

# 4<sup>th</sup> Annual Aseptic Processing Summit

FRANKFURT, GERMANY | NOVEMBER 19-20, 2020

## Key Practical Learning Points of the Summit:

- How ready are your cleanrooms for the Annex 1 updates?
- Implementation of quality risk management
- Final fill with SU Equipment
- ADC/HPAPI aseptic processing fill and finish
- Robotics in aseptic processing
- Gloveless Isolators and dose control
- The Evolution of Aseptic Technologies
- Occupational safety requirements
- Multi-Product facilities
- Challenges for manufacturers in cell and gene therapy production systems

## Key Speakers:



Sponsorship-related questions to:  
[reglster@vonlanthengroup.com](mailto:reglster@vonlanthengroup.com)



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



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



**Alessandro Santini, PL**  
Head of Drug Product  
Polpharma Biologics S.A.



**Enrico Zanetti, CH**  
Sales & Business Development Manager  
Swissfillon



**Dr. Mauro Giusti, IT**  
Advisor, Site External Network  
Eli Lilly Italia



**Henrietta Vinnerås, SWE**  
Sr Manager Microbiology & Aseptic Technique / Global Manufacturing Pharmaceuticals  
Fresenius Kabi



**Dr. Thomas Schwarz, CH**  
Head of Strategic Planning & PMO NTO Aseptics  
Novartis



**Dieter Bachmann, US**  
Director Aseptic Processing  
Johnson & Johnson



**Di Morris, UK**  
Audit Manager CAG  
GSK



**Matthias Angelmaier, DE**  
Global Product Manager Isolator and Process Technology  
Syntegon



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## Sponsors:



# 4<sup>th</sup> Annual Aseptic Processing Summit

November 19-20, 2020  
Frankfurt, Germany

## Vonlanthen Group is pleased to invite you to the

**4th Annual Aseptic Processing Summit** scheduled on  
**November 19 – 20, 2020 in Frankfurt, Germany.**

**At this Summit**, participants will be given the opportunity to discourse and to network with peers involved in pharmaceutical manufacturing, aseptic fill and finish, quality control, engineering and container development. Key topics in aseptic processing will be discussed by some of the industry's leading lights.

**This conference will give you** a broad overview of current changes in the European regulations, modern technical trends, emerging technologies and innovations.

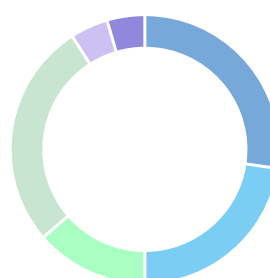
We are delighted to give you this opportunity to participate at this Summit.

We look forward to welcoming you in **Frankfurt** in November!

## Who Should Attend:

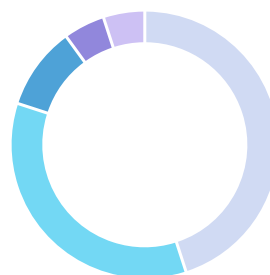
**Chief Executives, Directors, Vice Presidents, Heads, Leaders, Senior Managers, Scientists, Chemists, Engineers and Fellows specialising in:**

- ▶ Bioprocess Research and Development
- ▶ Biotechnology
- ▶ Container Development
- ▶ CMC
- ▶ Drug Development
- ▶ Engineering
- ▶ Fill and Finish
- ▶ Freeze-Drying
- ▶ Formulation
- ▶ Licensing
- ▶ Lyophilisation
- ▶ Medical Devices
- ▶ Nanomaterials
- ▶ Parenterals
- ▶ Packaging and Labelling
- ▶ Pharmaceutical Process and Technology
- ▶ Process Monitoring and Control
- ▶ Process Analytics
- ▶ Product Innovation
- ▶ Packaging
- ▶ QA/QC
- ▶ R&D
- ▶ Risk Management
- ▶ Regulatory Affairs
- ▶ Stability
- ▶ Standardisation Science
- ▶ Sterilisation
- ▶ Vaccine/Antibody/Cell Manufacturing
- ▶ Validation



Company type in %:

