GENAP SUMMIT 2024

Geneva, Switzerland

GENAP SUMMIT
ASEPTIC PROCESSING TECHNOLOGY | GENE & CELL THERAPY

22 — 23 February 2024

Hilton Geneva Hotel & Conference Centre

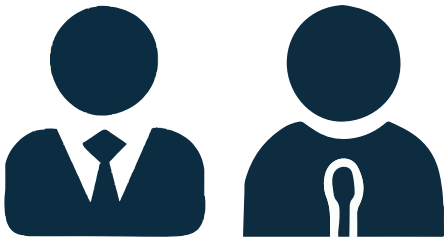
Aseptic Processing Technology (APT) | Gene & Cell Therapy: CMC Analytics & Manufacturing (GCT)

GENAP SUMMIT

Welcome to the GENAP Summit (Gene & Cell Therapy | Aseptic Processing Summit), where cutting-edge advancements in cell and gene therapies intersect with aseptic processing technologies. This premier event brings together 80+ industry leaders from top pharma and biotechnology companies for two days of knowledge exchange, collaboration, and innovation.

GENAP EXECUTIVE SUMMARY

WHO You Will Meet



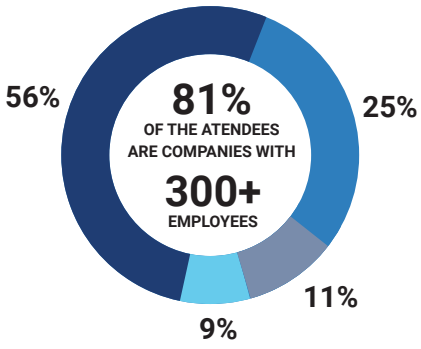
100+
Attendees

25+
Speakers

RATIO

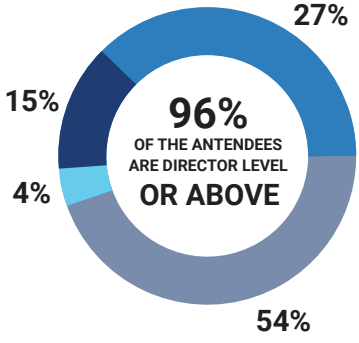
Bio/pharmaceutical manufacturing **75:35** Vendor/Solution Providers

Company Size of Attendees



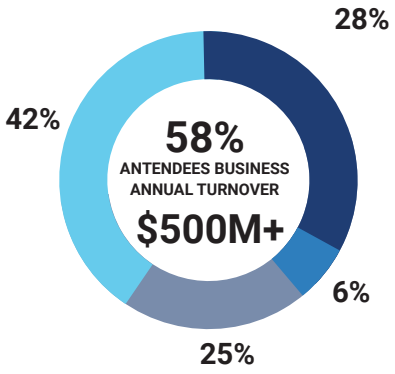
- 1000+ employees
- 300-999 employees
- 50-299 employees
- less than 49 employees

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 AS

★★★★★

Quality of the speakers

Sharing of the best practices

Spectrum of industries

Intimate atmosphere

Short-quick presentations

98%

WOULD RECOMMEND THE EVENT TO COLLEAGUES

Key Practical **Points**

GCT Track

- Navigating Regulatory Requirements: Key Considerations in Bringing Gene Therapies to Market
- Optimizing Vector Serotypes for Durable Gene Expression
- Strategic Vector Design and Development for Effective Gene and Cell Therapies
- Investor Perspectives on Gene Therapy Development: Insights and Strategies
- Reducing Timelines in Cell and Gene Therapy Drug Development: Success Stories and Challenges
- CMC Strategies Tailored for Rare Diseases in Gene and Cell Therapies
- Novel Approaches to Qualifying Starting and Intermediary Materials in CGT Processing
- Strategies for Accelerating CGT Process Development from Preclinical to Commercialization
- Controlling Immunogenicity: Developing Novel Vectors for Safer Gene Therapies
- Empty vs Filled Viral Particles – Key in Industrial Characterization

