June **21-22**, 2023 | **Vienna**, Austria | #VLaseptic

6th Annual Aseptic Processing Summit

+

3rd GENE AND CELL THERAPIES
CMC, CGT & VECTOR MANUFACTURING

Key Practical Learning Points:

- Overcoming aseptic processing challenges in the context of Annex 1 (Manufacture of Sterile Medicinal Products)
- Leveraging regulatory concerns, expectations, and embracing innovative aseptic processing technologies
- Avoiding pitfalls in aseptic manufacturing inspections, and discovering the future of GMPs in aseptic processing
- Overcoming hurdles to adopt new technologies in the aseptic processing of sterile medicinal products and to achieve safe highly potent aseptic production
- Better ways to model, predict, and control aseptic processes with automation, robotics, virtual reality, artificial intelligence, machine learning, and predictive modelling
- Design, development, and implementation of components in the aseptic manufacturing processes
- Addressing contamination control issues and establishing a robust contamination control strategy, enhanced with tech advances
- Critical evaluation of adopting enzyme H2O2 indicators in aseptic processing environments
- Navigating highly potent manufacturing requirements
- Developing and qualifying aseptic manufacturing processes for ATMPs, including cell and gene therapies, and mRNA vaccines
- Accepting new risk-based approaches to process design and control
- Exploring the key insights and implementations for the sterility assurance of the finished products
- Bringing higher productivity with continuous process manufacturing and improving efficiency of aseptic processes
- Critical considerations on clinical or small-scale aseptic manufacturing and facilities of the future
- Ensuring product quality at faster speeds and with more flexibility through a partnership of manufacturers, suppliers, and regulators

Moderator

Richard Denk, CH
Senior Consultant Aseptic Processing & Containment
Skan AG

Dr. Simone Biel, DE
Senior Regulatory Consultant/Life Science, Quality & Regulatory Management
Merck KGaA

Amnon Eylath, US
VP Head of Global Quality
Minovia Therapeutics Ltd

Jeremiah Genest, US
Head of Quality Management Systems
Amylyx Pharmaceuticals

Miriam Guest, UK
Principal Microbiologist, Pharmaceutical Technology & Development, New Modalities & Parenterals Development
AstraZeneca

Walid El Azab, BE
Industrial Pharmacist, Qualified Person Technical Service Manager
STERIS Corporation

Pino Cabrera, ES
Consulting Manager
QUALIPHARMA

Chris Berridge, UK
Global Technical Consultant, Bioquell Specialist
Ecolab Life Sciences

Bianca Bohrer, DE
CEO
PSM GmbH

Nicole Zangl, AT
Business Development Mixing Technology
ZETA GmbH

Donald Singer, US
Senior Microbiology Technical Consultant, North America
Ecolab

Dr. Oliver Schläfli, CH
Senior Vice President, Global Quality
Lonza

Dr. Thomas Schwarz, CH
Chief Commercial Officer
SiO2

Dr. Gilberto Dalmaso, IT
Technical & Scientific Director
Palladio Consulting Srl

James L. Drinkwater, DE
Head of GMP Compliance
Franz Ziel GmbH

Sergio Cuevas Luján, ES
Packaging Materials Engineer
Boehringer Ingelheim

Christian Scarpato, IT
Process Engineering Manager
Merck Italia

Fabian Stutz, DE
CEO
Pharmabotix AG

Dr. Sebastian Trennheuser, DE
Scientific Project Manager
PSM GmbH

SPONSORSHIP SPEAKING &
EXHIBITION OPPORTUNITIES AVAILABLE

Sponsors:

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6th Annual Aseptic Processing Summit

Sponsorship-related questions to: **gabriela.vladimirova@vonlanthen-conferences.com**

Introduction

The demand of aseptic manufacturing is rising, and, therefore, the challenges of aseptic processing will continue to grow in complexity.

Ensuring product quality at faster speed and with better flexibility is becoming the key priority.

