PEC PHARMA EDUCATION CENTER

EUROPEAN REGULATORY AFFAIRS FORUM 2023

MAY 16 - 17 - 18 | VIRTUAL

Pharma Education Center warmly invites regulatory affairs professionals from pharmaceutical companies to take part to the next **"EUROPEAN REGULATORY AFFAIRS FORUM", which will take place virtually on May 16th, 17th and 18th.**

The Forum represents the annual meeting of European Regulatory Affairs experts, willing to share experiences and last updates on current **issues, changes, strategies and new trends in the European Regulatory Affairs landscape.** The conference wishes to offer networking opportunities and promote debate among European Regulatory Affairs delegates.

The Forum will offer a fruitful occasion to address some practical aspects, thanks to the precious contribution of **experts in the field**, sharing their own "hands-on" experience.

WHY ATTEND

The Forum will feature several sessions on the hot topics of the moment, with **case studies, interactive Q&A moments and round tables** with the involvement of all the delegates: a great opportunity to understand different points of view and expertise.

The involvement of international Regulatory Affairs experts, opinion leaders, regulatory body representatives, new technologies suppliers and consultants from all over Europe, make this a must-go event for Pharma, Biotech, Medical Device companies and for IT Suppliers.

WHO SHOULD ATTEND

- Regulatory Affairs VP, Directors, Manager, Head of Pharma, Biotech and Medical Device Industries
- Regulatory Bodies
- Technology IT Suppliers

FEATURED TOPICS

MAY 16

MODULE 1 - REGULATORY STRATEGIES FOR APPROVAL OF NEW DRUGS IN THE U.S. AND EU MARKETS

This session will be dedicated to examining the regulatory strategies that are employed in the United States and European Union markets for the purpose of developing and approving new products. In order to ensure that the development and registration of new products can be carried out quickly and efficiently in both markets, it is crucial to possess a thorough comprehension of the contrasts between the regulatory frameworks of the two regions and to implement a productive strategy for achieving successful approval of innovative pharmaceuticals in both countries.

During this session, experts from the company will share their experiences, which will be presented in the form of case studies and applied tools. Additionally, they will impart valuable insights that they have gained from their involvement in global co-development plans.

Case studies and keynote presentations followed by a final panel discussion with the involvement of speakers and delegates.

MAY 17

MODULE 2 - REGULATORY STRATEGIES FOR EX- EU MARKETS AND PERSPECTIVES ON REGULATORY RELIANCE

The session at hand will focus on two key subjects: firstly, regulatory strategies implemented in the Japanese and United Kingdom markets; and secondly, regulatory reliance as an astute approach for gaining access to drugs.

During this session, regulatory affairs specialists from various companies will share their wealth of experience and offer valuable insights and advice regarding the cultural climate and regulatory stipulations that need to be taken into account during the product approval process for the Japanese and UK markets. They will also engage in discussions pertaining to the opportunities and challenges presented by these countries.

Furthermore, the experts will elucidate the regulatory reliance initiative, its present implementation in regulatory bodies across different nations, and the potential for this pathway to facilitate more efficient resource utilization and, ultimately, expedited access to medicinal products.

Keynote presentations followed by a final panel discussion with participants.

FEATURED TOPICS

MAY 18

MODULE 3 - PHARMACEUTICAL STRATEGY FOR EUROPE

The final session of the forum on the last day, addresses the theme: EMA's Regulatory Science to 2025 in the Context of the Pharmaceutical Strategy for Europe.
Experts will explain the main objectives of the Pharmaceutical Strategy for Europe: Where we are, expected changes in the Regulations, major steps taken to date, challenges and opportunities.
Some specific talks will focus on Orphans and Paediatrics, analysing the potential impacts (risks and opportunities) that the planned revision of EU regulations may have on the development of innovative treatments for children and rare diseases.
A final talk will be focused on European Green Deal and the Circular Economy: how to shape the regulatory framework to advance on the "road to sustainability?"

Keynote presentations followed by a final panel discussion with participants.

