PEC PHARMA EDUCATION CENTER

EUROPEAN REGULATORY AFFAIRS FORUM 2022

MAY 12 - 13 | 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 12th and 13th**. The Forum represents the annual meeting of European Regulatory Affairs experts and pharma professionals, willing to share experiences and last updates on current issues, regulatory 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.

Also this year, the Forum will be enriched with half a day of **workshop on May 13th**. It will be a perfect 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 European Regulatory Affairs experts, opinions leaders, regulatory body representatives, new technologies suppliers and consultants from all over Europe, makes 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 12th

1 - INNOVATIVE THERAPIES: THE REGULATORY FRAMEWORK

The session will be focused on the regulatory landscape of innovative medicines. To ensure quick access to new medicines for patients, it is essential for Europe to have a regulatory environment that understands and embraces innovation.
Experts from companies will share experiences about the regulatory strategies and tools that can allow early approval of Innovative Medicines.

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

2 - DRUG-DEVICE COMBINATION PRODUCTS: MDR IMPLEMENTATION

In the EU, the manufacturers/MAH are required to fully apply to specific requirements in order to ensure a timely asked and accurate market access of new combination products, a market that is constantly growing over the years.
Regulatory Affairs experts from companies will give an overview on the EU requirements and their impact on the submission process of combination products.

Keynote presentations followed by a final panel discussion with participants

3 -EXTRA EU MARKETS: REGULATORY ASPECTS AND CHALLENGES

Extra EU markets as Brasil and MENA (Middle East and North Africa) markets require a constant effort to ensure an effective market access.
Experts will share their regulatory experience, discussing the opportunities and challenges posed by these countries.

Keynote presentations followed by a final panel discussion with participants

FEATURED TOPICS MAY 12th

4 - THE PHARMA DIGITALIZATION

The digital transformation is affecting the whole product life cycle, from R&D to product supply.
In this session Regulatory Experts from leading industries will share experiences about the digitalization process with focus on the Regulatory Information Management Systems and the IDPM implementation.

Keynote presentations followed by a final panel discussion with participants

5 - THE CLINICAL TRIAL REGULATION

The implementation of EU CTR n° 536/2014 has become complete with the go live (31 Jan 2022) of the CTIS (Clinical Trials Information System) enabling clinical trial application submission through a single informatic system within the EU.
The experts will share the main changes introduced by this implementation and their effects on the regulatory department activities.

The presentation will be followed by a final panel discussion with the involvement of participants.

THE WORKSHOP MAY 13th

6 - REGULATORY FRAMEWORK FOR BIOLOGICAL PRODUCTS

The session aims to give an overview on the regulatory requirements (EMA/FDA/AIFA) applied to biological medicinal products, with a special focus on the drug substance and the drug product. Experts from leading companies will share their experience with different Health Authorities.

The presentation will be followed by a Q&A time involving the audience.

7 - PRICING AND REIMBURSEMENT OF MEDICINAL PRODUCTS IN ITALY

The session is dedicated to an in-depth analysis of the pricing and reimbursement system in Italy, useful for understanding deeply the operational details for companies interested to market their product in Italy.

The presentation will be followed by a Q&A time involving the audience.

8 - RISK MANAGEMENT PLAN OBLIGATIONS

Interesting topic with a technical presentation aimed at exploring the operational details required by the Italian Medicines Agency (AIFA) for the approval of the educational materials related to the products authorised and distributed on the Italian market.

The presentation will be followed by a final panel discussion with the involvement of participants.

9 - NATIONAL MONITORING REGISTERS OF MEDICINAL PRODUCTS

The pharma company review of AIFA monitoring registers is a crucial step in the assessment on the eligibility of the patients for a specific therapy inside the reimbursement access.
During the presentation, the experts will give an overview about the main steps of this process and the attention to be paid in reviewing it.

The presentation will be followed by a final panel discussion with the involvement of participants.

SPEAKERS

Ankit Geete
Associate Director - Global Regulatory Affairs | Merck Group

Tina Amini
Medical Device & Combination Products Division Director - NDA Group

Oriella Nasta
QA & GCP Auditor

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

Pier Paolo Olimpieri
Data analysis coordinator, Monitoring Registries - AIFA

Giovanna Cappellari
Regulatory Affairs Manager - Roche

Raffaella Pandini
Regulatory Affairs Operational Manager – Pharma D&S

Simão Correa da Silva
Head of Regulatory Affairs Latam Dr. Reddy's Laboratories

Nicola Panzeri
Head of Regulatory Affairs - Roche

Gunnar Häcker
Business Project Manager Regulatory Affairs - Boehringer Ingelheim

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

Javad Jabbari
Associate Director Regulatory Affairs Device - Ascendis Pharma

Andreas Vogel
Senior Director, Head of International Regulatory Affairs - Apellis Pharmaceuticals.

