

INNOVATION & QUALITY IN STERILE PRODUCTS MANUFACTURING: PATHWAYS TO SUSTAINABILITY



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OCTOBER
1ST – 2ND
2025



Innovation & Quality in Sterile Products Manufacturing: Pathways to Sustainability

October 1st-2nd, 2025
Merck Italy, Modugno-Bari 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

AGENDA DAY 1 – October 1st, 2025

12:00 – 13:00 Arrival, registration & Welcome buffet at Merck Italy, Modugno-Bari Site.

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 Driving Sustainable Pharma: Case Studies Showing Practical Approach for Water and Energy Savings in Pharma Manufacturing 4.0 & 5.0,
Paolo Leani, STILMAS & Igor Venanzoni, MGA - Masco Group

14:10 – 14:40 Digital Transformation in Pharma – Leveraging AI and IoT for quality and sustainability, ***Toni Manzano - Aizon***

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 Developing a Cost-Effective Borosilicate Glass Deconstruction System, ***Steve Whettingsteel - Krysteline***

16:40 – 17:10 Emerging Technologies and Their Impact on Pharma Quality Systems, ***Sofia Lange – Veeva***

17:10 – 17:40 Sustainability in wastewater management in a DS/DP manufacturing plant: a case Study, ***Fabio Zenobi - BSP***

17:40 – 18:30 **Q&A and interactive 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 2nd, 2025

8:30 – 9:00 Welcome Coffee: arrival & registration

9:00 – 9:30 Sustainability in Manufacturing: Best Practices and Case Studies, **Jeffrey Whitford - Merck**

9:30 – 10:00 Sustainable Choice to Bring-in HyperPure® H₂O₂ Green Sterilization to Reduce Water and Energy Consumption: a case study, **Sara Ferretti, Patheon by ThermoFischer & Andrea Muggiasca - De Lama**

10:00 – 10:20 **Coffee Break**

10:20 – 10:50 Continuous Manufacturing in process automation linked to energy calculation: focus on Integrated Diagnostics/ Ease of data transmission/ Non-intrusive measurements, **Giuseppe Landolo & Claudia Di Biase - Emerson**

10:50 – 11:20 Continuous Freeze-Drying: Innovative Strategies for Unit-Dose Manufacturing, **Prof. Roberto Pisano - Politecnico di Torino**

11:20 – 13:20 **Merck Italy, Modugno-Bari Site tour**

13:20 – 14:20 **Lunch break**

14:20 – 14:50 The Future of the Military Chemical Pharmaceutical Plant Between Scientific Innovation and Environmental Sustainability, **Col. Arcangelo Moro - Stabilimento Chimico Farmaceutico Militare**

14:50 – 15:20 **Q&A and interactive Panel Discussion** with all speakers & technical experts. Chair: **Marisa Delbò former AIFA Chief GMP Inspectorate**

15:20 – 15:30 Closing remarks, **Filippo Trionfara 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 at the page dedicated to the Event.

REGISTRATION FEES (VAT 22% included)

Free of charge Regulators

- € 122,00 University
- € 300,00 PDA & AFI members (**1-day only**: € 219)
- € 480,00 PDA or AFI NON-members (**1-day only**: € 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 1st, 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. After receiving the payment, the Organizing Secretariat (Centro Congressi Internazionale srl) will issue a regular invoice.

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.

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 Italy, Modugno-Bari Site.

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](http://www.parcodeiprincipibari.it). Send a booking request email to info@parcodeiprincipibari.it indicating in the text “**rate dedicated to the Merck – PDA event**”.

Promotion valid until September 15th.

PDA Events & Organizing Secretariat



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