The Annex 1 of the EU GMP Guide "Manufacture of Sterile Medicinal Products" is considered to be the most important European regulatory standard for the manufacture of sterile pharmaceutical products. The changes to Annex 1 are bringing new obstacles to pharma company operations that should be overcome from both technical and organisational perspectives.

At the **6th Annual Aseptic Processing Summit** on **June 21-22, 2023**, experts from the industry will highlight the requirements to robust aseptic processing, targeted implementation strategies, recent experience on establishing aseptic manufacturing processes for ATMPs and vaccines in particularly, and adoption of innovative aseptic processing technologies, including robotics.

The #VLaseptic brochure contains additional info and the key insights.

Partner of the Event

Gene Therapy Net is the information resource for basic and clinical research in gene therapy, and the site serves as a network for the exchange of gene therapy information and breaking news items. Visitors can keep track of the latest scientific papers, conference announcements, gene therapy jobs, regulations and guidelines.

Who should attend

Chief Executives, Directors, Vice Presidents, Heads, Leaders, Senior Managers, Scientists, Chemists, Engineers, and Fellows specialising in:

- Advanced Therapy Medicinal Products (ATMP)
- Analytics
- Artificial Intelligence (AI)
- Aseptic Processing
- Cell and Gene Therapies (CGTs)
- Chemistry, Manufacturing & Controls (CMC)
- Cleaning Validation
- Engineering
- Environmental Monitoring
- External Collaboration
- Facilities Management
- Formulation
- Good Manufacturing Practice (GMP)
- Highly Potent Active Pharmaceutical Ingredients (HPAPI)
- Industrial Automation
- Industrial, Process, Product Innovation
- Lyophilisation
- Maintenance
- Manufacturing
- Medical Devices (MD)
- Messenger RNA (mRNA)
- Microbiology
- Nanomaterials
- New Technologies
- Operations
- Packaging Technology
- Parenterals
- Process Science
- Production
- Quality Assurance (QA)
- Quality Control (QC)
- Regulatory
- Robotics
- Technical Science
- Vaccines
- Validation
- Virtual Reality (VR)

...and Others

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Sponsors

Located in modern factories near Venice in Italy, Steelco Group is a major global supplier of infection control and contamination prevention for the healthcare, laboratory, and pharmaceutical sectors. Steelco Pharma division offers complete 'turnkey' solutions for washing and sterilization processes in the pharmaceutical industry, with the ability to undertake all stages of a project from concept to delivering solutions that exceed customer expectations.

Steelco's portfolio includes:

- Pharma-grade parts and bin washers
- Pharma-grade saturated steam sterilizers
- Pharma-grade decontamination air lock with H2O2
- Innovative fully automated closure processing equipment
- Class 100 Depyrogenization oven and Granulate Dryer
- Terminal sterilization solutions
- Ethylene Oxide low-temperature sterilization
- Automation systems to maximize productivity and safety

Steelco
Miele Group Member

The **ZETA Group**, with 1,200 highly qualified employees and 27 subsidiaries worldwide, specializes in planning, automation, digitalization, and qualification of customized biopharmaceutical facilities for aseptic process solutions. ZETA acts as an end-to-end solution provider, combining plant engineering with HVAC and cleanroom design. ZETA supports its customers along the entire drug development and manufacturing pathway with sophisticated solutions from laboratory to industrial production scale.

ZETA

The **Optima Pharma** Division plans, develops and produces filling, closing and process technology for pharmaceutical products requiring the highest cleanliness standards. This is characterized by high process reliability and flexibility. Optima Pharma's extensive turnkey portfolio is completed by pharmaceutical freeze-drying and isolators. As a technology partner for pharmaceutical companies, Optima Pharma improves the life of patients and users worldwide.