APT Track

- The Evolution of Aseptic Technologies
- Cleanrooms for Annex 1 Updates: Implementation Challenges and Best Practices
- Innovative Approaches in Quality Risk Management for Aseptic Processes
- Navigating Antibody Drug Conjugates (ADCs) and Highly Potent APIs (HPAPIs) Production
- Advancements in Lyophilization for Highly Potent Products and Aseptic Processing
- Occupational Safety Requirements in Aseptic Environments
- Overcoming Technical Challenges in Decontamination Processes for Enhanced Safety
- Robotic Applications in Aseptic Processing: Current Status and Future Trends
- Single-Use Systems Implementation in Aseptic Environments
- Enhancing Filtration: Strategies for Effective Filter Integrity Testing in Aseptic Operations

Speakers

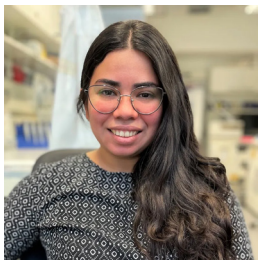
GCT Track (Gene & Cell Therapy)

Alison Armstrong

Senior Director, Global Head Technical and Scientific Solutions at Merck KGaA

Chaminda Salgado

Head of Analytics at eXmoor Pharma

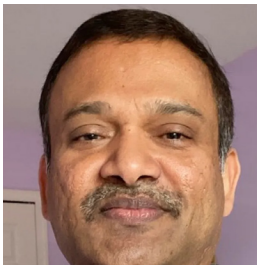


Silvia Roman

Postdoctoral Researcher at Institute for Transfusion Medicine and Gene Therapy - University of Freiburg

Rene-Pascal Fischer

Scientist at Fraunhofer IESE



Veera Dheenadhayalan

Director Biosafety and Bioassay Development at AstraZeneca

Kevin Vela

Collaborations Manager at the Cell and Gene Therapy Catapult

Shengjiang Shawn Liu

CEO & CSO at Avirmax Biopharma Inc

Roland Pach

Global Analytical Expert CGT & alternative formats at Roche

Stephen R. Hughes

Director of New Platform Development at GenScript USA Inc

Jitendra Kumar

Director Innovation and Technology at Thermo Fisher Scientific

Christoph Meyer

Global Head Quality Control Cell and Gene at Lonza

Roman Mathaes

CEO at Clear Solutions Laboratories

Abdul Ally

Area Director, Laboratory Science & Operations at Thermo Fisher Scientific

Sandy Tretbar

Group Leader at Fraunhofer-Institute for Cell Therapy and Immunology

APT Track (Aseptic Processing Technology)

Christian Scarpato

Process Engineering Manager at Merck

James Drinkwater

Head of GMP Compliance at Franz Ziel

Sebastian Scheler

Managing Director at Innerspace GmbH

Mauro Giusti

Senior Director, Site External Network at Eli Lilly and Company & President, PDA Italy Chapter

Richard Denk

Senior Consultant Aseptic Processing & Containment at SKAN AG

Zhihao Peter Qiu

External Advocacy Lead China at Roche Genentech

Petra Merker

Biological Quality Control Expert at Bayer AG

Dalmaso Gilberto

Technical & Scientific Director at Palladio Consulting srl

Dr. Ulrich Köllisch

Partner at GxP-CC

Klaus Ullherr

Senior Product Manager at Syntegon Technology GmbH

Robert Kibele

Business Development Manager at Groninger & co. gmbh

Simone Biel

Senior Regulatory Consultant at Merck Life Science KGaA

Scientific **Agenda**

DAY 0 — 21.FEB.2024

18:00 - 20:00 Pre-Conference Cocktail Reception

Hilton Geneva Hotel & Conference Centre

DAY 1 — 22.FEB.2024

Chair:
APT & GCT Richard Denk, SKAN

08:00 - 09:00 Registration & GENAP Opening Speech

09:00 - 09:30 Safe and flexible - a future oriented approach of filling small batches