- Pharmaceutical
- Biotechnology
- CRO
- CMO
- NOP
- Other



Geographic distribution in %:

- Europe
- United States
- Canada
- APAC
- Other



08:30 Registration and Welcome Coffee  
09:00 Opening Address from the Chairman

1

2

## CURRENT REGULATORY UPDATES

09:10 **CASE STUDY**  
**How to integrate Annex 1 requirements to a Pharma Company**



**HENRIETTA VINNÉRÅS**

Sr Manager Microbiology & Aseptic Technique /  
Global Manufacturing Pharmaceuticals  
Fresenius Kabi

- Implementation of a comprehensive contamination control strategy (CCS) across a multiple manufacturing location and global company with various products – how can a process to roll-out a system and a strategy for a CCS be handled?
- Added Annex 1-detail to requirements for equipment/technology and cleanrooms – how to manage existing facilities, equipment and technologies with different age and complexity in relation to new regulatory expectation?
- New contents in Annex 1 – what is new and how will this affect our existing processes as well as project planning for new manufacturing locations?

09:50  **SPEED NETWORKING**

A special time slot for interaction between sponsors, delegates and speakers. All participants will gather around exhibitors and share experiences with each other while creating new contacts

10:30 **CASE STUDY**  
**Update on the new draft Annex 1**



**RICHARD DENK**

Senior Consultant Aseptic Processing & Containment  
Skan AG, Switzerland

- Contamination Control Strategy
- Barrier System
- Feedback from the ISPE Annex 1 Commenting Group

11:10  **MORNING COFFEE AND NETWORKING BREAK**

## ADVANCED CONTAMINATION CONTROL

11:40 **CASE STUDY**  
**Contamination control**  
**WALID EL AZAB**  
Industrial Pharmacist, Qualified Person/  
Technical Service Manager  
STERIS Corporation



- To be announced

12:20 **CASE STUDY**  
**To be Announced**  
**DIETER BACHMANN**  
Director Aseptic Processing  
Johnson & Johnson



- To be announced

13:00  **NETWORKING BUFFET LUNCH**



Sponsorship-related questions to:  
[register@vonlanthengroup.com](mailto:register@vonlanthengroup.com)

14:00  SPONSORED SPEAKING SLOT

**CASE STUDY**

To be announced

**MATTHIAS ANGELMAIER**

Global Product Manager Isolator and Process Technology  
Syntegon

**SYNTEGON**  
PROCESSING & PACKAGING

• To be announced

14:30 **CASE STUDY**  
To be Announced  
**SPEAKER TO BE ANNOUNCED**

• To be announced

15:10  AFTERNOON COFFEE AND NETWORKING BREAK

CLEANING VALIDATION

15:40 **CASE STUDY**  
To be Announced  
**SPEAKER TO BE ANNOUNCED**

• To be announced

16:20  SPONSORED SPEAKING SLOT

**CASE STUDY**

**Aseptic filling: RABS vs.  
Isolator- Pros&Cons. An experience  
from CMOs**

**ALESSANDRO SANTINI**

Head of Drug Product  
Polpharma Biologics S.A.

**polpharma**  
biologics

**swissfillon**  
Specialized Contract Filling

**ENRICO ZANETTI**

Sales & Business Development Manager  
Swissfillon

• To be announced

16:50  PANEL DISCUSSION - MODERATED BY CHAIRMAN OF DAY 1

17:30  CHAIRMAN'S CLOSING REMARKS AND END OF DAY ONE

18:30  
20:30  BUSINESS DINNER

08:30 Registration and Welcome Coffee  
09:00 Opening Address from the Chairman

## MANUFACTURING TENDENCIES

09:10 **CASE STUDY**  
**A model for Aseptic operations governance (structure, skills and competences)**  
**DR. MAURO GIUSTI**  
Advisor, Site External Network  
Eli Lilly Italia

*Lilly*

- Well defined organization (workers, supervisors, professionals, experts, leaders with related functions)
- Appropriate governance and business processes (information/escalation/decision making)
- Proper technical competency distributed across the organization

09:50 **CASE STUDY**  
**To be Announced**  
**DI MORRIS**  
Audit Manager CAG  
GSK

