Challenges & Strategies in
EU Pharma Regulatory Affairs

www.euraforum.com

#EURA2020

ONLINE

October 15, 2020

European Regulatory Affairs Forum 2020

PEC PHARMA EDUCATION CENTER

ABOUT

Pharma Education Center
warmly invites Regulatory Affairs professionals from Pharma Companies to join the **"EUROPEAN REGULATORY AFFAIRS FORUM"**, which will take place the 15th of October 2020 ONLINE. The Forum wishes to create in Italy an annual meeting of European Regulatory Affairs experts and pharma professionals to share experiences and last updates on current issues, regulatory changes, strategies and new trends in the Regulatory Affairs European landscape.
An important aim of this conference is to offer networking opportunities and promote debate among European Regulatory Affairs delegates.

WHY ATTEND?

The involvement of European Regulatory Affairs experts, opinions leaders, regulatory body representatives, new IT technologies suppliers and consultants from Italy and Europe, makes this event highly appreciated by Pharma, Biotech, Medical Devices companies and also by the IT Suppliers, for the great opportunity to meet professionals and get and share technical knowledge and strategies about the future of the Regulatory Affairs in Europe.

FOCUS

The Congress will offer several sessions about hot topics, case studies, including round-table on:

- ***The European Regulatory Affairs landscape: changes, impacts of new Regulations and regulatory trends of new therapeutic products***
- ***Regulatory Information Management: experiences and challenges***
- ***Getting ready for novel data and approaches that will challenge regulatory decision-making***
- ***Extra EU registration: challenges & strategies***

GOLD SPONSOR

ArisGlobal
We Bring the Future to Life™

SPEAKERS

Patrizia Ciavatta, Global Regulatory Affairs Executive Director – Angelini Pharma

Sol Yates, Global Regulatory Affairs Manager at Grünenthal - Germany

Alessandra Leone, Global CMC Senior Manager - PTx at Pfizer

Rudiger Faust, Regulatory Strategy & Intelligence Lead, Innovation Unit Devices & Technologies - Grünenthal Group

Camille Metais, Global Program Team Lead at Alexion Pharma GmbH

Pratyusha Pallav, ArisGlobal

Raffaella Pandini, Regulatory Affairs Operational Manager Pharma D&S

Paola Tocchetti, Global Regulatory EU Italfarmaco

WHO SHOULD ATTEND?

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

AGENDA

08:30 **Registration**

09:15 **Welcome**
PEC representative

09:20 **Opening remarks by the Chairpersons of EuRA Forum**
Raffaella Pandini - *Regulatory Affairs Operational Manager - Pharma D&S*

SESSION I - THE EUROPEAN REGULATORY AFFAIRS LANDSCAPE: CHANGES, IMPACTS OF NEW REGULATIONS AND REGULATORY TRENDS OF NEW THERAPEUTIC PRODUCTS

09:30 **EU Clinical Trials Regulation; An update on the current status and some thoughts on its implementation**
• The upcoming EU Clinical Trial Regulation No 536 (EC) 2014 implementation: what does it mean?
• Perspective from a mid-sized pharma company
• A summary of the main changes versus the current situation
• Current status of implementation
• How will implementation of this regulation impact our processes
• Challenges and opportunities
Sol Yates - *Global Regulatory Affairs Manager at Grünenthal – Germany*

10:00 **Q&A**

10:10 **How Orphan drug designation and scientific advice procedures fit in the overall clinical development of a medicinal product?**
The presentation will describe the objectives, the criteria and the procedure to obtain ODD and SA in EU for an orphan products. In addition, advice will be provided on important considerations to take into account when preparing for such procedures.
• Objectives and procedures to obtain ODD in EU
• Objectives and procedures to obtain SA in EU
• Important considerations to take into account:
- Importance of global development and consultation with other regulatory authorities
- Importance of additional stakeholders engagement in parallel with regulators (Physicians, Patients advocacy groups, payers/HTA bodies)
• Opportunities and challenges of such approaches
Camille Metais, *Global Program Team Lead at Alexion Pharma GmbH*

10:40 **Q&A**

10:50 **Networking & Coffee Break**

11:20 **Biologicals and Biosimilars: a regulatory perspective**
• What makes biological molecules different to small molecules?
• What is a biosimilar
• EMA/FDA attitude towards biosimilars, safety/efficacy/quality, clinical and non-clinical evaluation, PK/PD study, immunogenicity, extrapolation, PV, prescription information
• Regulatory procedures for approval in EU and US
Paola Tocchetti, *Global Regulatory EU - Italfarmaco*

11:50 **Q&A**

AGENDA

SESSION II – IDMP & REGULATORY INFORMATION MANAGEMENT

12:00 **Regulatory Information Management**
Regulatory Information Management (RIM), handling of structured data and new ways of information exchange with external stakeholders is becoming more and more important for regulatory affairs (RA) departments. This session will accompany you on the digital transformation journey by discussing RIM in light of the maturity of a RA department, potential performance metrics and guide you into a discussion on the need for improved ways of informing empowered patients about product information with modern technology.
Rudiger Faust, *Regulatory Strategy & Intelligence Lead, Innovation Unit Devices & Technologies - Grünenthal Group*

12:40 **Q&A**

12:50 **Lunch & Networking Time**

14:00 **Key considerations for IDMP enabled regulatory transformation platform**
Pratyusha Pallav, *ArisGlobal*

14:25 **Q&A**

SESSION III - EXTRA EU REGISTRATION: CHALLENGES AND STRATEGIES

14:40 **Developing a global regulatory strategy in times of regulatory uncertainty and change**
- Assessing commonalities and differences between specific local requirements across regions
- Outlining the challenges facing regulatory professionals in post approval world and ensuring supply continuity
- Overcoming the challenges of variety and variability of regulations and timelines across the globe

Alessandra Leone, *Global CMC Senior Manager - PTx at Pfizer*

15:20 **Q&A**

15:40 **ROUND TABLE**
THE EVOLUTION OF EUROPEAN REGULATORY AFFAIRS LANDSCAPE: CURRENT AND FUTURE CHALLENGES
How the RA environment is changing due to the political changes, to the technological and scientific progress, to the more patient-centric view - which are the future challenges of EU RA for a better support in the innovation and life cycle of medicines?
Moderators: **Raffaella Pandini**, *Pharma D&S*
Participants:
Patrizia Ciavatta – *Novartis*
Rudiger Faust - *Grunenthal*
Alessandra Leone - *Pfizer*
Camille Metais - *Alexion*
Pratyusha Pallav - *ArisGlobal*
Paola Tocchetti - *Italfarmaco*
Sol Yates - *Grunenthal*

16:40 **Conclusion & Networking Time**

PEC PHARMA EDUCATION CENTER

SPONSORSHIP OPPORTUNITIES

The European Regulatory Affairs Forum provides an excellent opportunity to get in touch with RA professionals and decision makers.

Contact us to know how you can sponsor the event:
info@pharmaeducationcenter.it

HOW TO REGISTER

ENTRY FEE
620 € until September 15th
720 € from September 16th

PEC PHARMA EDUCATION CENTER

Discounts are not cumulative
VAT not included

BOOK NOW
www.pharmaeducationcenter.it

TERMS OF PAYMENT
Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa – Florence (Italy),
IBAN: IT90U0503402815000000001400,
Bic/SWIFT: BAPPIT21G74 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 5 days 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/