EURA
INTERNATIONAL CONFERENCE

EUROPEAN REGULATORY AFFAIRS CONGRESS 2026

14-21 MAY | Virtual

PEC PHARMA EDUCATION CENTER

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Pharma Education Center is excited to invite regulatory affairs professionals to the upcoming **"EUROPEAN REGULATORY AFFAIRS CONGRESS 2026."**
This year the format will enclose a second module addressing hot topics related with EU and US landscape.

The Forum aims to foster an environment of knowledge-sharing covering topics of high interest for Regulatory Affairs experts.
We are proud to provide a platform for industry professionals to exchange experiences, discuss industry challenges, highlight current issues and changes, gain insights into effective regulatory strategies, and explore the latest trends **in EU and US regulations.**
This will provide delegates with a unique opportunity to gain practical insights and enhance their professional skill sets and expertise.
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 professional network

WHO SHOULD ATTEND

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

FEATURED TOPICS
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 **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 EU legislation requirements, and industry codes
- Common pitfalls and compliance risks observed by regulators and industry review bodies

FEATURED TOPICS
MODULE I - May 14th

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SESSION III – SERIALIZATION: Italian Regulatory Framework

From February 2027 onward, Italy will complete its move toward a harmonized European approach, supported by a **centralized verification infrastructure** managed by AIFA and the Ministry of Health.
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**, the updated technical specifications for safety features (including the newly regulated carta valori support and Data Matrix requirements), and the practical challenges stakeholders face in achieving compliance.

Through expert insights and real world case examples from pilote, attendees will gain clarity on the operational impacts, enforcement timelines, 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.
- Insights from pilot phase and common pitfalls observed during testing

FEATURED TOPICS
MODULE II - May 21th

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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 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

SESSION II - HOW AND WHEN TO INTERACT WITH FDA AND EMA

Navigating interactions with major regulatory authorities is a critical factor in accelerating development timelines and ensuring the success of innovative therapies and technologies.

This session provides a clear, practical roadmap for engaging with the FDA and EMA at the right moments and in the right ways throughout the product lifecycle.

The session will **highlight similarities and differences between FDA and EMA expectations, outline best practices for preparing briefing packages, and offer guidance for managing questions, timelines, and follow up commitments.**

Through real world examples and common pitfalls, attendees will learn how to build a proactive engagement plan that supports smoother reviews, reduces regulatory uncertainty, and maximizes the probability of timely approvals.

Key discussion points:

- Comparing FDA vs. EMA expectations
- Regulatory touchpoints across the development lifecycle: differences between US and EMA
- Real world case examples: common pitfalls and lessons learned

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MODULE II - May 21th

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SESSION III - ORPHAN DRUG DESIGNATION FOR US 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 important differences between FDA and EMA 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 from regulatory representatives, who will outline the pathways, criteria, and expectations for securing orphan status in both regions.
Through practical examples and real world learnings, the esperts will highlight how to avoid common pitfalls and how to integrate orphan designation into a broader regulatory strategy.

Key discussion points:

- Comparison of FDA and EMA Pathways
- Sharing of Best Practices for effective Applications

ENTRY FEE

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MODULE I:
400 € Early bird single day
450 € Single day

MODULE II:
190 € Early bird single day
250 € Single day

FULL CONGRESS:
550 € Early bird
650 € Full

Early bird fees expire on April 21th

VAT not included

Discounts are not cumulative

REGISTER HERE

For further information and/or further assistance please contact
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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.