OPTIMA

6th Annual Aseptic Processing Summit

Schedule

DAY 1 | June **21**, 2023 | VIENNA, AUSTRIA | #VLaseptic

13:30 Registration / Networking / Welcome Coffee / Exhibition

14:15 Opening by Moderator

13:55

Aseptic processing – future outlook

- Implementation of Annex 1 and what this means
- GMP Annex 1 compliance with robotics

Richard Denk, CH | Senior Consultant, Aseptic Processing & Containment | Skan AG

14:25

Sterilisation of advanced therapeutic medicinal products – regulatory background and challenges

Advanced therapeutic medicinal products (ATMP) typically cannot be sterilised in the final container and need to be sterile filtered. If the product is not filterable, the entire process needs to be closed. Aseptic manufacturing requirements of ATMPs are described in EU GMP Part IV and additional guidance on sterilisation methods can be found in Annex 1. Challenges and solutions will be discussed:

- Variation of the product – filter validation every time?
- Small batch size – small sample volume for bioburden test
- Closed processing – whenever possible

Dr. Simone Biel, DE | Senior Regulatory Consultant | Life Science, Quality, & Regulatory Management | Merck KGaA

14:55

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15:35 NETWORKING / COFFEE / EXHIBITION BREAK

16:00

Contamination control, risk, and the quality management system

Contamination control is a fairly wide term used to mean “getting microbiologists out of the lab” and involved in risk management and the quality management system. This presentation will evaluate best practices in building a contamination control strategy and ensuring its use throughout the quality system. Leveraging a house of quality approach, participants will learn how to:

- Create targeted/risk-based measures of contamination avoidance
- Implement key performance indicators to assess status of contamination control
- Ensure a defined strategy for deviation management (investigations), CAPA, and change management

Jeremiah Genest, US | Head of Quality Management Systems | Amylyx Pharmaceuticals

16:30

Best practices for controlling contamination in your cell and gene therapy manufacturing process

- Pragmatic GMP contamination control strategy for your manufacturing
- Proven phase-appropriate controls
- Sterility assurance from the aseptic core outwards

Donald Singer, US | Senior Microbiology Technical Consultant, North America | Ecolab
Chris Berridge, UK | Global Technical Consultant, Bioquell Specialist | Ecolab Life Sciences

17:00

Microbiological hot topics and issues in aseptic processing of gene and cell therapies activities

- Human/personnel impact for microbiological contamination
- How to design the aseptic process simulation
- Environmental monitoring plans

Dr. Gilberto Dalmaso, IT | Technical & Scientific Director | Palladio Consulting Srl

17:30

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18:00

The use of chlorine dioxide gas as a highly effective and easy-to-validate agent for sanitisation, decontamination, and sterilisation of cell therapy processing equipment, isolators, areas, and facilities

- Based on the work done in developing and validating this technology

Amnon Eylath, US | VP Head of Global Quality | Minovia Therapeutics Ltd

18:30

Transformational technologies in sterile manufacture to support robust contamination control strategies

Miriam Guest, UK | Principal Microbiologist, Pharmaceutical Technology & Development, New Modalities & Parenterals Development | AstraZeneca

19:00 Q&A / PANEL DISCUSSION (ALL SPEAKERS OF THE DAY ARE INVITED) & MODERATOR'S CLOSING REMARKS

19:20 NETWORKING / EXHIBITION BREAK

19:40 BUSINESS DINNER & NETWORKING

Check Our

Upcoming Event

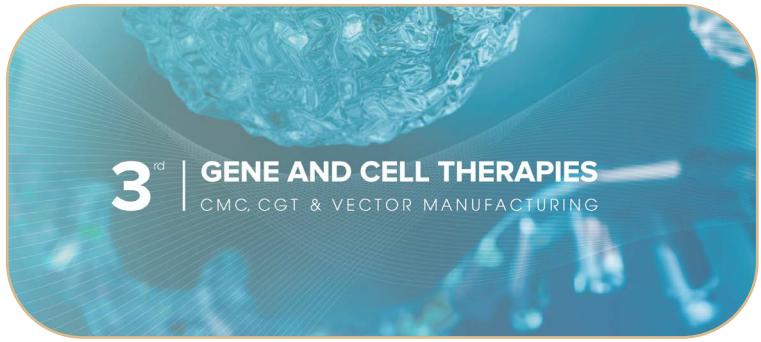
3rd Gene and Cell Therapies: CMC, CGT & Vector Manufacturing Summit

June **20-21**, 2023 | **Vienna**, Austria | **#VLGeneCell**

The gene and cell therapies clinical impact, production, and processes efficiency depend on the unique challenges related to CMC, analytical, process development, automation, manufacturing, facility design, aseptic processing, supply chain and others that developers of gene and cell therapies must resolve.

