EURA
INTERNATIONAL CONFERENCE

EUROPEAN REGULATORY AFFAIRS CONGRESS 2026

INTERNATIONAL CONFERENCE

14-21 MAY | Virtual

PEC PHARMA EDUCATION CENTER

INFO@PHARMAEDUCATIONCENTER.IT WWW.PHARMAEDUCATIONCENTER.IT

Pharma Education Center is excited to invite regulatory affairs professionals to the upcoming "**EUROPEAN REGULATORY AFFAIRS CONGRESS 2026**."
This year the European Regulatory Affairs Congress becomes GLOBAL promoting international level content designed for a worldwide audience.

This year the format will enclose hot topics related with EU, UK and US landscape.

Join us to gain practical insights, strengthen your expertise, and engage in meaningful discussions with international industry leaders and Regulatory Body representatives.
We look forward to your participation and joining us in promoting a productive and engaging discussion.

WHY ATTEND

- Connect with leading Regulatory Affairs experts, opinion leaders, and regulatory body representatives
- Stay updated on the latest EU-US regulations and policy changes
- Gain valuable, practical insights from industry specialists
- Expand your international network

WHO SHOULD ATTEND

Regulatory Affairs & Market Access VP, Directors, Manager, Head and Professionals of Pharma, Biotech and Medical Device Industries.

MODULE I
May 14th

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SESSION I - NEW EU VARIATIONS GUIDELINES: SHARING OF APPLICATIONS

The EU Variations Guidelines are evolving to create a more streamlined, simplified process for updating medicine marketing authorizations. The new framework will take effect on **15 January 2026**, introducing simplified variation classifications—Types IA, IB, and II—and new tools to support more efficient lifecycle management as **PACMPs** (Post Approval Change Management Protocols) and **PLCMs** (Product Lifecycle Management documents), along with mandatory worksharing.
To prepare, MAHs should comply with updated submission expectations for changes and other routine post approval variations. Early readiness will support a smooth transition and ensure continued compliance in the evolving regulatory environment.
The session will feature insights from the Italian regulatory authority representative from **AIFA**, while leading pharmaceutical companies will share their early experiences applying the new regulation across the product lifecycle.

Key discussion points:

- Updates on post-authorization changes and procedures for medicinal products for human use
- New challenges and first experiences of the application of this new regulation from regulatory body and pharma companies
- Implications for product lifecycle management including practical implications for planning, compliance, and strategic decision making

SESSION II - PROMOTIONAL MATERIALS REQUIREMENTS IN EUROPE: Navigating a Complex and Evolving Landscape

Ensuring compliance in the development, review, and dissemination of promotional materials for medicinal products in Europe remains one of the most intricate areas of pharmaceutical regulation. With the participation of representatives from the Italian regulatory authorities (**AIFA** and the **Italian Ministry of Health**), this session will explore the diverse and evolving **Italian and EU requirements on advertising to healthcare professionals and patients**, highlighting the challenges caused by differing interpretations from regulators and industry associations.
Participants will gain insights into best practices for review and approval processes, common pitfalls, and the strategic considerations needed to maintain compliance while supporting effective product communication.

Through real world examples and expert perspectives, the session will provide practical guidance for navigating this complex regulatory pathway with confidence.

Key discussion points:

- Overview of the European regulatory landscape governing promotional materials, including Italian legislation requirements, and industry codes
- Common pitfalls and compliance risks observed by regulators and industry review bodies

MODULE I
May 14th

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SESSION III – SERIALIZATION: Italian Regulatory Framework

From February 2027 onward, Italy will complete its move toward compliance with the **Falsified Medicines Directive (FMD - 2011/62/UE)**, supported by a centralized verification infrastructure managed by AIFA and the Ministry of Health, for a harmonized approach with the other European countries.
This evolution will require Marketing Authorization Holders, CMOs, wholesalers, and pharmacies to adapt rapidly upgrading packaging lines, adjusting supply chain controls, and implementing robust data management systems.
This session will provide a comprehensive overview of the new regulatory landscape, outlining Italy's transition from the Bollino system, with the participation of **General Manager of NMVO Italia** and the sharing of experiences of companies taking part in the "*Pilot Project*", attendees will gain clarity on the operational impacts, enforcement timelines, updated technical specifications requirements for safety features (Data Matrix and anti-tampering measures) and strategic preparations needed to navigate this new serialization era effectively.

Key discussion points:

- Key regulatory milestones leading to the go live of the harmonized system.
- NMVO's Pilot Project: updates, insights and sharing of experience observed during testing

MODULE II
May 21st

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SESSION I - CONTENT AND DEVELOPMENT OF FIRST IN HUMAN SUBMISSION PACKAGES FOR US AND EU

This session provides a comprehensive, practical overview of how to design, prepare, and successfully deliver **First in Human (FIH) regulatory submission packages** for both the United States and the European Union. Participants will gain a clear understanding of the core scientific, clinical, and quality elements required for early phase regulatory dossiers—specifically INDs in the US and CTAs/IMPDs in the EU—and how these components work together to support the safe initiation of human studies.