Klaus Ullherr
Senior Product Manager at Syntegon Technology GmbH

Section 1: Exploring Next-Gen Bioprocessing

09:30 - 10:00 End-to-End CCS in CGT through advanced risk profiling

Sebastian Scheler
Managing Director at Innerspace GmbH

Section 1: Exploring Next-Gen Bioprocessing

10:00 - 10:30 Speed Networking

10:30 - 11:00 Morning Coffee Break

During this networking break, Sponsors will also have the opportunity to deliver a 5-minute presentation at their designated exhibition space to engage with all our attendees during scheduled times

Chair:
APT Richard Denk, SKAN
GCT Veera Dheenadhayalan, Astrazeneca

11:00 - 11:40 [Virtual] Large High-Speed Isolators

Mauro Giusti
Senior Director, Site External Network at Eli Lilly and Company & President at PDA Italy Chapter

Section 2: Advanced Aseptic Techniques and Technologies

Changing landscape of Cell and Gene Therapies: Novel technology choice to ensure speed to market

Alison Armstrong
Senior Director, Global Head Technical and Scientific Solutions at Merck KGaA

Section 2: Exploring Novel Technologies in Cell and Gene Therapies

11:40 - 12:20 EU GMPs Annex: 2022 - New role for microbiologist and engineers on pharmaceutical aseptic processes

Gilberto Dalmaso
Technical & Scientific Director at Palladio Consulting srl

Section 2: Advanced Aseptic Techniques and Technologies

RNAuto – automated production of mRNA therapeutics

Rene-Pascal Fischer
Scientist at Fraunhofer IESE

Sandy Tretbar
Group Leader at Fraunhofer-Institute for Cell Therapy and Immunology

Section 2: Exploring Novel Technologies in Cell and Gene Therapies

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12:20 - 13:00

Quality Risk management and implementation of continuous real-time environmental monitoring for aseptic filling

Petra Merker
Biological Quality Control Expert at Bayer AG

Mounting demand for high-quality plasmid DNA, status of current plasmid production, and next-generation automated platform for commercial plasmid production

Stephen R. Hughes
Director of New Platform Development at GenScript USA Inc

Section 2: Exploring Novel Technologies in Cell and Gene Therapies

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13:00 - 14:00 Lunch & Networking Break

Chair:
APT Simone Biel, Merck Group
GCT Alison Alison, Merck Group

14:00 - 14:30

What is Important to consider in Annex 1 and how could automation become the key for an holistic contamination control strategy

Richard Denk
Senior Consultant Aseptic Processing & Containment at SKAN AG

Section 3: Regulatory Landscape and Contamination Control

Optimizing Cell and Gene Therapy Process Development: Navigating the Decentralized Supply Chain Landscape

Chaminda Salgado
Head of Analytics at eXmoor Pharma

Section 3: Process Development and supply Chain Optimization

14:30 - 15:00

[Virtual] FDA's Regulatory Review and inspection of Biological Products Manufactured using Aseptic Processing

Zhihao Peter Qiu
External Advocacy Lead China at Roche Genentech

Section 3: Regulatory Landscape and Contamination Control

Introducing alternate methods for cell therapy products

Veera Dheenadhayalan
Director Biosafety and Bioassay Development at AstraZeneca

Section 3: Process Development and Supply Chain Optimization

15:00 - 15:30

Gloveless manufacturing – How to enable a scale-out approach in light of ATMP fill and finish

Robert Kibele
Business Development Manager at groninger & co. gmbh

Overcoming challenges with CGT supply chain and ensure safety and visibility of therapies throughout the supply chain

Jitendra Kumar
Director Innovation and Technology at Thermo Fisher Scientific

Abdul Ally
Area Director, Laboratory Science

Section 3: Process Development and Supply Chain Optimization

15:30 - 16:00 Afternoon Coffee Break

16:00 - 17:00

Panel Discussion: Navigating Annex 1 Guidelines for Enhanced Sterile Product Manufacturing

Interpreting the Impact of Annex 1 Revisions on Sterile Product Manufacturing Best Practices for Achieving Compliance and Maintaining Quality in Sterile Production

