GENAP SUMMIT 2026

Hotel NH Danube City
Vienna, Austria

GENAP SUMMIT
ASEPTIC PROCESSING TECHNOLOGY | GENE & CELL THERAPY

5 — 6 May 2026

Aseptic Processing Technology (APT)

Gene & Cell Therapy: CMC Analytics & Manufacturing (GCT)

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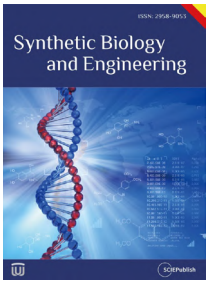
HealthcareTech OUTLOOK

LAB WORLD



PHARMA network

BioPharma Asia

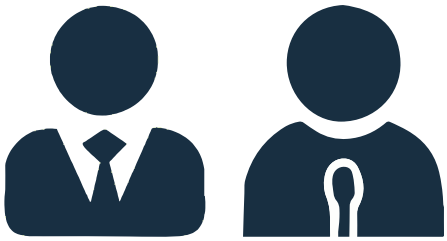
P-BIO Portugal's Biotechnology Industry Organization Associação Portuguesa de BioIndústria

CCP COLD CHAIN PLATFORM

GENAP Summit 2026 comes to Vienna with a focused, single-track program dedicated to the real challenges shaping aseptic processing and ATMP manufacturing today. Over two days, the Summit brings together regulatory experts, pharmaceutical manufacturers, technology providers, and ATMP developers to examine how Annex 1 expectations translate into inspection reality, operational decisions, and long-term manufacturing strategies. The agenda spans sterility assurance, contamination control strategies, aseptic process simulations, environmental monitoring, endotoxin control, and material-related risks, alongside advances in fill/finish technologies, gloveless and robotic systems, and smart manufacturing approaches. GENAP 2026 also addresses the critical interfaces between upstream bioprocessing, CMC strategy, and aseptic manufacturing for gene and cell therapies, offering practical insight into scale-up, validation, and lifecycle management. With an emphasis on case studies, inspection-driven thinking, and cross-functional dialogue, GENAP Summit 2026 provides a structured forum for professionals navigating the evolving regulatory and technical landscape of sterile and advanced therapy manufacturing.

EPM Group Executive Summary

WHO You Will Meet



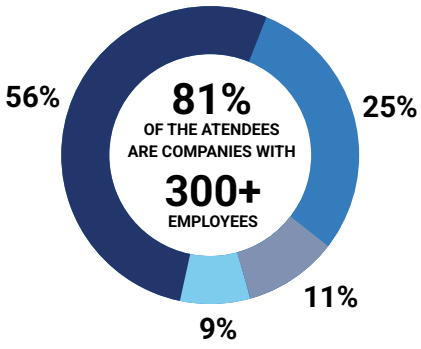
80+
Attendees

20+
Speakers

RATIO

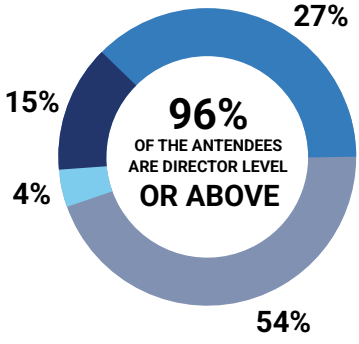
Bio/pharmaceutical manufacturing **65:35** Vendor/Solution Providers

Company Size of Attendees



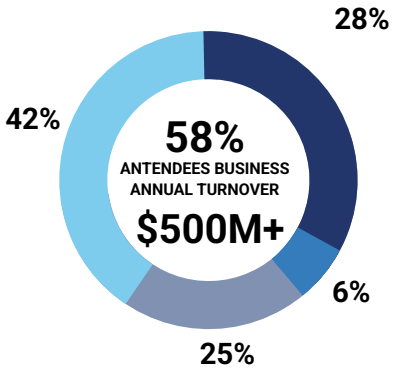
- 1000+ employees
- 300-999 employees
- 50-299 employees
- less than 49 employees

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

Applying Risk-Based Thinking under Annex 1
Understand how regulators interpret risk-based approaches in aseptic manufacturing, moving beyond “zero-risk” mindsets toward defensible, inspection-ready strategies.