Special emphasis will be placed on **regional regulatory expectations**, points of convergence and divergence across FDA and EMA/NCAs, common pitfalls observed during FIH reviews, and best practices for ensuring consistency, clarity, and scientific justification throughout the submission.

Attendees will learn how to approach the FIH submission, how to build a robust, risk proportionate early development program that aligns with regulatory guidance, supports dose selection and starting dose rationale, and anticipates agency questions.

Key discussion points:

- Core Components of FIH Submission Packages for US and EU
- Regulatory Expectations in the US vs. EU and critical regional differences
- Real world case examples: common pitfalls and lessons learned

SESSION II - ORPHAN DRUG DESIGNATION FOR US, UK AND EU

Orphan drug designation is a key milestone for companies developing therapies for rare diseases. In this session, speakers will explore the core similarities and key differences in the regulatory frameworks for US, EU and UK processes, sharing best practices for preparing high quality applications, coordinating parallel submissions, and responding effectively to common agency questions.

Participants will also gain valuable insights directly experts and regulatory agencies representatives, who will outline the pathways, criteria, and expectations for securing orphan status in the different regions.

Through practical examples and real world learnings, the experts will highlight how to avoid common pitfalls and how to integrate orphan designation into a broader regulatory strategy.

Key discussion points:

- Comparison of FDA, MHRA and EMA Pathways
- Sharing of experiences and best practices for effective Applications

SPEAKERS

Raffaella Pandini
Italy Regulatory Affairs & Operations BU Director | Product Life Italia

Laura Braghiroli (TBC)
Post Authorization Procedures Office | AIFA

Attilio Sarzi Sartori
Head of Pharmaceutical Affairs | Chiesi italia

Ilaria Brocchi
Regulatory Affairs Senior Project Manager | Product Life Italia

Cinzia Berghella (TBC)
Dirigente Ufficio Informazione sui Medicinali e Vigilanza sulla Pubblicità | AIFA (TBC)

Antonio Federici
Direzione Generale dei Dispsitivi Medici e del Farmaco Ufficio 2 – Attività farmaceutica | Ministero della Salute

Pierluigi Crisà
Director – Pharmacovigilance, Promotional and Scientific Service, Italy | Eli Lilly

Monica Bertocci
Italy Quality & Manufacturing BU Head | Product Life Italia

Alexandru-Mihail Simion
Clinical assessor, COMP representative (Belgium)

Marcello Matarrelli
General Director | NMVO Italia

Alessandro Pelizzi
Serialization & Supply Chain Business Line Manager | Lifebee, a PLG company

Vito De Berardinis
Global Supply Chain PM & Packaging & Serialization Associate Director | Dompé

Michael Fusakio
Senior Consultant, Regulatory Affairs | Halloran Consulting Group, a PLG Company

Amit Salvi
Director, Clinical and Non-Clinical Operations | ProductLife Group

Aurélie Lambert
Global Regulatory Affairs Director | BioMarin Pharmaceutical

Sam Bryant
Global Regulatory Affairs Expert | Zwiers Regulatory Consultancy, a PLG Company

Paolo Dametto
Director, Head of International Regulatory Affairs | Deciphera

Maria Ana Gomez Ferreria
Principal Consultant - Drug Development - Cell and Gene Therapy | Zwiers Regulatory Consultancy, a PLG Company

Marcello Milano
Director, R&D and Regulatory Policy | BioMarin Pharmaceutical

AGENDA

MODULE I - May 14th

*ALL TIMINGS ARE CET (UTC +1) AND SUBJECT TO CHANGE

SESSION I - NEW EU VARIATIONS GUIDELINES: sharing of applications

2.0 pm **Welcome**
Lucia Costanzo, Director | Pharma Education Center

2.05 **Introduction to the agenda**
Raffaella Pandini, Italy Regulatory Affairs & Operations BU Director | | Product Life Italia

2.15 **New EU Regulation and Guidance on the Classification of Variations to the Marketing Authorisation: Key Updates and Current Status**
Laura Braghiroli, Post Authorization Procedures Office | AIFA (TBC)

2.35 **Sharing of experiences**
Raffaella Pandini, Italy Regulatory Affairs & Operations BU Director | Product Life Italia

3.00 **Panel Discussion/Q&A**
Moderator: **R. Pandini**
Panelists: **L. Braghiroli (TBC)**, **Attilio Sarzi Sartori**, Head of Pharmaceutical Affairs | Chiesi italia

3.30 **Coffee Break**

SESSION II - PROMOTIONAL MATERIALS REQUIREMENTS IN EUROPE: Navigating a Complex and Evolving Landscape

3.45 **Introduction**
Ilaria Brocchi, Regulatory Affairs Senior Project Manager | Product Life Italia

3.50 **Governance of Medicinal Advertising in Italy: AIFA's Regulatory Approach, Outcomes, and Future Directions**
Cinzia Berghella, Dirigente Ufficio Informazione sui Medicinali e Vigilanza sulla Pubblicità | AIFA (TBC)

4.10 **The advertising of medicines and authorization regime: analysis of a model**
Antonio Federici | Direzione Generale dei Dispositivi Medici e del Farmaco, Ufficio 2 – Attività farmaceutica - Ministero della Salute

4.30 **Panel discussion** [Italian language 🇮🇹]
Moderator: **I. Brocchi**
Panelists: **C. Berghella (TBC), A. Federici, Pierluigi Crisà,** Director - Pharmacovigilance, Promotional and Scientific Service, Italy | Eli Lilly Italia S.p.A.