Moderator:
Richard Denk, SKAN

Panelists:
- Klaus Ullherr, Syntegon
- Technology GmbH
- Petra Merker, Bayer
- Simone Biel, Merck Life Science KGaA
- Christoph Meyer, Lonza
- Robert Kibele, groninger & co. gmbh

19:00 - 21:00

GENAP Summit: Gala Dinner

DAY 2 23.FEB.2024

08:00 - 09:00

Registration & Coffee

Chair:
APT James Drinkwater, Franz Ziel
GCT Roland Pach, Roche

09:00 - 09:30

CMC & GMP: Connection Control Strategies for Biologics and ATMP processing

Section 4: Cell-Based ATMPs, Aseptic Processing Simulation & Sterile Filtration

James Drinkwater
Head of GMP Compliance at Franz Ziel

Section 4: Clinical research and Advanced Therapies

Collaborations Manager at the Cell and Gene Therapy Catapult

Kevin Vela
Collaborations Manager at the Cell and Gene Therapy Catapult

09:30 - 10:00

A better approach to APS for lyophilized products - APS approach for freeze-drying considering Annex 1 requirements and scientific rationales

Section 4: Cell-Based ATMPs, Aseptic Processing Simulation & Sterile Filtration

Christian Scarpato
Process Engineering Manager at Merck

Targeted Epigenome Editing of Immune Checkpoints in CART Cells

Section 4: Clinical research and Advanced Therapies

Silvia Roman
Postdoctoral Researcher at Institute for Transfusion Medicine and Gene Therapy - University of Freiburg

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10:00 - 10:30

Demystifying Sterile Filtration: Understanding Regulatory Requirements and Dispelling Common Misconceptions

Section 4: Cell-Based ATMPs, Aseptic Processing Simulation & Sterile Filtration

Simone Biel
Senior Regulatory Consultant at Merck Life Science KGaA

Comparison of AAV vectors produced using Sf-9 and HEK293 cell culture systems

Section 4: Clinical research and Advanced Therapies

Shengjiang Shawn Liu
CEO & CSO at Avirmax Biopharma Inc

10:30 - 11:00 | Morning Coffee Break

During this networking break, Sponsors will also have the opportunity to deliver a 5-minute presentation at their designated exhibition space to engage with all our attendees during scheduled times

Chair:
APT & GCT James Drinkwater, Franz Ziel

11:00 - 11:30 | Compliant implementation of AI/ML models in GMP environments

Section 5: Advancements in Technology and Compliance

Dr. Ulrich Köllisch
Partner at GxP-CC

11:30 - 12:00 | The role of Quality in the Commercialization of Cell and Gene Therapies

Section 5: Advancements in Technology and Compliance

Christoph Meyer
Global Head Quality Control Cell and Gene at Lonza

12:00 - 13:00 | Panel Discussion: Innovative Strategies in GCT Manufacturing Revolutionizing Large-Scale GCT Production Navigating Regulatory Challenges for GCT Advancements

Moderator:
Alison Armstrong, Merck Group
Panelists:
- Veera Dheenadhayalan, AstraZeneca
- Jitendra Kumar, Thermo Fisher Scientific
- Roland Pach, Roche
- Sandy Tretbar, Fraunhofer-Institute
- Kevin Vela, Cell and Gene Therapy Catapult

13:00 - 14:00 | Lunch & Networking Break

Chair:
APT & GCT Christian Scapato, Merck Group

14:00 - 14:30 | Navigating Unique Challenges in Cell Therapy Manufacturing: A focus on Particle Control Strategies and regulatory expectations

Section 6: Vector Design and Manufacturing Considerations

Roman Mathaes
CEO at Clear Solutions Laboratories Biopharma Inc

14:30 - 15:00 | Empty vs filled viral particles - an industrial view on the characterisation of this critical quality attribute

Section 6: Vector Design and Manufacturing Considerations

Dr. Roland Pach
Global Analytical Expert CGT & alternative formats at Roche

15:00 | End of GENAP Summit

Networking Events
APT Track
GCT Track
APT & GCT Track

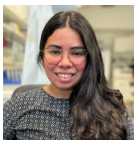
Biographies

Alison Armstrong Senior Director, Global Head Technical and Scientific Solutions at Merck KGaA