*gsk*

- To be announced

10:30  **SPONSORED SPEAKING SLOT**

Open Opportunities for Sponsors

11:00  **MORNING COFFEE AND NETWORKING BREAK**

## MANUFACTURING TENDENCIES

11:30 **CASE STUDY**  
**Site Transformation Stein Steriles: From Small Molecule to Combination Product Processing**  
**DR. THOMAS SCHWARZ**  
Head of Strategic Planning & PMO NTO Aseptics  
Novartis

*NOVARTIS*

- 20 years filli finish evolution at Stein Steriles
- From small molecule to biotech combination products
- Disruptive changes (Isolator technology, process oriented organisation)
- Vertical Integration
- Future aseptic processing

12:10  **NETWORKING BUFFET LUNCH**

13:10  **SPONSORED SPEAKING SLOT**

Open Opportunities for Sponsors

13:50  **PANEL DISCUSSION - MODERATED BY CHAIRMAN OF DAY 2**

14:30  **CHAIRMAN'S CLOSING REMARKS AND END OF DAY ONE**



Sponsorship-related questions to:  
[register@vonlathengroup.com](mailto:register@vonlathengroup.com)



**Richard Denk, CH**  
Senior Consultant Aseptic Processing &  
Containment  
**SKAN AG, Switzerland**



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



**Alessandro Santini, PL**  
Head of Drug Product  
**Polpharma Biologics S.A.**



Alessandro Santini holds a bachelor's in chemical engineering and has 14 years of experience in biopharmaceutical industry. For the first 6 years of his career, he held engineering role with responsibility for the maintenance of all of the equipment involved in the filling of sterile liquid and freeze-dried plasma-derived products. In 2012, still for the same Italian biopharmaceutical company, he became responsible of the Aseptic Filling Department consisting of 6 lines suitable both for liquid and lyophilized forms. Since 2018 he joined Polpharma Biologics (Gdansk, PL) as Head of Drug Product manufacturing where he is following the startup of the new state of the art fill and finish department designed for the production of biologics (mAb).



**Dr. Mauro Giusti, IT**  
Advisor, Site External Network  
**Eli Lilly Italia**



Dr. Mauro Giusti holds a Master Degree in Chemistry at University of Florence and he is Board Certified by National Chemist association. After completion of mandatory military service as Army officer, he joined Eli Lilly at the Italy manufacturing plant site in 1988. Over the 32 years with Eli Lilly, Dr. Giusti has covered several positions within the Lilly Manufacturing organization (Regulatory, Technical Services, Project Management, Quality Control, Quality Assurance, Production of oral and parenteral products, Technical Director/Qualified Person, Six Sigma Champion. Manufacturing Science and Technology, Manufacturing Procurement), dealing both with Lilly manufacturing plants as well as with Contract manufacturing in the Europe/Africa/Asia. Among the several experiences with Lilly, he has worked approximately 5 years outside of Italy, both in United States (2.5 yrs, from 1992 to 1994) and in United Kingdom (2.5 yrs, from 1997 to 1999). Since late 2003, with the Lilly Italia mission change from Sterile and Oral cephalosporin to Insulin/Biotech products, he has had responsibility for Lilly Italy TSMS (Technical Svcs/Mfg Science Department), with responsibility for Metrology, C&Q of facilities, utilities and equipment, Sterility Assurance, Process Validation, set-up of new manufacturing processes and of new manufacturing technology for Biotech products, including automatic assembly of disposable Insulin pens and Autoinjectors. In September 2009 he also added to his TSMS duties, the responsibility for Manufacturing Sourcing and Vendor Management. In September 2019 he has taken a new role, as Advisor, Site External Network, dealing with external entities linked to the Lilly Sesto Manufacturing site (especially Universities) and leading a Lilly Global project for improvement of technical capabilities in Parenteral Manufacturing. For more than 12 years he has served as a member of the Italy Chapter of PDA, with several participations to national and international forum both as speaker and as chairman.



