PEC PHARMA EDUCATION CENTER

EUROPEAN REGULATORY AFFAIRS FORUM 2024

Facing the Future Regulatory and HTA Landscape

MAY 21 - 28 | VIRTUAL

Pharma Education Center is excited to extend a warm invitation to all Regulatory Affairs professionals to participate in the upcoming **"EUROPEAN REGULATORY AFFAIRS FORUM."**

As the annual meeting of European Regulatory Affairs experts, the event aims to foster an environment of knowledge-sharing. We are proud to provide a platform for industry professionals to exchange their experiences, highlight current issues and changes, discuss effective strategies, and explore new trends within the European Regulatory Affairs landscape.

In addition to fostering networking opportunities, the Forum will feature experts who will share their invaluable "hands-on" experiences. This will provide delegates with a unique opportunity to gain practical insights and enhance their professional skill sets.

We look forward to your participation and joining us in promoting a productive and engaging discussion.

WHY ATTEND

Our Forum brings together international Regulatory Affairs experts, opinion leaders, Regulatory body representatives, and consultants, making this a must-go event for Pharma, Biotech, Medical Device Industries.

WHO SHOULD ATTEND

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

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FEATURED TOPICS

MAY 21 | 2 - 6 PM UTC +1

SESSION 1 - REVOLUTIONIZING REGULATORY AFFAIRS: HARNESSING ARTIFICIAL INTELLIGENCE AND DIGITALIZATION FOR ENHANCED PROCESSES

Explore the transformative potential of AI and digitalization in regulatory affairs with our expert's panel. Starting from the EMA 's AI workplan extending to 2028, to the EU Regulation Proposal, and the Reflection Paper on AI's role in medicine lifecycles, delve into the journey towards the EU AI ACT regulation. Discover how these technologies can enhance the Healthcare ecosystem bringing significant improvements by streamlining processes, accelerating drug development, and fostering transparency. We will discuss how to integrate AI and digitalization into our regulatory framework discovering the benefits; we will also explore the challenges behind it and the need of having clear rules to deal with these emerging technologies.
Reimagining regulatory processes: How can AI and digitalization optimize and reshape our current regulatory activities?
Keynote presentations followed by a final panel discussion with participants.

MAY 28 | 2 - 6 PM UTC +1

SESSION 2 - EU LEGISLATION: WHAT'S NEW?

Welcome to our informative session on the latest updates from EU legislation impacting Regulatory Affairs. Our experts will cover key changes related to PRIME, SPP & SMP, EU Guidance on MA Variations, and CTIS/CTR.
Gain insights into these updates and understand how they may affect your work in Regulatory Affairs.

SESSION 3 - EUROPEAN HEALTH TECHNOLOGY ASSESSMENT (EU HTA): A NEW PARADIGM FOR ASSESSING THE EFFECTIVENESS, SAFETY, AND VALUE OF DRUGS AND MEDICAL DEVICES

The introduction of the HTA Regulation (HTAR) in 2022 marks a significant milestone in the field of Health Technology Assessment (HTA). Join us as we explore how this new legislation heralds a new era in evaluating the joint clinical assessment of pharmaceuticals and medical devices.
During this session, we will address the objectives of the HTAR, aimed to improve patient access by reducing duplication of assessment efforts while ensuring reproducibility and fostering collaboration across the Member States legislative landscape. Gain insights into the implementation acts and framework outlined in the HTAR and how they impact the assessment process and illuminate the pathways towards improved clinical evaluations.
Be part of the discussion where our experts will present the main objectives that this new regulation will get.
keynote presentations followed by a final panel discussion with the involvement of speakers and delegates.