REQUEST A BROCHURE*

* *To request a brochure for this Summit, please contact our sales person:* ***gabriela.vladimirova@vonlanthen-conferences.com.*** *We will send you the agenda via email.*



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6th Annual Aseptic Processing Summit

Schedule

DAY 2 | June **22**, 2023 | VIENNA, AUSTRIA | #VLaseptic

08:00 Registration / Networking / Welcome Coffee / Exhibition

08:25 Opening by Moderator

08:30

Quality operations

Dr. Oliver Schläfli, CH | Senior Vice President, Global Quality | Lonza

08:55

Aseptic process simulation

Changes and new requirements in newly published Annex 1

- APS as part of the monitorisation program
- New acceptance limits for APS
- Considerations to be taken into account during the design of APS

Pino Cabrera, ES | Consulting Manager | QUALIPHARMA

09:20

Isolator environmental and process monitoring approach

Identification of limits through use of process knowledge and data, response to the single excursion, and response to regular, isolated, or consecutive events.

- Engineering approach to respond in a timely manner while avoiding over-reaction
- Use of historical data to assess limits, multivariate analysis on critical process parameters
- Create a defined strategy for deviation management in case of out of limit events

Christian Scarpato, IT | Process Engineering Manager | Merck Italia

09:45

How to fulfil the requirements of the new Annex 1 regarding fully automated gloveless fill-finish system

- Contamination control strategy
- Containment for potent substances

Bianca Bohrer, DE | CEO | PSM GmbH

Sebastian Trennheuser, DE | Co-CEO | PSM GmbH

10:10

Viral vector manufacturing – Combined platform for formulation and commercial scale fill and finish in an isolator

- Overview of the challenges of commercialisation of viral vector manufacturing
- Combined formulation (pooling, sterile filtration, and concentration) of viral vectors and filling into vials at commercial scale with use of automation within barrier technology
- Challenges of GMP compliance in ATMP/viral vector manufacture considering regulation changes

James L. Drinkwater, DE | Head of GMP Compliance | Franz Ziel GmbH

10:45

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Sponsorhip-related questions to:
gabriela.vladimirova@vonlanthen-conferences.com

11:05 NETWORKING / COFFEE / EXHIBITION BREAK

11:35

Pharmaceutical packaging design for aseptic processing

- The role of packaging in the pharmaceutical industry and sterile drug production
- Appropriate design for aseptic processing packaging lifecycle (materials production, sterilisation, manufacturing, warehousing operations, transport, and distribution)
- Identify improvement opportunities to have safe, efficient, and sustainable packaging design for sterile drug production

Sergio Cuevas Luján, ES | Packaging Materials Engineer | Boehringer Ingelheim

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12:00

Revolutionising primary packaging: Not glass, not plastic – a new material

- New material: not glass, not plastic
- Advantages over traditional materials
- Applications

Dr. Thomas Schwarz, CH | Chief Commercial Officer | SiO2

12:20

Cleaning and disinfection program

Walid El Azab, BE | Industrial Pharmacist, Qualified Person Technical Service Manager | STERIS Corporation

12:50

Beyond robotics: State of the art automation solutions for (bio-)pharma

- Logistics first?
- Smart end-to-end solutions in a modern production environment
- Robotics in biologics manufacturing
- Key factors for the success of an automation project

Fabian Stutz, DE | CEO | Pharmabotix AG

13:20 Q&A / PANEL DISCUSSION (ALL SPEAKERS OF THE DAY ARE INVITED) & MODERATOR'S CLOSING REMARKS

13:40 NETWORKING / COFFEE / EXHIBITION BREAK

14:00 BUSINESS DINNER

Testimonials

What People Are Saying

PAST
Attendee

Fantastic opportunity to network with colleagues and explore the best practices related to aseptic processing

PAST
Attendee

There was well-explained the state of aseptic processing, trends, strengths and weakness, opportunities and threats, regulatory expectations, areas for improvement, and more. I would definitely attend again.