Dr. Alison Armstrong is Senior Director , Global Head of the Technical and Scientific Solutions team. Dr Armstrong has a long history in academic research as a postdoctoral scientist and Research fellow and has been involved in examining the role of viruses in various pathogenic conditions. She has led a number of teams in different divisions within Merck; operational teams, validation and scientific development, and she is currently responsible for a scientific consultancy team with the remit to support clients in technical, scientific, and regulatory issues. During her career Alison has authored many different articles on trends in biosafety testing and is a member of regulatory taskforce groups related to microbiology and virology methods and alternate and rapid technologies. She is an invited speaker at international conferences. Dr. Armstrong holds a PhD in Molecular Virology from the University of Glasgow.

Chaminda Salgado Head of Analytics at eXmoor Pharma

Highly experienced CMC Leader, with 14 years experience in CMC biological assets and 9 years in Cell & Gene therapies, ensuring the smooth flow of programs from Lead development through to commercialisation and beyond. Well versed in process improvement by automation of both lab procedures and data, with a strong back ground in analytical development. Held Leadership positions in large Pharma as well as small Biotechs and Contract manufacture and Research. Career highlight was being part of the leadership team that launched Strimvelis, the first gene therapy for children. Currently involved with Autologous, and Allogeneic cell therapies, Lenti and AAV production, and RNA vaccines.



Silvia Roman Postdoctoral Researcher at Institute for Transfusion Medicine and Gene Therapy - University of Freiburg

Biochemistry as undergraduate study concluded in 2014 (National University of Asuncion, Paraguay). Master in Molecular Biotecnology concluded in 2016 (University of Barcelona, Spain). PhD in Natural Sciences concluded in 2022 (University of Freiburg, Germany). Currently working as a Postdoctoral Researcher at the University of Freiburg focusing on improving the cytotoxicity and persistence of CAR T cells.

Rene-Pascal Fischer Scientist at Fraunhofer IESE

Rene Fischer is an enthusiast, researcher, and active participant in the transfer of "Industrie 4.0" concepts into the pharmaceutical domain. In his role as a software architect and scientist he helps to drive transformative change by integrating digital solutions – such as digital twins – into the manufacturing and pharmaceutical realms.

Veera Dheenadhayalan Director Biosafety and Bioassay Development at AstraZeneca

Dheen holds Master degree in Biology and a Ph.D., in Immunology. Currently he is working as a Director of Biosafety and Bioassay Development at AstraZeneca in Gaithersburg, USA. His role is to support biologics with functional assays and regulatory requirements for biosafety. He is also working on implementing next generation technologies for the biosafety testing. Over 20 years of research experiences in developing bioassays for product characterization and biosafety evaluation for various vaccines. His training came from his post doctoral research work on DNA vaccines at Cornell University, and also from US FDA. Previously he worked various organization covering vaccine evaluation, safety assessment, assay development and quality control.

Kevin Vela Collaborations Manager at the Cell and Gene Therapy Catapult

Kevin joined the Cell and Gene Therapy (CGT) Catapult in October 2022 as Collaborations Manager, where he leads the creation and establishment of impactful collaborations and multi-party consortia that deliver innovative solutions to key challenges in the CGT sector. His orchestration of collaborations spans across the entire CGT value-chain, with a particular focus on championing the adoption and use of automation and digital technologies to drive innovation in Research and Development, Manufacturing and Supply of CGTs.

Shengjiang Shawn Liu CEO & CSO at Avirmax Biopharma Inc

Dr. Liu is an experienced biotechnologist, biopharma scientist, entrepreneur and executive. After receiving his Ph.D. in biochemistry from Kansas State University and completing his post-doctoral training with Dr. Arthur Kornberg, Stanford University, he served as the group leader at Genentech Virology Research Lab. He discovered and characterized rabbit calicivirus (RCV) which caused rabbit hemorrhagic disease (RHDV) in 1984. He developed an inactivated RHDV vaccine and several fast detection methods that were effectively used for controlling and preventing RHD disease Worldwide.

