations, a wellness area, and outstanding dining options, making it an ideal venue for professional gatherings and a memorable experience for all participants.

Berliner Str. 93, 80805
Munich, Germany