PAST
Attendee

The speakers presented some important best practices, and this is expected to significantly improve the manufacturing environment of pharmaceuticals. It worth to join.

Sponsorship-related questions to: **gabriela.vladimirova@vonlanthen-conferences.com**

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Richard Denk, CH | Senior Consultant, Aseptic Processing & Containment | Skan AG

Richard Denk has studied mechanical engineering and did an examination on experts of GMP, qualification and validation, pharmaceutical auditing, pharmaceutical engineering, and quality control at the University of Applied Sciences in Albstadt/Sigmaringen, Germany. Richard works at SKAN AG, headquartered in Allschwil, as the head of sales containment. He founded the expert containment group of the ISPE DACH eight years ago. The containment group published the containment manual in September 2015. Richard has spent nearly 20 years working with highly active/highly hazardous substances and has developed the containment pyramid.

Donald Singer, US | Senior Microbiology Technical Consultant, North America | Ecolab

Don Singer is a senior microbiology technical consultant, North America, for Ecolab, and a fellow in the American Society for Quality. He was formerly a GSK senior fellow. Don has been chair of the USP general chapters - microbiology committee of experts and a member since 2000. He is a certified GMP professional, a certified specialist microbiologist, a member of the European pharmacopeia group 1 microbiology committee, and a certified six sigma green belt. Don is also an adjunct professor in the biopharmaceutical quality graduate program at the University of Maryland, Baltimore County. Don's career spans over 40 years of research and quality control.

Dr. Simone Biel, DE | Senior Regulatory Consultant | Life Science, Quality, & Regulatory Management | Merck KGaA

Simone Biel is a senior regulatory consultant and provides regulatory expertise to our customers and internal stakeholders with a focus on single-use technology and filtration. Over the years, Simone has supported biopharmaceutical drug manufacturer's implementation of single-use technology in their manufacturing process and gained a deep understanding of market needs and industry trends in this field. Her objective is to ensure that product performance meets quality and regulatory requirements. Simone holds a PhD from the University of Frankfurt in microbiology.

Amnon Eylath, US | VP Head of Global Quality | Minovia Therapeutics Ltd

Amnon Eylath is a seasoned quality leader who's experienced in the complete life cycle of biological and small molecule drug development, from discovery through nonclinical and tox studies, clinical trials, process and method development, GMP manufacturing, validation, regulatory submissions, and US/EU/MHRA commercial product approvals. Amnon has direct experience with cell and gene therapy and with developing and troubleshooting aseptic processes, including design and fabrication of isolators and the implementation and validation of highly effective decontamination and sterilisation technology. Amnon has worked at various capacities in international companies, such as Amgen, Ely Lilly, and Genzyme-Sanofi, as well as at cell therapy companies such as Cellcore Therapies, Histogenics, and Minovia Therapeutics. Currently, Amnon is the global vice president of quality at Minovia Therapeutics, working out of the Massachusetts site and developing quality systems and implementation of continuous improvement methods to the development of clinical cell therapy processes. Active volunteer with the Parenteral Drug Association (PDA), chair for the drafting of Technical Report T-56 (Application of Phase-Appropriate Quality System and cGMP), co-author for TR-65 (Technology Transfer), and former president of the New England Chapter of the PDA.

Jeremiah Genest, US | Head of Quality Management Systems | Amylyx Pharmaceuticals

Jeremiah Genest is a quality professional with over 20 years of experience in the pharmaceutical industry. He's based in Boston, MA, and currently employed at Amylyx Pharmaceuticals as the head of quality management systems. His past work includes Takeda, Sanofi, Thermo Fisher, and Vertex Pharmaceuticals. His experiences within quality systems include builds for new organisations, remediation under consent decree, and full transformations at more established companies.

