



# A Roadmap to an enhanced Aseptic Filling: exploring new trends and new technologies

November 6<sup>th</sup>-7<sup>th</sup>, 2025

STERILINE HQ & Sheraton Lake Como Hotel  
Como – Italy



# INTRODUCTION



*Aseptic filling is always a hot and extremely interesting topic!*

*Let's explore all new trends and smart solutions identified and compliance-proved to fulfill the increasingly stringent demands of the authorities.*

*It is fundamental to understand effective solutions based on practical experience and with this two-day congress, you can discover together with experts the best good practices lurking among all possible options.*

*Participate actively on our round table to discover manufacturing complexity and peculiarities. Don't miss learning about these topics:*

- *How to successfully approach a ramp up of a new line*
- *Suitable development, validation and routine use of an isolator*
- *Aseptic material transfer*
- *Elastomers sterilization*
- *Automation advantages and AI opportunities*
- *Latest news on PDA guideline literature for "Aseptic Filling".*

## ORGANIZING COMMITTEE

- Ilaria Fumagalli, CEO Steriline
- Federico Fumagalli, CSO Steriline
- Filippo Parini, Sales Manager Steriline
- Mirko Monti, Marketing Manager Steriline
- Mirko Gabriele, Consultant /PDA Italy Chapter President
- Filippo Trionfera, BSP Pharmaceuticals / PDA Italy Chapter President-Elect
- Claudio Puglisi / Entourage, PDA Italy Chapter Treasurer
- Orazio Cultrera, Cultrera Consulting / PDA Italy Chapter Board
- Mauro Giusti, Lilly / PDA Italy Chapter Past-President
- Gabriele Peron, Stevanato Group / PDA Italy Chapter Secretary
- Lucia Ceresa, Consultant / PDA Italy Chapter Board

# AGENDA DAY 1 – Nov. 6<sup>th</sup> 2025



- 12:30-13:30 Arrival, registration **DAY-1** & Welcome buffet at the congress venue.
- 13:30-13:50 Opening remarks and proposed discussion topic **DAY- 1** & Hot Topics in aseptic filling environment  
**Mirko Gabriele, PDA Italy Chapter President**  
**Filippo Trionfera, BSP Pharma. & PDA Italy Chapter' President-Elect**
- 13:50-14:00 Welcome and Introduction,  
**Ilaria Fumagalli, CEO Steriline**
- 14:00-14:50 **Sponsors' technologies & capabilities presentations**
- 14:50-15:10 Pioneering Fill & Finish with Advanced Robotics, **Filippo Parini, Steriline & Andrea Tanzini, Staubli**
- 15:10-16:30 Peculiarity of filling different sterile medicinal products filling:
- Annex 1 compliance and Capacity increase for ophthalmic eyes drops and Lyo ophthalmic products - **Teresa Riccioni & Maurizio Perrella - Tubilux Pharma, part of Content Group**
  - Integrating EU Annex 1 into Ophthalmic Manufacturing: Challenges and Opportunities, **Nicole Ferrari, Bausch + Lomb & James Rorke, Steriline North America**
- 16:30-16:50 **Coffee Break with the sponsors & technologies**
- 16:50-17:10 Innovative VPHP bio decontamination validation of a new filling line, **Serena Ambrosini, AstraZeneca UK**
- 17:10-17:30 Material transfer and first air criticalities, **Antonio Candela, GSK Parma & Valentina Bianchi, AM Instruments Srl**
- 17:30-17:50 CFD-based aerodynamic analysis of unidirectional airflow areas within a RABS protecting a filling line, **Lapo Galligani, Techniconsult Group & Mario Fusi, Steriline**
- 17:50-18:10 How Industry Technological Trends and Regulatory Evolution are shaping the future Aseptic Transfer Process, **Paolo Liverani, Getinge**
- 18:10-18:40 Panel discussion with all speakers and FDA representative  
Chair: **Marisa Delbò, former AIFA Chief GMP Inspectorate**
- 18:40-18:50 Wrap-up and remarks from **DAY-1,**  
**Mirko Gabriele, PDA Italy Chapter President**
- 19:30-22:30 Transfer to the **networking dinner at Villa Carminati Resta**