PROGRAM May 21th

SESSION I
Revolutionizing Regulatory Affairs: Harnessing Artificial Intelligence and Digitalization for Enhanced Processes

2.00 pm UTC +1	Welcome and introduction Chairperson, *Pharma Education Center*
2.10	Opening remarks Raffaella Pandini, *RA Director | Pharma D&S*
2.20	Impacts of AI in the overall drug lifecycle Gabriele Breda, *Research & Innovation Director | PLG*
2.50	EU AI ACT: overview and main challenges Patrizia Ciavatta, *Global Regulatory & Pharmacovigilance Chief | Angelini Pharma*
3.20	Impacts of Eu AI ACT on regulatory activities Aymeric Lebon, *Commercial Director | Medtech*
3.50	Q&A Time
4.05	ePI in the EU – Key principles Laurence Brihaye, *formerly Associate Director European Regulatory Procedure Strategy, at a Top-10 biopharma company*
4.35	Moderna's case study of ePI during the pandemic and beyond Colleen McGraw, *Sr. Director, Global Regulatory Labeling | Moderna (US)*
5.05	Q&A Time
4.20	ROUND TABLE How can be integrated AI and digitalization into our regulatory framework? Challenges & oppor tunities Moderator: G. Breda Panelists: L. Brihaye P. Ciavatta A. Lebon C. McGraw
6.00	Closure of the day Raffaella Pandini, *RA Director | Pharma D&S*

PROGRAM May 28th

SESSION II
EU Legislation: What's new?

2.00 pm UTC +1 — **Introduction**
Raffaella Pandini, *RA Director | Pharma D&S*

2.10 — **A snapshot on EU Regulatory landscape: what's new?** *New EU Guidance on MA Variations PRIME-Priority Medicines Scheme Shortage Prevention Plan (SPP) & Shortage Management Plan (SMP)*
Angela Esposito, *Head of Global Regulatory Policy & Strategy | Angelini Pharma*

2.40 — **EU-CTR & CTIS Updates: A Closer Look from a Regulatory Perspective**
Anna Carratù, *Senior Global Program Regulatory Manager | Novartis*

3.05 — **Q&A Time**

3.20 — **EU Patent Package overview and Key messages impacting RA**
Barbara Politi, *Innovation & IP Expert | Addì srl*

3.50 — **Q&A Time**

SESSION III
European Health Technology Assessment (EU HTA): a new paradigm for assessing the effectiveness, safety, and value of drugs and medical devices

4.00 — **Introduction**
Mariangela Prada, *General Manager | Intexo*

4.15 — **The implementation of the new HTA Regulation: expected benefits and challenges for the 2025**
Entela Xoxi, *Lecturer with collaboration Agreement for Research Projects | Università Cattolica del Sacro Cuore, Rome Italy*

5.00 — **ROUND TABLE**
How to prepare for the future of EU HTA?
Moderator: Entela Xoxi
Round table participants panel under definition

5.55 — **Closure of the session**
Mariangela Prada, *General Manager | Intexo*

6.00 — **Closure of the day**
Raffaella Pandini, *RA Director | Pharma D&S*

SCIENTIFIC BOARD

Ilaria Brocchi
Regulatory Affairs Senior Project Manager | Pharma D&S a PLG company

Patrizia Ciavatta
Global Regulatory & PV Chief | Angelini Pharma

Paolo Dametto
Director, Regulatory Affairs | Deciphera

Raffaella Pandini
Regulatory Affairs Director | Pharma D&S a PLG company

SPEAKERS

Gabriele Breda
Research & Innovation Director - PLG

Laurence Brihaye
formerly Associate Director European Regulatory Procedure Strategy, at a Top -10 biopharma company

Patrizia Ciavatta
Global Regulatory & PV Chief | Angelini Pharma

Anna Carratù
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General Manager | Intexo

ENTRY FEE

350 € Early bird single day
400 € Single day

600 € Early bird - 2 days
700 € 2 days

Early bird fees expire on April 21th

VAT not included

Discounts are not cumulative

For multiple registrations contact:
info@pharmaeducationcenter.it

TERMS OF PAYMENT

Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa – Florence, IBAN IT81P0503402801000000007431, Bic/SWIFT BAPPIT21N25 made payable to Pharma Education Center S.r.l., Via dei Pratoni 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant enrolling. Attendance to the event will be allowed upon payment received. Invoice of payment will be issued after the second half of the month after the course.

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

COURSE/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 refound 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.

PARTICIPANT REPLACEMENT

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

HOW TO REGISTER

Please, fill the form on the web site https://www.pharmaeducationcenter.it/

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