Dr. Gilberto Dalmaso, IT | Technical & Scientific Director | Palladio Consulting Srl

Gilberto Dalmaso has over 35 years' experience in pharmaceutical microbiology and sterility assurance, primarily with GlaxoSmithKline (GSK). Over his last five years with GSK, Gilberto led a series of initiatives implementing process analytical technologies (PAT) and rapid microbial methods (RMM) that improve quality and process understanding while yielding significant cost savings. In 2003, his laboratory gained the distinction of obtaining the world's first rapid microbial PAT approval from the US FDA. Today, Gilberto was the technical science director for Europe and Asia for Veltek Associates Inc., and in this role, he collaborated with pharmaceutical companies and authorities to develop and implement science-based strategies and processes that utilise quality by design (QbD) principles to monitor, control, and improve the chemical, physical, and microbiological state of various production processes. With his extensive experience in sterility assurance and microbiology, Gilberto has the capability of supporting pharmaceutical manufacturers in a wide variety of aseptic processes, machinery, and methods.

Dr. Thomas Schwarz, CH | Chief Commercial Officer | SiO2

Thomas Schwarz started his career 20 years ago at Sanofi in Frankfurt in the area of recombinant insulin manufacturing. In 2006 he moved to Novartis, where he held several management positions (in Switzerland and US) with increasing responsibility within biotech manufacturing, quality assurance, and clinical supply operations. Before joining SiO2 as chief commercial officer, he served as head of strategic planning for Takeda.

Christian Scarpato, IT | Process Engineering Manager | Merck Italia

Christian Scarpato is a sterile manufacturing fill and finish expert with almost 12 years of experience in pharma companies. In the last years, he worked on the design, installation, and start-up of three new production lines (vials, cartridges, and syringes) with 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.

Pino Cabrera, ES | Consulting Manager | QUALIPHARMA

Pino Cabrera is a senior pharmaceutical consultant with 15 years' experience in the pharmaceutical industry. Pino has knowledge and practical experience in process and cleaning validation, equipment, utilities, facilities qualification, and risk analysis, quality system implementation, and GMP regulation compliance. As a GMP auditor, Pino has performed audits on suppliers of excipients, API and finished product manufacturers, as well as internal audits and gap analysis for GMP compliance.

Miriam Guest, UK | Principal Microbiologist, Pharmaceutical Technology & Development, New Modalities & Parenterals Development | AstraZeneca

Miriam Guest is a principal microbiologist at AstraZeneca, working in the new modalities and parenteral development group, based at their Macclesfield site in the UK. Miriam has worked in pharmaceutical development for over 20 years in a range of roles, from the microbiology laboratory executing method development to being a facility microbiologist supporting a multi-product aseptic manufacturing facility, as well as some time in formulation development. She returned to microbiology in 2012. In recent years, she has designed and developed AstraZeneca's "21st Century Microbiology Strategy" to innovate, industrialise, and implement technology solutions to drive efficiencies and process robustness benefits with the AZ global network. She leads the global microbiology forum at AstraZeneca, which connects microbiologists from approximately 25 sites across the globe – here she fosters a culture of collaboration to support the quality function in driving standardisation and optimisation projects. The forum is an open learning network with broad representation from other skill areas as well key contributions from microbiology. Miriam is an active committee member of the pharmaceutical microbiology interest group (Pharmig) and represents AstraZeneca on a range of cross industry collaboration networks. Outside of work, there is rarely a quiet moment – between being a taxi driver for her two teenage daughters and walking her two dogs, she also enjoys keeping active by playing football and squeezing in gym visits where she can.