Designing and Sustaining an Effective Contamination Control Strategy (CCS)
Learn how to build, maintain, and annually reassess a CCS using practical tools, APS outcomes, monitoring data, and lifecycle thinking.

Aseptic Process Simulation (APS): Challenges, Expectations, and Pitfalls
Gain insight into APS design, execution, and interpretation for complex products and ATMP processes, including common deficiencies seen during inspections.

Human Factors and Operator Interventions in Aseptic Manufacturing
Explore how personnel behavior, interventions, and organizational controls impact sterility assurance—even in highly automated environments.

Environmental Monitoring, Trending, and Data Integrity
Understand how to design robust environmental monitoring programs, manage excursions, and use trending data to support quality and regulatory decision-making.

Endotoxin Control Strategies: LAL vs Recombinant Methods
Examine the scientific, regulatory, and operational considerations when selecting and validating endotoxin testing methodologies.

Advanced Fill/Finish and Barrier Technologies
Learn about gloveless and fully automated fill/finish operations, isolator-based systems, and the practical considerations for implementation and validation.

Robotics and Automation in Aseptic and ATMP Manufacturing
Assess where robotics adds real value, where new risks emerge, and how automatation is viewed throught the lens of Annex 1.

Sterilizing Filtration Validation and Regulatory Expectations
Understand how to design and justify filtration validation strategies for downstream biologic manufacturing in line with current inspection practices.

Single-Use Systems and Material Risk Management
Explore risk assessment, lifecycle management, and regulatory expectations for single-use technologies in aseptic processing.

Extractables & Leachables and USP <665> in Practice
Gain practical insight into implementing USP <665>, managing E&L risks, and aligning engineering, quality, and regulatory requirements.

Container Closure Integrity (CCI): Expectations and Implementation
Learn how CCI fits into overall sterility assurance and what inspectors expect to see in terms of strategy, testing, and documentation.

Digitalization, Smart Manufacturing, and Pharma 4.0 under Annex 1
Examine how digital validation, data integrity, and smart manufacturing concepts can support—not complicate—regulatory compliance.

Inspection Readiness for ATMP Manufacturing
Understand how inspection expectations differ for ATMPs and how to prepare facilities, documentation, and teams accordingly.

ATMP Manufacturing Interfaces: From CMC to Aseptic Operations
Explore the challenges of scaling advanced therapies, aligning CMC strategy with aseptic manufacturing, and managing risk during technology transfer.

Future-Proofing Aseptic and ATMP Manufacturing
Gain perspectives on balancing compliance, innovation, and operational efficiency in an evolving regulatory and technological landscape.

Meet
The Speakers

Alberto Gonzalez

Global Sterility Assurance and Microbiology at Takeda

Andreas Krause

Senior RD&E Program Leader in RD&E Global Pharma and Personal Care at Ecolab

Zhihao Peter Qiu

External Advocacy Lead China at Roche Genentech

Ruben Van Der Galiën

Qualified Person / QA Specialist at GE HealthCare

Steve Marnach

EMEA Critical environments Specialist & Training Manager at DuPont

Shady Kamal

Principal Scientist at Galderma

Michele Cavalleri

Senior Scientific Director EBPT at Eurofins

Richard Denk

Senior Consultant Aseptic Processing & Containment at SKAN AG

Simone Biel

Senior Regulatory Consultant at Merck Life Science KGaA

Patrizia Muscas

Director Sterility Assurance, Global TS/MS at Eli Lilly and Company

Maria Bakoutsi

Senior Lab Operations Technician at Galapagos

Matthias Reis

Process Engineering Lead for Formulation & Filling at Takeda

Fabian Stutz

Pharmabotix

CEO at Pharmabotix AG

Frank J.T. Staal

Leiden University Medical Center

Professor at Leiden University Medical School

Allison Scott

BWT BEST WATER TECHNOLOGY

Principal Scientist at BWT Pharma & Biotech Inc

Marsha Steed

Founder & President at Steed MicroBio, LLC

David Estapé

Senior Fellow Bioprocess/ Associate at CRB Group GmbH

Klaus Ullherr

SYNTEGON

Senior Product Manager at Syntegon Technology

Joakim Larsson

GETINGE

Product Line Manager, Life Science Sterilization at Getinge Sterilization AB

Martin Lenz

TROX

Head of Business Development at TROX SE

Julia Vincenz

VTU engineering

MS&T Specialist at VTU Engineering

Scientific Agenda

DAY 0 MONDAY, MAY 4

18:00 - 20:00	Pre-Conference Cocktail Reception *Meliá Vienna, Altia Skybar – 58th Floor*

