



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

November 6-7<sup>th</sup>, 2025  
STERILINE HQ, Como – Italy





# ORGANIZING COMMITTEE

Ilaria Fumagalli / CEO Steriline (TBC)

Federico Fumagalli / CSO Steriline

Filippo Parini / Sale Manager Steriline

Mirko Monti / Marketing Manager Steriline

Claudio Puglisi / Entourage / PDA Italy Chapter Treasurer

Filippo Trionfera / BSP Pharmaceuticals / PDA Italy Chapter President-Elect

Lucia Ceresa / Consultant / PDA Italy Chapter Board

Mauro Giusti / Lilly / PDA Italy Chapter Past-President

Mirko Gabriele / Consultant / PDA Italy Chapter President

Orazio Cultrera / Cultrera Consulting / 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.
- 13:30-13:40 Opening remarks and proposed discussion topic day-1, **Filippo Trionfera - BSP Pharmaceuticals & PDA Italy Chapter' President-Elect**
- 13:40-13:50 Welcome and Introduction, **Steriline**
- 13:50-14:20 Regulatory update : Annex 11 and 22, Gianpiero Lorenti-**EMA & AIFA**  
*TBD*
- 14:20-14:40 How to harness robotics in contamination-controlled applications **Staubli & Steriline**
- 14:40-15:00 AI & robotics: preventive & predictive analyses -  
**Remo Sala Docente Politecnico di Milano** e Resp. Laboratorio Visione Artificiale Dip. Meccanica
- 15:00-15:20 Robotic & AI within manufacturing process *TBD*  
**Politecnico di Milano + Alessandro Caprioli / Business Development Director Robotics Division**
- 15:20-15:40 **Sponsors' capabilities presentation (8-10 table-top: 3 min each)**
- 15:40-16:10 **Coffee Break with the sponsors**
- 16:10-16:30 Successful approach to a development, validation and routine use of an isolator for a filling line – **Michele Zavaglia, Lilly**
- 16:30-16:50 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, **MariaLuisa Bernuzzi / MesaLab**
- 16:50-17:10 Material transfer and first air criticalities, **Alessia Gragnato - GSK Parma**
- 17:10-17:30 **Presentazione CFD - Steriline + Techniconsult** *TBD*
- 17:30-17:50 A CCI compliance : case study - *TBD*
- 17:50-18:20 Panel discussion with all speakers,  
Chair: **Marisa Delbò former AIFA Chief GMP Inspectorate**
- 18:20-18:30 Wrap-up and final remarks from Day-1, **Filippo Trionfera - BSP Pharmaceuticals & PDA Italy Chapter**
- 19:45-22:00 **Networking dinner**



# 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 Pharmaceuticals & PDA Italy Chapter' President-Elect**
- 09:10-09:30      Opportunities & challenges in harmonization during a rapid manufacturing expansions - **Cristiano Demolli, Lilly**
- 09:30-09:50      *Process Validation of parenteral products – Mauro Giusti, Lilly*
- 09:50-10:10      Comparing dosage systems and the process impact - **Marco Alberio, Ellab**
- 10:10-10:40      **Coffee Break with the sponsors**
- 10:40-11:40      Peculiarity of the different sterile medicinal products filling (Steriline):
- 11:40-12:10      **Q & A**
- 12:10-13:10      **Lunch with the sponsors**
- 13:10-13:30      **Transfer** from the congress venue to **Steriline Headquarters facility**
- 13:30-15:30      **Steriline Headquarters facility tour (rotating participant groups)**
- 15:30-15:50      **Transfer** from Steriline Headquarters facility to the congress venue
- 15:50-16:10      PDA Technical Report Aseptic Filling hot topics overview – **Rebecca Brewer QxP & PDA Interest Group - TBD**
- 16:10-16:30      **FDA INVITED - TBD**
- 16:30-17:00      **Panel discussion** with all speakers.  
Chair: **Marisa Delbò former AIFA Chief GMP Inspectorate**
- 17:00-17:10      Wrap up and final closing remarks, **Filippo Trionfera - BSP Pharmaceuticals & 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



### **Steriline SRL Headquarters**

Via Tentorio 30/31 22100 – Como

Transfers from/back to the **CONVENTIONED HOTEL** and **Steriline Headquarters facility** as well as from Steriline Headquarters facility to THE NETWORKING DINNER and from the Restaurant, to HOTEL will be arranged by Steriline based on the scheduled timing.

## CONVENTIONED HOTELS

Details will be published soon

## PDA Events & Organizing Secretariat



Centro Congressi Internazionale s.r.l.  
Via Guarino Guarini, 4 – 10123 Torino  
Tel. 011/2446925 – fax 011/2446950  
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 [www.pda-it.org](http://www.pda-it.org) at the page dedicated to the Event.

## REGISTRATION FEES (VAT 22% included)

FRE of charge for AIFA & Regulators

€ 122,00 University

€ 200,00 Young Professional

€ 366,00 PDA and AFI members (**1-day only**: € 219)

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

€ 549,00 PDA and AFI NON-members (1-day only: € 329)

€ 732,00 for 2 colleagues for the conference at the same time (PDA and AFI NON-members)

€ 1.038,00 for 3 colleagues for the conference at the same time (PDA and AFI NON-members)

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

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

Registration fee includes badge, program, admission to the scientific sessions, certificate of attendance, welcome cocktail, coffee breaks, lunches, networking dinner.

## 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. Exhibit at PDA Italy Chapter events and let your company's products or services become a valuable tool or resource for our attendees. Contact the CCI Organizing Secretariat at [pda@pda-it.org](mailto:pda@pda-it.org) to know the opportunities for this event (CCI, Via Guarini, 4, 10123 Torino, Tel.: 011 244 6911)