James L. Drinkwater, DE | Head of GMP Compliance | Franz Ziel GmbH

James L. Drinkwater is the ex-chairman and an honorary member of the Pharmaceutical and Healthcare Sciences Society (PHSS), a not-for-profit educational platform for GxP and current leader of PHSS special interest groups on aseptic processing and biocontamination. He's the PHSS co-lead of Annex 1 revision (sterile medicinal product manufacturing) focus group and contamination control strategy (CCS) guidance initiative. James is also the current head of GMP compliance at Franz Ziel GmbH and actively involved in pharmaceutical, biologics, and ATMP product manufacturing as well as fill and finish projects. Based in the UK, James has a global support role and is also a qualified trainer on aseptic processing.

Walid El Azab, BE | Industrial Pharmacist, Qualified Person Technical Service Manager | STERIS Corporation

Walid El Azab is an industrial pharmacist, a qualified person, and a lean six sigma green belt. He is a technical services manager for STERIS Life Sciences. He provides technical support related to cleaning, disinfectants, sterility assurance, and process validation. Finally, he leads audits at manufacturer sites and workshops to improve processes and inspection readiness levels. Walid is a lecturer at a pharmacy and medicine university. He has published different articles and book chapters, and he is also part of working groups on sterilisation and EU GMP Annex 1 guideline revision. He is a planning committee member of the annual PDA conference on pharmaceutical microbiology (12th and 13th editions) and part of the editorial committee of the PDA letter. Walid is an observer member of the ISPE Belgium affiliate board. Finally, he is the secretary of the Belgium Qualified Person Association.

Sergio Cuevas Luján, ES | Packaging Materials Engineer | Boehringer Ingelheim

Sergio Cuevas is a well-seasoned and experienced packaging materials engineer with beyond 15 years of experience. He has developed his career in Alcon, Novartis, Sanofi, and Boehringer-Ingelheim. His roles in all of those companies in the departments of supply chain and production have provided him a wide expertise in the pharmaceutical and medical devices industries. He is specialised in packaging projects coordination thanks to a broad vision of the entire packaging lifecycle (quality assurance, validation, production, etc.). Sergio carried out different studies related to design, production, and management of packaging. He is currently studying a degree in chemistry.

Chris Berridge, UK | Global Technical Consultant, Bioquell Specialist | Ecolab Life Sciences

Chris Berridge is a global technical consultant, Bioquell specialist for Ecolab Life Sciences. He has over seven years of experience working in graded cleanrooms for pharmaceutical manufacturing as well as biosafety laboratories and biomedical facilities. He is a bio-decontamination specialist and subject matter expert on Bioquell technology, products, and services and their uses in the life sciences and healthcare markets. He also manages projects focussing on the implementation of Bioquell's more complex integrated decontamination systems, including detailed design, building of bespoke documentation, and managing the validation and other siteworks. Chris is also an industry speaker at technical conferences and in webinars.

Fabian Stutz, DE | CEO | Pharmabotix AG

Fabian Stutz is the CEO and 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, Fabian is adept at driving business development while delivering exceptional service to customers with a direct communications approach. He is passionate about trying new ideas and providing honest feedback on feasibility to ensure customer satisfaction.

Bianca Bohrer, DE | CEO | PSM GmbH

Bianca Bohrer studied pharmaceutical technology at the University of Applied Sciences in Primasens (Germany). Early on, she gained experience in GMP-compliant work, especially in the area of qualification. As a division manager for analytical chemistry and a manufacturing manager for parenterals, she was able to further deepen these skills. Since September 2014, she has been head of quality control, and since 2019 she's been the managing director of PharmBioTec GmbH, a non-profit research institute, and since 2020 she's been the managing director of Topmedicare GmbH and PSM GmbH - both §13-AMG contract manufacturers for aseptic products.

Sebastian Trennheuser, DE | Co-CEO | PSM GmbH

Dr. Sebastian Trennheuser is the newest member of the Topmedicare and PSM family. After studying pharmacy at the University of Freiburg (Germany), he recently completed his PhD in pharmaceutical technology at the University of Heidelberg (Germany). His focus will be scientific project management.