DAY 1 TUESDAY, MAY 5

8:00 - 8:30	GENAP Summit 2026 Registration

Morning Chairperson:
Patrizia Muscas,Director Sterility Assurance, Global TS/MS at Eli Lilly and Company

Session 1: Regulatory Expectations, Annex 1 & Inspection Readiness
Setting the regulatory and inspection context

8:30 - 9:00	FDA Warning Letter Deficiencies in Aseptic Processing **Marsha Steed, Founder & President at Steed MicroBio, LLC**
9:00 - 9:30	How to Be Inspection Ready for ATMP Products **Zhihao Peter Qiu, External Advocacy Lead China at Roche Genentech**
9:30 - 10:00	Challenging the Zero-Risk Mindset: A Risk-Based Approach to Annex 1 **David Estapé, Senior Fellow Bioprocess / Associate at CRB Group GmbH**
10:00 - 10:30	Speed Networking
10:30 - 11:00	Morning Coffee Break *Sponsor Spotlight Presentation (5 minutes)*

Session 2: Sterility Strategy, APS & Contamination Control Strategies (CCS)
Designing, mapping, and sustaining sterility assurance through APS, CCS, and digital tools

11:00 - 11:30	Writing a global procedure using AI and process mapping **Alberto González, Global Sterility Assurance and Microbiology Associate Director at Takeda**
11:30 - 12:00	Contamination Control Strategies (CCS) for ATMP processes: Mitigating risk for transfer disinfection of living cells and challenging materials such as apheresis bags **Dr. Andreas Krause, Senior RD&E Program Leader in RD&E Global Pharma and Personal Care at Ecolab**

Session 3: Monitoring, Microbiology & Endotoxin Control
Detecting, trending, and interpreting contamination risks

12:00 - 12:30	Recombinant Cascade Reagent vs LAL: A Detailed Analysis of Endotoxin Testing Methods **Shady Kamal, Principal Scientist at Galderma**
12:30 - 13:00	Online Water Bioburden Monitoring and Associated Data Trending **Allison Scott, Principal Scientist at BWT Pharma & Biotech Inc**
13:00 - 14:00	Lunch Break

Afternoon Chairperson:
David Estapé, Senior Fellow Bioprocess/Associate at CRB Group

Session 4: FFill/Finish, Cleanroom Infrastructure & Barrier Systems

Integrating equipment, environments, and automation to ensure robust and compliant aseptic operations

14:00 - 14:30	Gloveless, Fully Automated Fill/Finish Operations: Highlights and Points to Consider **Klaus Ullherr, Senior Product Manager at Syntegon Technology**
14:30 - 15:00	The Backbone of Cleanroom Excellence: How Integrated Ventilation, Air Conditioning and Pressure Control Enable Reliable and Energy-Efficient Operation **Martin Lenz, Head of Business Development at TROX SE**
15:00 - 15:30	Validation Process for Cleanroom Protective Clothing According to the 2022 GMP Annex 1 **Steve Marnach, EMEA Critical environments Specialist & Training Manager at DuPont**
15:30 - 16:00	Transfer of mature products from RABS to isolator lines **Matthias Reis, Process Engineering Lead for Formulation & Filling at Takeda**
16:00 - 16:30	Afternoon Coffee Break
16:30 - 17:30	**Panel Discussion:** From Annex 1 Theory to Inspection Reality: What Really Makes an Aseptic Strategy Defensible? • **Where do inspectors draw the line between "risk-based" and "under-controlled"?** How regulators evaluate justification, rationale, and decision-making across APS, CCS, EM, and automation. • **What breaks first in real inspections: systems, data, or people?** Practical lessons from warning letters, CCS reviews, monitoring excursions, and operator interventions. • **How much automation is enough—and when does it create new risks?** Balancing robotics, gloveless operations, and human factors under Annex 1 expectations. **Panelists:** • Marsha Steed, Steed MicroBio • Zhihao Peter Qiu, Genentech • Klaus Ullherr, Syntegon • Andreas Krause, Ecolab • Alberto González, Takeda Moderated by David Estapé, CRB Group GmbH
17:30	End of Genap Summit 1st Day
20:00 - 22:00	GENAP Summit GALA Dinner *Meliá Vienna – Altia Restaurant, 57th Floor*