Joëlle Issa Blok
Director Regulatory Affairs, Quality & Pharmacovigilance, META | ACINO

Mariana De Angelo Silva Alegre
Associate Director Regulatory Affairs - LatAm | Johnson & Johnson - San Paulo, Brasil

PROGRAM
May 12th

9.00 am
UTC +1
Welcome and introduction
Chairperson, *Pharma Education Center*

9.10
Opening remarks
Raffaella Pandini, *RA Operational Manager* | *Pharma D&S*

SESSION I
THE REGULATORY FRAMEWORK OF INNOVATIVE THERAPIES

9.20
Advanced Therapies: Innovative Products, Innovative Pathways to Approval
Andreas Vogel, *Senior Director Head of International Regulatory Affairs* | *Apellis Pharmaceuticals*

9.45
Regulatory CMC strategies and challenges for Biologicals
Neha Parashar, *Principal Scientist / Associate Director - CMC Regulatory* | *argenx*

10.10
Q&A Session

SESSION II
DRUG COMBINATION PRODUCTS

10.35
Impact of EU Medical Device Regulation on Drug Device Combination Products
Tina Amini, *Medical Device & Combination Products Division Director* | *NDA Group*

11.00
Coffee Break

11.20
Device Submission Content in eCTD Format for "Combination Products" in the EU
Javad Jabbari, *Associate Director Regulatory Affairs Device* | *Ascendis Pharma*

11.55
Q&A session

SESSION III
EXTRA EU MARKETS: REGULATORY ASPECTS AND CHALLENGES

12.15 pm
Regulatory Affairs challenges and opportunities in the META Region
Joëlle Issa Blok, *Director Regulatory Affairs, Quality & Pharmacovigilance, META* | *ACINO*

PROGRAM
May 12th

12.40	**International Regulatory Cooperation: a Latin America overview** Mariana De Angelo Silva Alegre, *Associate Director Regulatory Affairs - LatAm* | *Johnson & Johnson - San Paulo, Brasil*
1.05	**Lunch Break**
2.00	**Brazilian and Latam Regulatory Environment – Key Aspects, Differences, Evolution** Simão Correa da Silva, *Head of Regulatory Affairs Latam* | *Dr. Reddy's Laboratories*
2.30	**Q&A session**

SESSION IV
DIGITAL TRASFORMATION IN RA

2.55	**Overcoming the "language barrier" - How IDMP requirements force digital transformation** Gunnar Häcker, *Business Project Manager Regulatory Affairs* | *Boehringer Ingelheim*
3.20	**Structured Regulatory data submissions** Ankit Geete, *Associate Director - Global Regulatory Affairs* | *Merck Group*
3.45	**The first step towards package leaflet digitalization** Giovanna Cappellari, *Regulatory Affairs Manager* | *Roche*
4:05	**Q&A session**

SESSION V
THE CLINICAL TRIALS REGULATION

4.25	**CTR and submission activities after the CTIS go live** Oriella Nasta, *QA & GCP Auditor*
4.45	**Q&A session**
5.00	**Closing Remarks** Raffaella Pandini, *RA Operational Manager* | *Pharma D&S*

PROGRAM
May 13th

9.00 am
UTC +1

Introduction
Raffaella Pandini, *RA Operational Manager* | *Pharma D&S*

SESSION VI
REGULATORY FRAMEWORK FOR BIOLOGICAL PRODUCTS

9.10 — **Biologicals: regulatory aspects and experiences with Regulatory Authorities**
Neha Parashar, *Principal Scientist / Associate Director - CMC Regulatory* | *argenx*

9.40 — **Q&A session**

SESSION VII
PRICING AND REIMBURSEMENT OF MEDICINAL PRODUCTS IN ITALY

09.55 — **Introduction to the session**
Ilaria Brocchi, *Senior Project Manager & Team Leader Regulatory Affairs* | *Pharma D&S*

10.00 — **Price and reimbursement dossier: a focus after one year of experience**
Raffaella Pandini | *Pharma D&S*

10.30 — **Q&A session**

10.45 — **Coffee break**

SESSION VIII
RISK MANAGEMENT PLAN OBLIGATIONS

11.10 — **Introduction to the session**
Raffaella Pandini | *Pharma D&S*

11.15 — **Educational materials – the Italian process for approval**
Ilaria Brocchi | *Pharma D&S*

11.45 — **Q&A session**

SESSION IX
NATIONAL MONITORING REGISTERS OF MEDICINAL PRODUCTS

12.00 pm — **Introduction to the session**
Raffaella Pandini | *Pharma D&S*

PROGRAM
May 13th

12.05	**AIFA monitoring registries: Post-marketing data collection and evidence evaluation** Pier Paolo Olimpieri, *Data analysis coordinator, Monitoring Registries* | *AIFA*
12.30	**AIFA registers as a real world evidence tool: the Roche experience and possible perspectives** Nicola Panzeri, *Head of Regulatory Affairs* | *Roche*
12.55	**Q&A session**
01.15	**Closing Remarks and end of the Forum** Raffaella Pandini | *Pharma D&S* Chairperson, *Pharma Education Center*

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PHARMACEUTICAL DEVELOPMENT & SERVICES

ENTRY FEE

One day – May 12th:
Early bird 575 € - expires on April 15th
Full price 675 €

Both days – May 12th and 13th
Early bird 750 € - expires on April 15th
Full price 850 €

Discounts are not cumulative

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/

ONLINE

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