**Dr. Thomas Schwarz, CH**  
Head of Strategic Planning &  
PMO NTO Aseptics  
**Novartis**



Thomas Schwarz has a PhD in chemistry and an executive MBA. He joined Aventis in 1999 in Frankfurt, where he worked in recombinant insulin production. He has worked at Novartis since 2006 in a variety of functions including process manager of sterile manufacturing, plant manager of biotech in the US and QA/QV team leader. He is currently the head of strategic planning for aseptics, which includes nine drug product sites around the globe.



**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 level. 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 secretary of the Belgium Qualified Person Association.



**Enrico Zanetti, CH**  
Sales & Business Development Manager  
**Swissfillon**



Enrico Zanetti holds a master's degree in agrochemical sciences. He's been working in the pharmaceutical field for many years, mostly on sales and business development of drug delivery and medical device companies taking care of European and far Eastern countries. After several years in the sales field he decided to improve his technical background by joining the R&D of a medical device company, working first as project manager, and then managing the R&D team located in the Swiss branch for about seven years. He also worked as a consultant, in 2017, for many companies, supporting them in finding new businesses/products/drug licenses, etc., and providing support to those companies interested in entering the medical device respiratory business. He recently joined Swissfillon to support the take-off of the business projects with all companies interested to partner with Swissfillon, a CDMO fill and finish company, with fully automatic systems, working in GMP sterile conditions, specialised in filling of biopharmaceuticals and high-potent products for clinical trials and for the commercial launch of vials, syringes and cartridges.



**Henrietta Vinnerås, SWE**  
Sr Manager Microbiology & Aseptic  
Technique / Global Manufacturing  
Pharmaceuticals  
**Fresenius Kabi**



Mrs Vinnerås has been with Fresenius Kabi since 2017, and previous to that since year 2000 worked for pharmaceutical and medical device companies such as Abbott and Pfizer within different quality departments and holding various management responsibilities and positions. Recently, as an associated senior quality consultant at ÅF Life Science she had assignments within the areas of quality assurance, risk management, validation and education at clients such as GE Healthcare, Thermo Fisher Scientific, Fresenius Kabi and smaller life science companies. Currently Mrs Vinnerås is part of a global competence center within Fresenius Kabi, supporting the companies' pharmaceutical manufacturing operations worldwide with e.g. establishing global corporate procedures, performing on-site assessments, education and training, trouble shooting, root cause investigations, CAPAs and continuous improvement projects; specifically within the areas of microbiology and aseptic technique.



**Matthias Angelmaier, DE**  
Global Product Manager Isolator and  
Process Technology  
**Syntegon**



Matthias Angelmaier has a bachelor's degree in industrial and mechanical engineering as well as a master's degree in business development. He joined Syntegon Technology GmbH in 2009. During his first 3 years, he was a project manager for handling complex customer projects. Since 2012, he is the globally responsible product manager for barrier systems, isolator and process technology. His expertise includes process engineering, sterilization, bio-decontamination, aseptic and high-potent Isolator applications, glove testing systems as well as topics related to advanced aseptic processing. He is a frequent speaker on international symposia and conferences including organizations like ISPE and PDA.

# PRE-REGISTRATION FORM

## 4th Annual Aseptic Processing Summit

Date of registration:



E-mail this form to: [register@vonlathengroup.com](mailto:register@vonlathengroup.com)

Upon receiving the registration form, you will get an invoice for payment.

| Package name                                                                                    | Register till<br>11 May | Register till<br>June | Last Minute<br>Discount | Standard |
|-------------------------------------------------------------------------------------------------|-------------------------|-----------------------|-------------------------|----------|
| <input type="checkbox"/> Delegate: Standard                                                     | € 1395 (save €600)      | € 1595 (save €400)    | € 1795(save €200)       | € 1995   |
| <input type="checkbox"/> Group Delegates: 2 +<br><small>*price per person</small>               | € 1295 (save €700)      | € 1495(save €500)     | € 1695(save €300)       | € 1995   |
| <input type="checkbox"/> Group Delegates: 4 +<br><small>*price per person</small>               | € 1195 (save €800)      | € 1295(save €700)     | € 1495(save €500)       | € 1995   |
| <input type="checkbox"/> Non-profit [fixed price]<br><small>*Institutions and academics</small> | € 1195                  | € 1195                | € 1195                  | € 1195   |

**\*Hotel accommodation & travel costs are not included in the registration fee.**

As soon as a **venue** is confirmed, organizer will post the information on its website. Registered delegates will be informed by e-mail.

