



Reimagining the factory: how to leverage automation, digital solutions and QRM

15-16 October, 2026

GSK – Rosia (SI)



INTRODUCTION

Digitalization is a continuous journey that requires multidisciplinary expertise to accurately assess the current state, define the target, and deliver an effective, efficient implementation. Deploying AI, robotics, automation, and computerized operations are key enablers: they raise quality, accelerate processes, and create flexible capacity to support change and deliver better outcomes for patients.

Digitalization is essential across the pharmaceutical value chain—from R&D and product development to commercialization and process monitoring. Important questions remain: What exactly does digitalization mean in our context? Where should it be applied? What are the main challenges? What are the DOs and DON'Ts?

This event is an excellent opportunity to discuss these questions with experts, review real-world case studies, and identify practical next steps.

ORGANIZING COMMITTEE

- Cristiana Campa, GSK / PDA Board of Directors
- Emiliano Battisti, GSK
- Mauro Giusti, Lilly / PDA Italy Chapter' Chapter Liaison
- Filippo Trionfera, BSP Pharmaceuticals / PDA Italy Chapter' President
- Mirko Gabriele, InfiniteVision / PDA Italy Chapter' Past-President
- Claudio Puglisi, Entourage / PDA Italy Chapter Bord Committee
- Orazio Cultrera, Cultrera Consulting / PDA Italy Chapter' Steering Committee
- Lucia Ceresa, Consultant / PDA Italy Chapter' President-Elect
- Gabriele Peron, Stevanato Group / PDA Italy Treasurer
- Marcorosario Cusmano, Merck / PDA Italy Chapter' Steering
- Anna Campanella, Takeda / PDA Italy Chapter' Steering
- Nicola Giardini, Marchesini Group

AGENDA DAY 1 – October 15th, 2026

- 12:00 – 12:30 Welcome Coffee: arrival & registration
- 12:30 – 12:40 Opening remarks and proposed discussion topics,
Filippo Trionfera, BSP Pharmaceuticals / PDA Italy Chapter President & Mauro Giusti, Lilly / PDA Italy Chapter' Chapter Liaison (10')
- 12:40 – 13:00 Welcome & Introduction to the congress DAY-1 – **Andrea D' Amato & Susan Hynes – GSK** (20')
- 13:00 – 13:30 **Regulatory** perspectives, **Giampiero Lorenti, EMA** (30')
- 13:30 – 14:00 **Regulatory** perspectives, **Marco Fulfaro, AIFA** (30')
- 14:00 – 14:25 The Regulatory Approach to AI: Good practices for using AI in drug manufacturing
- **Toni Manzano - Aizon & PDA Interest Group** (25')
- 14:25 – 15:00 **Regulatory Panel Discussion** (30')
- 15:00 – 15:10 Introduction to PDA – **Falk Klar, PDA Europe** (10')
- 15:10 – 15:40 **Sponsors' technologies & capabilities presentations** (10 sponsors)
- 15:40 – 16:00 **Coffee Break with the sponsors & technologies**
- 16:00 – 16:25 Redefining GMP Audits through Agentic AI – **Gabriele Gori, Chiesi** (25')
- 16:25 – 16:50 From GenAI to Operational Value: Designing Reliable Agents in GxP Environments — Real-World Case Studies, **Niccolò Rosini & Claudia Mandola, GSK** (25')
- 16:50 – 17:15 How AI, risk and people re-skilling are reshaping quality, **Salvatore Di Nottia & Michele Simone, Bracco Corporate Quality Management** (25')
- 17:15 – 17:35 **Q & A** (20')
- 17:35 – 18:05 **News from Technical Providers** (10' for 3 presentations)
- 18:05 – 18:15 Introduction to **Corima Production Plant tour Marchesini Group - Nicola Giardini, Marchesini Group**
- 18:15 – 19:30 **Corima Production Plant, Marchesini Group Aseptic Business Unit TOUR (transfer included)**
- 19:30 – 22:30 **Networking dinner at Corima Production Plant, Marchesini Group (transfer included)**