DAY 2 WEDNESDAY, MAY 6

8:20 - 8:30	Day 2 Registration – GENAP Summit

Morning Chairperson:
Marsha Steed, Founder & President at Steed MicroBio, LLC

Session 5: Sterilization, Filtration, Single-Use & Material Risk

Managing critical material interfaces and control strategies under Annex 1 and evolving regulatory expectations

8:30 - 9:00	Sterilizing Filtration Validation in Aseptic Manufacturing Processes in Downstream Biologic Manufacturing **Michele Cavalleri, Senior Scientific Director EBPT at Eurofins**

9:00 - 9:30	Steam Sterilization & Transfer Solutions: Beta-Bags/-Containers and Transfer to Filling Line - Challenges & Opportunities considering EU GMP Annex 1 **Joakim Larsson, LS Sterilization product line manager, Getinge Sterilization AB, Sweden**
9:30 - 10:00	Single-Use Systems for Aseptic Processing: What Is the Risk? **Simone Biel, Senior Regulatory Consultant at Merck Life Science KGaA**
10:00 - 10:30	E&L USP <665>: Experiences, Challenges, and Best Practices **Julia Vincenz, MSAT Specialist at VTU Engineering**
10:30 - 11:30	Morning Coffee Break *Sponsor Spotlight Presentation (5 minutes)*

Session 6: Managing Complexity in Modern Manufacturing: Digitalization, ATMP & GMP Risk

Exploring how innovation, advanced therapies, and operational change create new challenges across modern GMP environments

11:30 - 12:00	Ex Vivo Gene Therapies for Immune Disorders: Preclinical, Regulatory and Clinical Development **Frank J.T. Staal, Professor at Leiden University Medical School**
12:00 - 12:30	Smart Manufacturing in the Light of Annex 1 **Richard Denk, Senior Consultant Aseptic Processing & Containment at SKAN AG**
12:30 - 13:00	Hidden GMP Risks in Laboratory Moves and Decommissioning Projects **Maria Bakoutsi, Senior Lab Operations Technician at Galapagos**
13:00 - 14:00	Lunch Break

Afternoon Chairperson:
Richard Denk, Senior Consultant Aseptic Processing & Containment at SKAN AG

Session 7: Future Aseptic Manufacturing: Digitalization, Process Design & Regulatory Evolution

Bridging emerging technologies, evolving guidelines, and real-world implementation challenges

14:00 - 14:30	New PDA TR22 a Milestone revision for Aseptic Processing: Examining Updates Affecting Industry Practices **Patrizia Muscas, PhD Director Sterility Assurance , Global TS/MS (SAT) Lilly a Medicine Company**
14:30 - 15:00	Setup of a Contamination Control Strategy for ATMPs using the Hazard Analysis Critical Control Point GMP-Methodology **Ruben Van Der Galiën, Qualified Person / QA Specialist at GE HealthCare**
15:00 - 15:30	State of the Art Robotics in CGT – Challenges and Opportunities **Fabian Stutz, CEO at Pharmabotix AG**
15:30 - 15:45	Afternoon Break
15:45 - 16:30	**Panel Discussion:** Designing Robust Aseptic & ATMP Manufacturing for the Next Inspection Cycle • **Are current facility and process designs truly future-proof?** Lessons from filtration, single-use systems, E&L (USP <665>), and CCI when preparing for long-term compliance. • **Where do digitalization and smart manufacturing really add value under Annex 1?** Moving beyond buzzwords: what inspectors actually trust in digital validation and data-driven oversight. **What changes when aseptic manufacturing meets ATMP scale-up?**

Managing CMC handovers, material risks, and operational complexity as advanced therapies move toward commercialization.