# AGENDA DAY 2 – Nov. 7<sup>th</sup> 2025



- 08:30-09:00 Arrival, registration **DAY-2** at the congress venue
- 09:00-09:10 Opening remarks and proposed discussion topic **DAY-2, Filippo Trionfera, BSP Pharma. & PDA Italy Chapter' President-Elect**
- 09:10-09:30 Opportunities & challenges in harmonization during a rapid manufacturing expansion, **Cristiano Demolli, Lilly**
- 09:30-09:50 Process Validation of parenteral products, **Mauro Giusti, Lilly**
- 09:50-10:10 Stoppers in bulk or in bags: the biological validation of their sterilization cycle, the choice and use of the proper biological indicator, in compliance with regulatory requirements, **Maria Luisa Bernuzzi, Mesa Labs**
- 10:10-10:40 **Coffee Break with the sponsors**
- 10:40-11:00 AI & Robotics within pharma automation process, **Remo Sala, Politecnico di Milano & Eduardo Minieri, Politecnico di Milano**
- 11:00-11:20 AI & Robotics improvements in fill & finish machines design, management and maintenance, **Alessandro Caprioli, Steriline & Remo Sala, Politecnico di Milano**
- 11:20-11:40 CCI Test Method Development and Validation of fully assembled autoinjector device: a case study, **Alessia Pacioni, Polpharma Biologics S.A. & Francesca Caprioli, Lighthouse Instruments**
- 11:40-12:00 Comparing dosage systems and the process impact, **Marco Alberio, Ellab**
- 12:00-13:00 **Lunch with the sponsors**
- 13:00-16:00 Transfer from the Sheraton Hotel - **Steriline Headquarters facility tour** - Transfer back to the congress venue
- 16:00-16:20 New PDA Technical Manual on Aseptic Filling, **Rebecca Brewer, QxP & PDA IG**
- 16:20-16:40 Trends and Approaches in Aseptic Parenteral Drug Filling Operations, **Michael Shanks, Principal Consultant for Roan Mountainb Biologic Consulting, LCC and Retired US FDA Inspector**
- 16:40-17:10 **Panel discussion** with all speakers.  
Chair: **Marisa Delbò, former AIFA Chief GMP Inspectorate**
- 17:10-17:20 Wrap up of **DAY-2** and final closing remarks **Filippo Trionfera BSP Pharma. & PDA Italy Chapter' President-Elect**

# GENERAL INFORMATION

## LANGUAGE

The official language of the event is English and all presentations (.ppt slides) are in English.

## CONGRESS VENUE



### Sheraton Lake Como Hotel

Via Per Cernobbio, 41A, 22100 – Como

Steriline will arrange all transfers from the hotel to the Networking dinner location and to its HQ facility tour, based on the scheduled timing.

## NETWORKING DINNER

**Villa Carminati Resta** - Via Borgo Vico, 138, 22100 - Como CO

<https://villacarminatiresta.com/>

## PARTNER HOTEL

Participants are responsible for their own travel costs and accommodation

**Promo rates** at [Reservation-Link](#) for the period from November 5th to 8th.

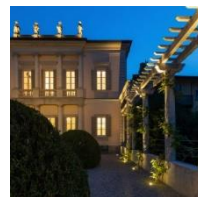
Cancellations Policy: 30 days before arrival.

## FACILITY TOUR



### Steriline SRL Headquarters

Via Tentorio 30, 22100 – Como



## PDA Events & Organizing Secretariat



Centro Congressi Internazionale s.r.l.

Via Guarino Guarini, 4 – 10123 Torino

Tel. 011/2446911 - e-mail: [pda@pda-it.org](mailto:pda@pda-it.org)

web: [www.pda-it.org](http://www.pda-it.org) - [linkedin.com/company/pda-italy](https://www.linkedin.com/company/pda-italy).

# GENERAL INFORMATION



## HOW TO REGISTER

For registration, general information, and payment enquiry, please visit  
<https://registration.ccicongress.com/cmsweb/Login.asp?IDcommessa=257093&Lang=EN>

## REGISTRATION FEES (VAT 22% included)

FREE of charge for AIFA & Regulators

€ 122,00 University

€ 200,00 Young Professional

€ 366,00 PDA and AFI members (**1-day only**: € 219) + 1 free pass\* for a second colleague (concurrent registration)

€ 280,00 for **new** PDA members (new membership August-September)

€ 549,00 PDA and AFI NON-members (1-day only: € 329) + 1 free pass\* for a second colleague (concurrent registration)

€ 732,00 for a **third colleague\*** for the conference at the same time (PDA and AFI NON-members)

Direct competitors of Steriline will not be able to participate in the guided tour.

**Early bird discount: 10% for confirmation received by October 20<sup>th</sup>, 2025**

Registration fee includes badge, program, admission to the scientific sessions, certificate of attendance, coffee breaks, lunches, networking dinner. Contact CCI Organizing Secretariat for any information regarding the free pass and transfers.

\*Subject to availability

## METHOD OF PAYMENT

Bank Transfer Beneficiary: Centro Congressi Internazionale srl

Bank: INTESA SANPAOLO SPA

Mandatory causal: **257093** + Name/Surname of the participant and Company

IBAN: IT08X0306901000100000067336

BIC SWIFT: BCITITMM

Copy of the bank transfer should be sent to the CCI Organizing Secretariat at  
[pda@pda-it.org](mailto:pda@pda-it.org).

After receiving the payment, the Organizing Secretariat (Centro Congressi Internazionale srl) will issue a regular invoice.

## SPONSORSHIP OPPORTUNITIES

Exhibition and Sponsorship Opportunities are available. Contact CCI Organizing Secretariat at [pda@pda-it.org](mailto:pda@pda-it.org) to know the opportunities for this event.

# SPONSOR



A SPECIAL THANKS TO THE SPONSORS FOR THEIR CONTRIBUTION  
TO THE REALIZATION OF THE CONGRESS