AGENDA DAY 2 – October 16th, 2026

- 8:30 – 9:00 *Welcome Coffee: arrival & registration*
- 9:00 – 9:10 *Opening remarks of DAY-2 and proposed discussion topics*
Cristiana Campa – GSK / PDA Board of Directors & Lucia Ceresa, Consultant / President-Elect PDA Italy Chapter
- 9:10 – 9:35 *When AI Enters Decision-Making, Who Remains Accountable? Rethinking Decision Governance in AI-Augmented Quality Systems -* **Damiano Dragone, Dragone Consulting (25')**
- 9:35 – 10:00 *Designing the Road to Automated Quality Control –* **Carina Seitz & Ines Schaidler, TAKEDA (25')**
- 10:00 – 10:25 *Automated Clearance & Manufacturing Intelligence: evolving from vision systems to digital and cognitive manufacturing –* **Giulio Bolzonello - Sea Vision (25')**
- 10:25 – 10:50 *A Digital Transformation Journey: from Data to Better Decisions in Manufacturing -* **Marcorosario Cusmano, Merck & Emmanuele Dicerto, KOERBER (25')**
- 10:50 – 11:10 **Q & A (20')**
- 11:10 – 11:40 **Coffee Break with the sponsors & technologies (30')**
- 11:40 – 11:05 *Beyond Traditional Handover: Accelerating Product Realization with Digital CMC and Unit Operation Models –* **Duccio Bianciardi & Ilaria Mori, GSK (25')**
- 11:05 – 11:30 *AI Augmented Deviation Investigation: from manual variability to structured, auditable intelligence –* **Vivek Seth, Simtra BioPharma Solutions & Marco Iacobelli, InfiniteVision (25')**
- 11:30 – 11:55 *Overcoming barriers when moving from paper to digital GMP related documentation -* **Janin Stratmann-Selke, Abbott & Kurt Stewart, Ecolab (25')**
- 11:55 – 12:20 *AI-Driven Digitalization of Design Qualification (DQ). From manual traceability to governed automation: a case study -* **Guido Apuzzo, CSV & Pablo Munoz Pierattini, Chemelectiva (25')**
- 12:20 – 12:30 **Q & A (20')**
- 12:30 – 13:00 **Round table panel discussion (all speakers & experts Day 1-2)**
- 13:00 – 14:00 **Lunch break**
- 14:00 – 15:30 **GSK Site tour (1h – 30')**
- 15:30 – 15:40 *Wrap-up and closing remarks from DAY-2,* **Mauro Giusti, Lilly / PDA Italy Chapter' Chapter Liaison**
- 15:50 **END of the congress**

GENERAL INFORMATION

LANGUAGE

The official language is **English**. Either slides or presentations will be in **English**. Simultaneous translation is not provided.

CONGRESS VENUE & FACILITY TOUR

Congress venue:



GSK
Sovicille - Località Bellaria
53018 Rosia (SI)



Corima Production Plant –
Marchesini Group Aseptic Business Unit
Strada delle Frigge 15, 5603
Monteriggioni (SI)

HOW TO REACH THE VENUE

- GSK Rosia site can be reached within 20-30 min from Siena Train Station (Piazza Carlo Rosselli). BUS ("Siena - Ferrovia" - Stop), Line **S33** (Stop at "Località Bellaria" / "Sovicille - Zona Industriale")
- Connections available by bus from **Firenze Autostazione** (close to Santa Maria Novella Train Station) to **Siena (Piazza Gramsci o Stazione FS)**.
<https://www.itabus.it/it/tratte-bus/firenze-siena>; <https://www.at-bus.it/it/linee-e-orari/regionali-131>

NETWORKING DINNER

Guest of Corima – Marchesini Group Production facility, Strada delle Frigge 15, 5603 Monteriggioni (SI)

GENERAL INFORMATION



HOW TO REGISTER

For registration, general information, and payment enquiry, please visit our web site:

<https://www.pda-it.org/eventi/eventi-in-programma> and contact our **CCI secretariat** pda@pda-it.org

for any information regarding the free pass, discounted rates and available transfers.

REGISTRATION FEES (VAT 22% included)

AIFA and Regulators	Free of charge
University	€ 61,00
Young Professional (under 26)	€ 200,00
New PDA members/new membership (up to August 2026)	€ 280,00
PDA and AFI <i>members</i>	€ 350,00
PDA and AFI <i>members</i> + 2 nd colleague	€ 366,00
PDA and AFI <i>members</i> + 3 rd colleague	€ 519,0
(extra discounted rate for a concurrent registration)	
PDA and AFI <u>NON-members</u>	€ 500,00
PDA and AFI <u>NON-members</u> + 2 nd colleague	€ 549,00
PDA and AFI <u>NON-members</u> + 3 rd colleague	€ 779,00
(extra discounted rate for a concurrent registration)	

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

Early bird discount: 10% for confirmation received by August 30th, 2026

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 (CCO - Centro Congressi Internazionale srl) will issue a regular invoice.

HOTEL

Participants are responsible for their own travel costs and accommodation,

Suggested Hotels:

- Hotel NH Siena, Via La Lizza, 1, 53100 Siena
- Villa Ermellina Siena, Via Custoza 2, 53100 Siena
- Hotel Italia, Viale Cavour 67 - 53100 Siena

GENERAL INFORMATION



SPONSORSHIP OPPORTUNITIES

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

PDA Events & Organizing Secretariat



Centro Congressi Internazionale s.r.l.
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