Panelists:
- Michele Cavalleri, Eurofins
- Simone Biel, Merck
- Julia Vincenz, VTU
- Patrizia Muscas, Lilly
- Ruben Van Der Galiën, GE

Moderated by Richard Denk, SKAN AG

16:30	End of GENAP Summit 2026

Speakers Biographies

DAY 1
TUESDAY, MAY 5

Marsha Steed
Founder & President at Steed MicroBio, LLC

Marsha is the Founder and President of Steed MicroBio, LLC which is an independent microbiology consulting firm and a Senior Microbiology Associate/Sterility Assurance Expert at Jeff Yuen & Associates, Inc. consulting firm. Marsha is a globally recognized consultant specializing in sterility assurance and contamination control matters in pharmaceutical, biotech and medical device companies. Marsha served as a USP Microbiology Expert Committee member (2020 – 2025 Cycle) and the chair of the USP Microbial Control and Sterility Assurance Subcommittee. Marsha studied Biology at Western New England University in Springfield, MA. Marsha is active in industry and currently serves on the Parenteral Drug Association (PDA) ATMP Advisory Board and has previously served on the PDA Education Advisory Board (EAB); Scientific Advisory Board (SAB) and has served on numerous PDA Task Forces and meeting planning committees.

Zhihao Peter Qiu
External Advocacy Lead China at Roche Genentech

Peter joined Roche/Genentech in 2022 from Innovent Biologics, China, where he was Chief Quality Officer. Prior to Innovent, Peter spent 14 years at FDA in multiple roles of increasing leadership responsibilities in the Office of Compliance and Biological Quality (OCBQ), Center for Biological Evaluation and Research (CBER), Office of In vitro Diagnostic Devices, Center for Devices and Radiological Health (CDRH), and the Office of Compliance (OC) and the Office of Pharmaceutical Sciences (OPMA), Center for Drug Evaluation and Research (CDER), where his most recent role was Division Director of the Division of Biotechnology Manufacturing in OPMA, responsible for managing the scientific review and quality evaluation of the manufacturing controls and facilities for Biologics license applications (BLA) and conducting pre-license/ pre-approval inspections for CDER regulated biological products.

David Estapé
Senior Fellow Bioprocess / Associate at CRB Group GmbH

David Estapé, a long-time biotechnology expert who holds a doctorate in chemical engineering and has over 25 years of experience in facility design and GMP consulting within the biotech, vaccine, blood plasma and ATMPs pharmaceutical segments. David has worked globally on major biotech projects of all sizes, from start-ups to lead pharmaceutical companies. With a strong interest in new technologies and regulatory trends, he participates heavily in organizations like the International Society for Pharmaceutical Engineering and BioPhorum. He works for CRB at the Basel office in Switzerland but works internationally.

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.

Andreas Krause
Senior RD&E Program Leader in RD&E Global Pharma and Personal Care at Ecolab

Dr. Andreas Krause is a Senior RD&E Program Leader in RD&E Global Pharma and Personal Care at Ecolab, based in Monheim, Germany. Andreas has 14 Years of experience in cleaning and disinfection of Pharma production areas and in the development of medical devices class III as sterile Injectables. He holds a PhD in chemistry with focus on regenerative medicine from the medical school of Hannover, Germany. Andreas leads cross functional R&D programs and portfolios for CIP/COP of product contact equipment, and manual cleaning and disinfection applications. He and the R&D team support the development and delivery of solutions for pharmaceutical manufacturing environments, with a strong focus on translating technical innovation into measurable business value. A key area of Andreas's work centers on cleaning and disinfection strategies for pharmaceutical production.

Shady Kamal
Principal Scientist at Galderma

Shady Kamal, PhD, is Principal Scientist, Manufacturing Science & Technology, at Galderma, Uppsala, Sweden, and Affiliate Researcher at Karolinska Institutet, Stockholm. He specializes in microbiological method development and validation, contamination control, and bacterial endotoxin testing, applying science-driven approaches to the manufacture of injectable biopharmaceuticals. He serves as an Expert Committee Member on the EDQM Bacterial Endotoxin Testing Working Party, contributing to the development and revision of European Pharmacopoeia standards, and is involved in the PDA Technical Report 82 revision. His career includes research appointments at MIT, Heidelberg University, and the University of Basel, with publications on microbial resistance and stress adaptation, bridging academic rigor and industry practice.