To register for the Summit, please provide the details below. This registration form is editable.

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Name:  Surname:   
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E-mail:

Special dietary requirements: ☐ Vegetarian ☐ Gluten-free ☐ Other (please specify)

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Name:  Surname:   
Position:   
Company:  If different from invoicing details  
E-mail:

Special dietary requirements: ☐ Vegetarian ☐ Gluten-free ☐ Other (please specify)

3  
Name:  Surname:   
Position:   
Company:  If different from invoicing details  
E-mail:

Special dietary requirements: ☐ Vegetarian ☐ Gluten-free ☐ Other (please specify)

4  
Name:  Surname:   
Position:   
Company:  If different from invoicing details  
E-mail:

Special dietary requirements: ☐ Vegetarian ☐ Gluten-free ☐ Other (please specify)

Payment method: ☐ Wire transfer ☐ Credit card

### Terms and Conditions:

**By sending this form, I confirm that I have read and accepted the Terms and Conditions.**

**Registration Confirmation and Payment Policy:** The organizer will confirm your participation after receiving the signed registration form. The client will receive the invoice within 24hrs of sending the signed form. The organizer requires the full payment of the registration fee within 10 working days of the invoice issue date. Registration fee includes 2 days participation, refreshments, lunches, dinner, and documentation package. Payments can be made by bank transfer or credit card. Payments by bank transfer are in Euros.

**Cancellations and Substitutions:** A delegate may be substituted up to 5 days before the event. Cancellation made one month prior to the start date of the event will be refunded less 50% of the registration fee. Refunds will be made after the event. Cancellations made within one month of the event start date will result in no refund. A written notice is required for cancellation. But the organizer understands that there are unforeseen circumstances that cause cancellations, in such events the organizer can provide a delegate-pass to an upcoming event that will be valid for one year from original event start date. Please note that the delegate-pass cannot be refunded due to further cancellation.

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### Promotional material distribution: Price

☐ Distribution of your company's promotional materials to all conference attendees €999

### Documentation package:

☐ I cannot attend but would like to purchase the documentation package for this event €499

**Presentations** that are available for download will be subject to distribution rights by speaker

### Sponsorship packages

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|----------------------------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------|-------------------------------------------|-----------------------------------------|----------------------------------------------|
| People attending                                                                 | 1                                               | 1                                               | 2                                         | 2                                         | 3                                       | 4                                            |
| Logo on conference website, program, and pre/post-event communication activities | ◆                                               | ◆                                               | ◆                                         | ◆                                         | ◆                                       | ◆                                            |
| Discount on additional passes                                                    | 10%                                             | 10%                                             | 15%                                       | 20%                                       | 30%                                     | 40%                                          |
| Promotional material distribution (provided by sponsor)                          | ◆                                               | ◆                                               | ◆                                         | ◆                                         | ◆                                       | ◆                                            |
| Recognition on Vonlathen Group's SM channels                                     |                                                 |                                                 | ◆                                         | ◆                                         | ◆                                       | ◆                                            |
| Ad placed in final conference program                                            |                                                 |                                                 | 1/4 Page                                  | 1/4 Page                                  | 1/2 Page                                | Full Page                                    |
| Recognition in chairman's opening address                                        |                                                 |                                                 | ◆                                         | ◆                                         | ◆                                       | ◆                                            |
| Speaking slot                                                                    | 20 min                                          |                                                 |                                           | 30 min                                    | 40 min                                  | 20 min                                       |
| Pop-up Stand                                                                     |                                                 | ◆                                               | ◆                                         | ◆                                         | ◆                                       |                                              |
| Host own seminar/workshop within the conference                                  |                                                 |                                                 |                                           |                                           |                                         | 40 min                                       |
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