Roland Pach Global Analytical Expert CGT & alternative formats at Roche

Dr. Roland Pach holds a PhD in molecular parasitology at the University Fribourg analysing the intracellular trafficking of transgenic RNA in human pathogens. Prior Roche, he was leading DiTe Vaccine Manufacturing unit and built up the Analytical Development department at Berna Biotech (former Swiss Vaccine and Serum Institute). As QC department head of Bio-Process Development at Merck-Serono, he supported with his team the process development activities and process characterisation.

At Roche, Roland is the global CMC Analytical Technical Lead in the cancer vaccines and cell- & gene therapy (CGT) area of Roche for more than 14 years. In his assigned area, he represents Roche in external development projects, industrial consortiums like CGT BioPhorum and numerous due diligences of in-licensing candidates or companies in the CGT fields.

Stephen Hughes Director of New Platform Development at GenScript

Stephen Hughes is Director of New Platform Development at GenScript, responsible for next-generation synthetic DNA production systems for gene therapy. He has negotiated optimum quotes from suppliers for a core system for scaled production of dsDNA, ssDNA, and IVT template DNA without plasmid, bacteria, or yeast for CAR-T, TCR-T, AAV, and lentiviral gene therapy. Previously at Spark Therapeutics he provided the overall strategic and tactical leadership for the establishment and implementation of automation and robotics associated with optimizing operations and compliance for preclinical development, manufacturing, and testing. He was responsible for designing the automation strategy to enable new hardware technology development and implementation to scale for automation of preclinical development, manufacturing, and testing capabilities across all therapeutic areas for Spark.

Jitendra Kumar Director Innovation and Technology at Thermo Fisher Scientific

Jitendra Kumar is a results-oriented, innovative global life science technology leader with a successful record of delivering values to both business and customers. Jitendra has been working with Thermo Fisher Scientific for 21+ years and in the current role of Director, Digital Innovation, he is leading Digital Innovation function in Clinical Trials while based in Basel, Switzerland

Christoph Meyer Global Head Quality Control Cell and Gene at Lonza

Dr. Christoph Meyer currently is Lonza`s Cell and Gene Global Quality Control Head addressing all Quality Control aspects related to cell and Gene Therapies. Christoph has more than 18 years of experience in the Pharmaceutical Industry working in Research, Development, Global Quality and Operations. Prior to Lonza Christoph spent more than 16 years at Novartis where he hold position such as Global Product Quality responsibility for Cell and Gene, QC head for the largest Novartis Operations site (Stein Switzerland), Global Head Strategy and Operations for Development Quality, and Lab Head in Research and Development. Christoph studied chemistry at the Universities in Tübingen, Germany and San Diego, USA and holds Doctorate degree in organic analytical chemistry from the University of Tübingen, Germany, including research stay at the National Institute of Standards and Technology, Gaithersburg, USA.

Roman Mathaes CEO at Clear Solutions Laboratories

Roman Mathaes is the CEO of Clear Solutions Laboratories. Before that, he was Head of Pharmaceutical Services at Lonza Drug Product Services. In this role, he was responsible for pre-clinical Drug Product manufacturing for vials, prefilled syringes, and ampoules and also lead the packaging & combination product development department as well as the lab automation group Roman joined Lonza from Roche. He is a Pharmacist by training and holds a Ph.D. in Pharmaceutical technology from the University of Munich and an MBA. Since 10 years he is a lecturer at the University of Basel teaching Biopharmaceutical product development.

Abdul Ally Area Director, Laboratory Science & Operations at Thermo Fisher Scientific

Abdul Ally has 45 years of combined experience in Molecular Biology, DNA Chemistry and Mechanical Engineering with an emphasis on development of biological research products and lab instrument development. Abdul has worked for Thermo Fisher Scientific for 22+ years and is currently in the Technology and Innovation Group at the Frederick, Maryland location.