Allison Scott
Principal Scientist at BWT Pharma & Biotech Inc

Allison Scott has evaluated and supported rapid microbial technologies for air and water applications for over fifteen years. As part of this work, she is an active member and facilitator of the Modern Microbial Methods (M3) Collaboration, a group of industry experts dedicated to advancing the knowledge, adoption, and implementation of modern microbial technologies. Allison serves as a Principal Scientist at BWT Pharma & Biotech Inc., where she specializes in online water bioburden analyzers, and is also a member of the United States Pharmacopeia (USP) Microbiology Expert Committee. Allison holds a joint Ph.D. in Materials Science and Engineering from the University of Arizona and Materials Chemistry from the University of Rennes.

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.

Martin Lenz
Head of Business Development at TROX SE

Martin Lenz is Head of Business Development at TROX SE, bringing over a decade of experience in ventilation and air handling technologies. He began his career at TROX in 2011 within R&D, progressing through multiple leadership roles covering ventilation units, filters, fire protection, and software development. In 2020, he became Head of R&D before transitioning to his current role in international business development in 2023. Martin holds a degree in Mechanical Engineering, completed through a dual study program in cooperation with Bosch Packaging Technology. He is actively involved in industry standardization and associations, serving as Chairman of Eurovent's Product Group Air Handling Units and contributing to several working groups within Eurovent, CEN, VDI, and DIN.

Steve Marnach
EMEA Critical environments Specialist & Training Manager 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), and many more.

Matthias Reis
Process Engineering Lead for Formulation & Filling at Takeda

Matthias Reis is Process Engineering Lead for Formulation & Filling at Takeda. He has a background in electrical engineering and molecular nutrition, complemented by executive management studies, and brings broad industrial experience from companies including ABB, RUAG Space, and Nestlé. At Takeda, Matthias has held roles spanning change ownership, operational excellence, and process engineering, with a strong focus on translating engineering solutions into robust, GMP-compliant manufacturing operations.

Michele Cavalleri
Senior Scientific Director EBPT at Eurofins

Michele Cavalleri | GLP Facility Manager of the Biocidal Products Division in Eurofins BioPharma Product Testing Italy Senior Scientific Director of Eurofins BioPharma Product Testing Europe for the validation of efficacy processes, including aseptic filter validation and virus retention processes. He is also Eurofins Business Unit Cluster Manager the Biocide & Virus testing units of Eurofins BioPharma Product Testing Italy as well as GLP/ ISO 17025 test facility manager at the Eurofins site of Milan. Michele has a sound background in microbiology (MSc in microbial genetics) and virology and worked in Eurofins as an analyst and GLP study director in the microbiology department for many years. He strongly contributed to setup the filter validation testing lab in the site of Milan to meet the requirements of the biopharmaceutical and medical device industries.

Joakim Larsson
Product Line Manager, Life Science Sterilization at Getinge Sterilization AB

Joakim Larsson holds a Master's degree in Thermo and Fluid Dynamics from the Mechanical Engineering Faculty at Chalmers University of Technology in Gothenburg, Sweden. He joined Getinge in 1998 as a Process Engineer and has since held several key positions, including Process Design Manager and Technical Manager. Since 2012, he has been working as Product Line Manager for life science sterilization solutions, with a strong focus on innovation and customer-oriented product development.

Simone Biel
Senior Regulatory Consultant at Merck Life Science KGaA

Simone Biel is a Senior Regulatory Consultant with expertise in Single-Use Technology and filtration. She offers valuable regulatory guidance to both customers and internal stakeholders. With a strong focus on biopharmaceutical manufacturing, Simone has successfully assisted numerous drug manufacturers in implementing Single-Use Technology, gaining a comprehensive understanding of market needs and industry trends. Her primary goal is to ensure product performance aligns with quality and regulatory standards. Simone holds a Ph.D. in Microbiology from the University of Frankfurt.

Julia Vincenz
MS&T Specialist at VTU Engineering

Julia Vincenz is a consultant for the biopharmaceutical and pharmaceutical industry, with a focus on extractables and leachables strategies for biopharma drug substance and drug product development. She supports clients such as in the pharmaceutical industry in the late stages of process development and during commercial manufacturing. Julia Vincenz has a background in biotechnology, pharmaceutical quality management and medical devices.

