



# Innovation & Quality in Sterile Products Manufacturing: Pathways to Sustainability

October 1-2<sup>nd</sup>, 2025  
Bari, Merck Serono Site



# INTRODUCTION

Today the pharmaceutical industry is at the crossroads of innovation, quality and sustainability. This event proposed by PDA Italy chapter, and hosted by Merck Bari site, has as its objective was created with the aim of exploring how companies successfully address global challenges and transform them into opportunities for responsible growth, through & practical innovative solutions and advanced quality systems.

Industry experts, quality professionals, production managers and specialists will present the main topics related to this strategic change: from the Quality by Design approach in pharmaceutical manufacturing, to the latest digital technologies such as artificial intelligence and the Internet of things, in order to improve efficiency and sustainability.

Wide space will be dedicated to Lean Manufacturing Initiatives and “green” strategies for waste reduction and process optimization, as well as the impact of emerging technologies on pharmaceutical quality systems.

The event will also offer the opportunity to learn about concrete case studies and best practices related to improve sustainability within pharmaceutical production, with a focus on the effective integration between innovation and quality as the key to a more enjoyable future.

The initiative will culminate with a guided tour of the Merck production plant in Bari, a center of excellence for the manufacturing and control of sterile drugs, which represents a virtuous example of innovation applied to quality and sustainability in the pharmaceutical sector.

## ORGANIZING COMMITTEE

Michele Simone / Bracco / PDA Italy Chapter Steering Committee  
Francesco Esposito / Merck Group / PDA Italy Chapter Steering Committee  
Orazio Cultrera / Cultrera Consulting / PDA Italy Chapter Board  
Filippo Trionfera / BSP Pharmaceuticals / President-Elect PDA Italy Chapter  
Gabriele Peron / Stevanato Group / PDA Italy Chapter Board  
Mirko Gabriele / Consultant / President PDA Italy Chapter  
Lucia Ceresa / Consultant / PDA Italy Chapter Board  
Mauro Giusti / Lilly / PDA Italy Chapter Past-President

# AGENDA DAY 1 – October 1<sup>st</sup>, 2025

- 12:00 – 13:00 Arrival, registration & Welcome buffet
- 13:00 – 13:10 Opening remarks and proposed discussion topic,  
**Mirko Gabriele, President PDA Italy Chapter**
- 13:10 – 13:40 Keynote Presentation: Innovating Pharma: Driving Quality and Sustainability -  
**Michele Simone, Bracco**
- 13:40 – 14:10 Quality by Design in Pharma Manufacturing – **Igor Venanzoni, Stilmas**
- 14:10 – 14:40 Digital Transformation in Pharma – Leveraging AI and IoT for quality and sustainability – **Toni Manzano**
- 14:40 – 15:10 Lean Manufacturing and Green Initiatives: Strategies for waste reduction and process optimization – **Filippo Canrossi, Chiesi**
- 15:10 – 15:20 **Sponsors' capability presentations**
- 15:20 – 15:40 **Coffee Break**
- 15:40 – 16:10 Addressing the Requirements of the 2025/40 Packaging and Packaging Waste Regulation: Integrating Chemical Material Compliance in the Design of Safe and Sustainable Packaging", **Elmedina Shimaj, Stevanato Group**
- 16:10 – 16:40 The economic recovery, recycling and re-use of pharmaceutical glass -  
**Steve Whettingsteel, Krysteline**
- 16:40 – 17:10 Emerging Technologies and Their Impact on Pharma Quality Systems –  
**Sofia Lange – Veeva**
- 17:10 – 17:40 Case study – **Fabio Zenobi, BSP**
- 17:40 – 18:30 **Q&A and Panel discussion** with all speakers & technical experts.  
Chair: **Marisa Delbò former AIFA Chief GMP Inspectorate**
- 18:30 – 18:45 Wrap up and closing remarks,  
**Mirko Gabriele, President PDA Italy Chapter**
- 19:00 – 22:00 **Networking Dinner**

# AGENDA DAY 2 – October 2<sup>nd</sup>, 2025

- 8:30 – 9:00 Welcome Coffee: arrival & registration
- 9:00 – 9:30 Keynote Presentation: Integrating Innovation and Quality: The Road to a Sustainable Future – **Col. Arcangelo Moro, Stabilimento Chimico Farmaceutico Militare**
- 9:30 – 10:00 Sustainability in Manufacturing: Best Practices and Case Studies – **Jaffrey Whitford, Merck**
- 10:00 – 10:30 Continuous Manufacturing in process automation linked to energy calculation: focus on Integrated Diagnostics/ Ease of data transmission/ Non-intrusive measurements – **Giuseppe Iandolo & Claudia Di Biase Emerson**
- 10:30 – 11:00 Lyophilization production: continuous manufacturing - **Prof. Roberto Pisano, University of Torino**
- 11:00 – 13:00 ***Merck Healthcare SITE tour***
- 13:00 – 14:00 **Lunch break**
- 14:00 – 15:00 Q&A and interactive ***Panel discussion*** with all speakers & technical experts. Chair: ***Marisa Delbò former AIFA Chief GMP Inspectorate***
- 15:00 – 15:15 Closing remarks, **Filippo Trionfera President Elect PDA Italy Chapter**

## NOTES

PDA Italy will arrange transfers from the hotel to the facilities based on the scheduled timing. Participants are responsible for organizing and paying their travel costs and accommodation to the Hotel.

# 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)

### Free of charge Regulators

€ 122,00	University
€ 300,00	PDA & AFI members ( <b>1-day only</b> : € 219)
€ 480,00	PDA or AFI NON-members ( <b>1-day only</b> : € 329)
€ 750,00	for 2 colleagues for the conference at the same time (PDA or AFI NON-members)
€ 850,00	for 3 colleagues for the conference at the same time (PDA or AFI NON-members)

Early bird discount: **10%** discount for confirmation received within September 1<sup>st</sup>, 2025.

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

## METHOD OF PAYMENT

Bank Transfer Beneficiary: Centro Congressi Internazionale srl

Bank: INTESA SANPAOLO SPA

Mandatory causal: 257088 + 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.

# GENERAL INFORMATION



## LANGUAGE

The official language is Italian. No simultaneous translation is provided. All presentations (.ppt slides) are in English.

## CONGRESS VENUE &

### FACILITY TOUR

**Merck Serono S.p.A.**

Via delle Magnolie, 13, 70026 Modugno BA

## SUGGESTED HOTELS

A suitable number of rooms have been reserved at a discounted rate at [Parco dei Principi Bari Palese Aeroporto](#). Send a booking request email to [info@parcodeiprincipibari.it](mailto:info@parcodeiprincipibari.it) indicating in the text “**rate dedicated to the Merck – PDA event**”.

*Promotion valid until September 15th.*

## SPONSORSHIP OPPORTUNITIES

Sponsorship opportunities are available to support the event. Let your company's products or services become a valuable tool or resource for our attendees.

## PDA Events & Organizing Secretariat



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