Sandy Tretbar Group Leader at Fraunhofer-Institute for Cell Therapy and Immunology

Dr. Sandy Tretbar obtained her PhD in Molecular Biology at Leipzig University in Germany. Sandy pursued her first Postdoc in the field of RNA biochemistry and biophysics at the University of Wisconsin-Madison. Her second Postdoc was in an immunology lab at the Martin-Luther-Universität Halle-Wittenberg. She joined the Fraunhofer Institute for Cell Therapy and Immunology IZI (Fraunhofer IZI) in 2018 as Research Associate. Currently, she is the Group Leader of the Cell and Molecular Biology Unit of the Department for Cell and Gene Therapy Development. She combines her long-standing RNA research experience with cell therapy development in immuno-oncology to investigate mRNA-based cell and gene therapies for the treatment of cancer and various other diseases.

Christian Scarpato Process Engineering Manager at Merck

Christian Scarpato is a sterile manufacturing fill and finish expert with almost 13 years of experience in pharma companies (Aenova group, Baxter, GSK and Merck). In the last years, He worked on the design, installation, and start-up of three new production lines (vials, cartridges, and syringes) with advanced cutting-edge technology like isolator in Merck's Bari site. He currently leads the Process Engineering in Merck Bari. He graduated with honours in chemical engineering from Federico II University of Naples. He is an active contributor for ISPE and BioPhorum (such as contributor of the doc "User vision for the filling line of the future" August 2023)

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. The PHSS also supports training resources for PICS on implementation of Annex 1.

Sebastian Scheler Managing Director at Innerspace GmbH

Sebastian Scheler is a visionary leader with a passion for advancing risk assessment technologies and Virtual Reality (VR) to revolutionize risk management in highly critical environments. Leading a dynamic team of professionals, he is at the forefront of developing high-end VR simulators and advanced risk assessment methodologies. His expertise is centered around Frame-by-Frame Risk Profiling, an innovative and automated approach that drives process improvement, automation, autogenerated SOPs, and immersive training curricula. Sebastian's profound background in psychology informs his work, focusing on the intersection of human behavior and technology. His pioneering VR simulator methodologies redefine experiential learning, training, and behavior measurement systems.

Mauro Giusti Senior Director, Site External Network 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.

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.

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. Before joining FDA, Peter spent ten years in biotech and device industry, primarily, in R&D and GMP manufacturing.

Petra Merker Biological Quality Control Expert 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. After her Post-Doc at the Max-Planck-Institute for Molecular Biology in Berlin she joined Schering/ Bayer by implementing a Real-Time PCR Technology for the detection of specified microorganisms in pharmaceutical preparations. 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)

Dalmaso Gilberto Technical & Scientific Director at Palladio Consulting srl

Gilberto Dalmaso has over 35 years' experience in pharmaceutical microbiology and sterility assurance, primarily with GlaxoSmithKline (GSK) where he started in 1984 with Glaxo Verona (Italy). During his distinguished career at GSK he led a series of technology-driven process improvements using scientific methods, while achieving GMP compliance and regulatory approvals.

Ulrich Köllisch Partner at GxP-CC

Dr. Ulrich Koellisch, Partner with GxP-CC, has been on the forefront of quality and compliance consulting with a focus on digital compliance and for data integrity initiatives in his previous eight years. He has supported many organizations in the pharmaceutical, biotech and medical device sector executing data integrity campaigns and training initiatives. Ulrich has experience in audit preparation and conduction in the GMP and the GCP area, supporting both sides, auditors and auditees.

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. He is a well-known speaker and trainer covering trends and solutions for fill/finish equipment.

Robert Kibele Business Development Manager at groninger & co. gmbh

Robert Kibele is product manager for groninger's fill & finish equipment for ready-to-use containers with a strong focus on fully robotic solutions. He has been with groninger for 2.5 years and holds degrees in packaging technology and industrial management. His main responsibilities are conducting market and trend analyses, product portfolio management, new product development, business development and partnerships. He is a member of the VDI, the PDA and the ISPE and works as an expert in the DIN/ISO group for pharmaceutical primary packaging.

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.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