SESSION III – SERIALIZATION: State of Art

5.00 **Introduction**
Raffaella Pandini, Italy Regulatory Affairs & Operations BU Director | Product Life Italia

5.05 **Status Update on Serialization in Italy**
Marcello Matarrelli, General Director | NMVO Italia

5.25 **Panel discussion & sharing of Pilot experience**
Moderator: M. Bertocci, Italy Quality & Manufacturing BU Head | Product Life Italia
Panelists: M. Matarrelli, Alessandro Pelizzi, Serialization & Supply Chain Business Line Manager | Lifebee, a PLG company , **Vito De Berardinis,** Global Supply Chain PM & Packaging & Serialization Associate Director | Dompé

6.0 **Closure of day**
Raffaella Pandini, Italy Regulatory Affairs & Operations BU Director | Product Life Italia
Lucia Costanzo, Director | Pharma Education Center

AGENDA

MODULE II - May 21st

*ALL TIMINGS ARE CET (UTC +1) AND SUBJECT TO CHANGE

SESSION I - CONTENT AND DEVELOPMENT OF FIRST-IN-HUMAN SUBMISSION (FIH) PACKAGES FOR US AND EU

2.0 pm **Welcome**
Lucia Costanzo, Director | Pharma Education Center

2.10 **Regulatory framework for First-In-Human Submission Packages for EU and US**
Amit Salvi, Director, Clinical and Non-Clinical Operations | ProductLife Group
Michael Fusakio, Senior Consultant, Regulatory Affairs | Halloran Consulting Group, a PLG Company, US

2.40 **Speech Title TBD**
Aurélie Lambert, Global Regulatory Affairs Director | BioMarin Pharmaceutical (TBC)

3.00 **Interact with FDA and EMA: How and When?**
Michael Fusakio, Senior Consultant, Regulatory Affairs | Halloran Consulting Group, a PLG Company, US
Sam Bryant, Global Regulatory Affairs Expert | Zwiers Regulatory Consultancy, a PLG Company

3.20 **Panel discussion**
Moderator: **Lucia Costanzo,** Director | Pharma Education Center
Panelists: **M. Fusakio, A. Salvi, S. Bryant, A. Lambert (TBC), Pharma company representative (TBC)**

3.50 **Coffee Break**

SESSION II - ORPHAN DRUG DESIGNATION FOR US AND EU

4.10 **Introduction**
Lucia Costanzo, Director | Pharma Education Center

4.15 **Orphan Drug Designation in the EU and US: Regulatory Frameworks, Convergence, and Key Differences**
Paolo Dametto, Director, Head of International Regulatory Affairs | Deciphera

4.35 **New UK framework for ODD: Rare disease therapies and regulatory considerations (TBD)**
MHRA Representative (TBD)

5.00 **ODD: sharing experiences in US and EU**
Michael Fusakio, Senior Consultant, Regulatory Affairs | Halloran Consulting Group, a PLG Company, US
Maria Ana Gomez Ferreira, Principal Consultant: Drug Development - Cell and Gene Therapy | Zwiers Regulatory Consultancy, a PLG Company

5.25 **Panel discussion**
Moderator: **Lucia Costanzo,** Director | Pharma Education Center
Panelists: **Alexandru- Mihail Simion**, clinical assessor, COMP representative (Belgium), **M. Milano**, Director, R&D and Regulatory Policy | BioMarin Pharmaceutical, **M. Fusakio**, **M. A. G. Ferreira, P. Dametto**

6.00 **Closure of day**
Lucia Costanzo, Director | Pharma Education Center

ENTRY FEE

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REGISTER HERE

For multiple registrations contact:
info@pharmaeducationcenter.it

	MODULE I	MODULE II	FULL CONGRESS	
Early bird	400 €	190 €	550 €	Deadline April 21st
Full price	450€	250 €	650 €	

- Hospitals, universities and freelance professionals get a 40% discount to be applied to published prices
- VAT not included | Discounts are not cumulative
- Attendance to the event will be allowed upon receipt of payment

For further information and/or further assistance please contact (+39) 055 7224179 or email: amministrazione@pharmaeducationcenter.it

EVENT CANCELLATION

If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date. Formal communication will be given within 5 days before the event date. In this case Pharma Education Center will refund the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

CANCELLATION TERMS

In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

ATTENDEE REPLACEMENT

It is possible to replace a participant with another without additional costs, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement request within 5 days before the starting date of the event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.