Frank J.T. Staal
Professor at Leiden University Medical School

Frank Staal received his training at Utrecht University (Netherlands) studying Medical Biology receiving his Bachelor of Science (BSc) and Master of Science degrees both with distinction (cum laude). He obtained his PhD degree from Stanford University Medical School in Genetics under the guidance of professors Leonard and Lenore A. Herzenberg. He moved back to his native country working at the Dutch Cancer Institute (Amsterdam) and subsequently at Utrecht University as Fellow of the Dutch Royal Academy of Sciences (KNAW) with professor Hans Clevers. In the year 2000, he started his own laboratory as assistant professor at the Department of Immunology, Erasmus University of Rotterdam, where he became associate professor 4 years later.

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.

Maria Bakoutsi
Senior Lab Operations Technician at Galapagos

Maria Bakoutsi is a Senior Lab Operations Technician at Galapagos BV in Leiden, the Netherlands, working within the Global Digital Technology and Quality Engineering department. She holds a Bachelor’s degree in Biochemistry and Biotechnology and an MSc in Stem Cells and Regenerative Medicine. She joined Galapagos in 2023 as an R&D Technician, where her strong scientific background was complemented by a growing passion for management and continuous improvement, leading her to transition into Lab Operations. She brings hands-on experience from fast-paced biopharma environments, supporting GMP laboratory operations and leading cross-functional initiatives in lab optimization, equipment management, change control, and compliance.

Patrizia Muscas
Director Sterility Assurance, Global TS/MS at Eli Lilly and Company

33 years of experience in Pharmaceutical and Bio pharmaceutical fields. Experience raised working with International Companies (GSK; Chiron Vaccine; Eli Lilly). During these years of experience, I have been involved, as project team member, in validation and improvement of production sites for Sterile liquids, Dry powders, Vaccines, and non-sterile products. For more than 10 years my primary role was dedicated to oversight of all sterility assurance aspect/topics with regards to the Eli Lilly Italian production lines (Isolator and RABS technology). I was a key member of the project teams involved in the design /construction of new global platform lines with responsibility for all Sterility Assurance topics/strategies I contributed to the creation of the Company Global Sterility Assurance Strategies.

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.

Fabian Stutz
CEO at Pharmabotix AG

Fabian Stutz is CEO & Head of Sales with Pharmabotix AG, a company that provides clients with innovative robotics and automation solutions for the pharmaceutical industry. From building an effective team to maintaining a large customer network, he is adept at driving business development while delivering exceptional service to customers with a direct communications approach. Fabian is passionate about trying new ideas and providing honest feedback on feasibility to ensure customer satisfaction.

Conference Venue
Hotel NH Danube City

The NH Danube City, located at Wagramer Straße 21, 1220 Vienna, Austria, provides a modern and professional setting for the GENAP Summit 2026. Ideally positioned next to the Vienna International Centre and just minutes from the city center via direct underground connections, the hotel offers excellent accessibility for international attendees. The venue features contemporary meeting facilities with natural daylight, spacious conference rooms, and a dedicated foyer area ideal for networking and exhibitions. Guests can enjoy comfortable accommodations, on-site dining at the Tarragona restaurant, and fitness facilities, making NH Danube City a convenient and well-equipped location for a productive and engaging summit experience.

Wagramer Str. 21, 1220
Wien, Austria

Networking Venue Meliá Vienna

The Meliá Vienna, located in the iconic DC Tower 1, will host the GENAP Summit 2026 networking events, including the Pre-Conference Cocktail Reception and Gala Dinner.

The Gala Dinner will take place at the Altia Restaurant (57th floor), the highest restaurant in Austria, offering breathtaking panoramic views over the city through its floor-to-ceiling windows. The Pre-Conference Cocktail Reception will be held at the Altia Skybar (58th floor), providing a stylish and relaxed setting with stunning views across Vienna.

With its modern design, elevated setting, and exceptional atmosphere, the Meliá Vienna offers the perfect environment for high-level networking and memorable evening experiences.

Mélia Vienna
Donau-City-Straße 7, 1220 Wien, Austria