Sponsored by

PHARMA D&S
PHARMACEUTICAL DEVELOPMENT & SERVICES

PROGRAM
May 16th

MODULE I
REGULATORY STRATEGIES FOR APPROVAL OF NEW DRUGS IN THE US AND EU

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	A practical approach to regulatory strategies Paolo Dametto, *Associate Director, Regulatory Strategist | Moderna*
2.50	Q&A Session
3.00	US regulatory overview to accelerate product launch Ambareen Sheriff, *Head of Regulatory Services | DS InPharmatics LLC*
3.30	Q&A Session
3.40	Cases studies on the approval of new drug device combination product in US and EU Neha Parashar, *Principal Scientist / Associate Director - Regulatory CMC | argenx*
4.10	Q&A Session
4.20	ROUND TABLE - Q&A SESSION Sharing of experiences and lesson learned in global co-development plans with the involvement of participants Moderator: Raffaella Pandini Panelists: Paolo Dametto Daniela Drago, *NDA Partners* N. Parashar A. Sheriff
5.00	Closure of the session

PROGRAM
May 17th

MODULE II
REGULATORY STRATEGIES FOR EX- EU MARKETS AND PERSPECTIVES ON REGULATORY RELIANCE

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

Japan market: the regulatory frame and registration strategies

2.10 — **The registration strategy in Japan: required data package for NDA and regulatory process by PMDA**
Masashi Tagashira, *Regulatory Affairs International Strategy | Vifor Pharma*

2.50 — **Q&A**

UK market: regulatory framework and registration strategies

3.00 — **Optimising UK Regulatory Pathway**
Sacha Lynch, *Principal Consultant | DRLC Ltd*

3.40 — **Q&A**

3.50 — **Strengthening Regulatory Capacity with Regulatory Reliance: From Concepts to Applications**
Daniela Drago, *Expert consultant | NDA Partners*

4.30 — **Q&A**

4.40 — **ROUND TABLE**
The evolution of reliance: where we are and future perspectives
with the involvement of participants
Moderator:
Raffaella Pandini
Panelists: Patrizia Ciavatta, *Angelini Pharma*
Daniela Drago
Sacha Lynch
Tagashira Masashi

5.15 — **Closure of the Forum**
Raffaella Pandini, *RA Director | Pharma D&S*

PROGRAM
May 18th

MODULE III
PHARMACEUTICAL STRATEGY FOR EUROPE

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	**EMA Regulatory Science to 2025 in the context of the Pharmaceutical Strategy for Europe** Patrizia Ciavatta, *Global Regulatory Affairs & Pharmacovigilance Executive Director | Angelini Pharma*
2.50	**Development of medicines for rare diseases in view of the upcoming review of the EU Regulation 141/2000): what's to expect?** Marta Parmar, *Head of Regulatory Affairs Iron Deficiency and Cardio-Renal | CSL Vifor*
3.20	**Q&A**
3.30	**Development of paediatric medicines and the EU regulatory framework: recent updates, anticipated changes** Marcello Milano, *Director, Global R&D and Regulatory Policy | BioMarin UK*
4.00	**Q&A**
4.10	**ROUND TABLE** **How the review of the pharmaceutical legislation can drive innovation, attract investment in life science and make Europe an attractive environment** with the involvement of participants **Moderator:** Raffaella Pandini **Panelists:** Patrizia Ciavatta Marcello Milano Marta Parmar Maren von Fritschen | Moderna
5.00	**Closure of the Forum** Raffaella Pandini, *RA Director | Pharma D&S*

SCIENTIFIC BOARD

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

Paolo Dametto
Associate Director Regulatory Strategist | Moderna

Patrizia Ciavatta
Global Regulatory & PV Chief | Angelini Pharma

Raffaella Pandini
Regulatory Affairs Director | Pharma D&S

SPEAKERS

Neha Parashar
Principal Scientist / Associate Director - Regulatory CMC | argenx

Daniela Drago
Expert consultant | NDA Partners

Marta Parmar
Head of Regulatory Affairs Iron Deficiency and Cardio-Renal |CSL Vifor

Marcello Milano
Director, Global R&D and Regulatory Policy, BioMarin UK

Ambareen Sheriff
Head of Regulatory Services | DS InPharmatics LLC

Sacha Lynch
Principal Consultant | DRLC Ltd

Masashi Tagashira
Regulatory Affairs International Strategy | CSL Vifor

ENTRY FEE
350 € single module
900 € all 3 modules

VAT not included

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/

Tel (+39) 055 7224179
(+39) 055 7224076
Fax (+39) 055 7227014

info@pharmaeducationcenter.it

PEC PHARMA EDUCATION CENTER

To stay updated on our courses Follow us on