PEC PHARMA EDUCATION CENTER

International experts will be discussing hot topics and case studies, including interactive Q&A and round tables with the involvement of all the participants. Speakers and delegates will share their experiences on emerging markets, strategies and new trends in Regulatory Affairs.

EUROPEAN REGULATORY AFFAIRS FORUM 2021

MAY 12 - 13 | ONLINE

#EURA2021

TOPICS

THE REGULATORY FRAMEWORK OF INNOVATIVE THERAPIES

This session will introduce the regulatory landscape and will discuss hands on experiences of registration process related to Novel Therapies - ATMPs. Due to their high complexity and multiple potential, ATMPs are subject to continuously evolving regulatory requirements. Regulatory professionals will share their experience on the registration synergies needed for accelerating the availability of these therapies on the market.

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

THE REGULATORY LANDSCAPE AFTER BREXIT

Brexit affected significantly many activities in the pharmaceutical and lifescience industry, such as marketing authorisations and drug approval procedures, rules on Good Manufacturing Practice (GMP), pharmacovigilance and clinical trials.

A MHRA expert has been invited to present the main impacts of Brexit implementation on regulatory and marketing, at four months from come into force.

Q&A session will follow.

DRUG-DEVICE COMBINATION: An evolving global Regulatory scenario

The manufacturers/MAH are required to fully understand and apply the specific requirements in each country in order to ensure a timely and accurate market access of new combination products, a market that is constantly growing over years.

Regulatory Affairs experts from companies will share their experience during keynote presentations and a panel discussion with the involvement of participants.

EXTRA EU AND EMERGING MARKETS: REGULATORY ASPECTS AND CHALLENGES

Emerging markets have complex healthcare systems under rapid evolution, requiring 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

THE PHARMA DIGITALIZATION

The digital transformation is affecting the whole product lifecycle, from R&D to product supply and patient care, bringing patients and their quality of life to the centre of the pharma business.

In this session Regulatory Experts from leading industries will share their point of view about digital regulatory models and digitalization in therapies.

Keynote presentations followed by a final panel discussion with participants

TOPICS
workshop

THE ICH Q12 GUIDELINE: CHALLENGES AND OPPORTUNITIES

The key points of the guideline will be presented and discussed, together with the potential benefits for the MAH of using the tools and enablers described in ICH Q12 guideline, with reference to the current EU legal framework.

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

NITROSAMINES ASSESSMENT

Regulatory experts will share their experience about the implementation of the assessment of Nitrosamines impurities in the finished product dossier and the related regulatory impacts with the different authorities.

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

PRICING AND REIMBURSEMENT OF MEDICINAL PRODUCTS IN ITALY

The new AIFA guideline on prices and reimbursement will be discussed, with a focus on the new requirements compared with the last version.

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

ELECTRONIC COMMON TECHNICAL DOCUMENT eCTD

The eCTD is now an established digital format that pharmaceutical companies adopt for the registration of drugs, as recommended by the International Conference on Harmonisation (ICH). The speakers will share their experiences illustrating the advantages and challenges they have faced in the management of this document.

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

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PROGRAM

MAY 12, 2021

09.00 **Introduction**
Chairperson: *Raffaella Pandini* - Regulatory Affairs Operational Manager – Pharma D&S
Co-chairperson: *Ilaria Brocchi* - RA Senior Project Manager - Pharma D&S

SESSION I – THE REGULATORY FRAMEWORK OF INNOVATIVE THERAPIES

09.15 **New therapeutic scenarios in the evolution of pharmaceuticals**
Raffaele Cerbini - Executive Medical Director

09.35 **Early Access Regulatory Pathways (EMA FDA) for new Therapies**
Paolo Dametto - Sr. Manager - International Regulatory Science - Moderna

10.00 **Rolling review & emergency procedures for COVID 19 vaccines**
Federica Grotti - Head of Regulatory Affairs - Pfizer

10.25 **Panel discussion**
Moderator: Raffaele Cerbini
Participants:
- *Patrizia Ciavatta* - Global Regulatory Affairs Executive Director - Angelini
- *Paolo Dametto* - Moderna
- *Federica Grotti* - Pfizer

11.00 **Coffee break**

SESSION II – THE REGULATORY LANDSCAPE AFTER BREXIT

11.20 **A Globally Attractive UK ?**
Phil Brown – Director, Regulatory & Compliance - Association of British HealthTech Industries

11.50 **Q&A time**

SESSION III – EXTRA EU AND EMERGING MARKETS: REGULATORY ASPECTS AND CHALLENGES

12.05 **Regulatory Strategies for Inclusion of China into the Global Development of Innovative Drugs**
Stefano Accorsi - MSc EMBA - Head of Regulatory Affairs "China and International", Global Regulatory Affairs – Chiesi Farmaceutici S.p.A.

PROGRAM

12.30 **Eurasian Economic Union: an overview and experience from the first wave of harmonizations**
Alessandra Leone - Global CMC Senior Manager – PTx - Pfizer

13.00 **Lunch**

14.00 **Panel discussion**
- *Stefano Accorsi* - Chiesi Farmaceutici S.p.A
- *Marcello Colao* - Sr Director,Global Quality Head China Vaccines – GSK
- *Alessandra Leone* - Pfizer

SESSION IV – THE PHARMA DIGITALIZATION

14.30 **Business impacts caused by the switch from eCTD 3.2 to the next major version eCTD 4.0**
Frank Dickert - Senior Business Consultant - EXTEDO

14.50 **Q&A time**

15.00 **Digital health transformation and innovative technologies in healthcare**
Roberto Ascione - CEO - Healthware Group

15.25 **The evolving global regulatory landscape for digital health software**
Priya Tiwari - Associate Director Global Regulatory Affairs – Digital Health, Combination Products and Medical Devices - Biogen

15.50 **Panel discussion**

SESSION V - DRUG-DEVICE COMBINATION: AN EVOLVING GLOBAL REGULATORY SCENARIO

16.10 **Comparison MDR-FDA legislation in the registration of combined products**
Priya Tiwari - Associate Director Global Regulatory Affairs – Digital Health, Combination Products and Medical Devices - Biogen

16.35 **Q&A time**

16.50 **Final remarks & Closure**
Raffaella Pandini – Regulatory Affairs Operational Manager – Pharma D&S

17.00 **End of the Forum**

MAY 13, 2021

09.00 **Introduction**
Chairperson: *Raffaella Pandini* - Regulatory Affairs Operational Manager – Pharma D&S
Co-chairperson: *Stefano Nepi* - Team Leader Project Manager - Pharma D&S

SESSION VI – THE ICH Q12 GUIDELINE: CHALLENGES AND OPPORTUNITIES

09.15 **Lifecycle Management of Pharmaceutical Products Global Harmonization of Post-Approval Changes (ICH Q12)**
Jean Louis Robert - EU topic leader for Life Cycle Management ICH Q12 - former chair of CHMP-QWP

09.45 **Implementation of ICH Q12 - an Industry Perspective**
Mihai Bilanin - Director, Global Regulatory CMC - GSK Biopharmaceuticals

10.15 **Panel discussion**

SESSION VII – NITROSAMINES ASSESSMENT

10.30 **NITROSAMINES: RA points of situation and experience with European HAs**
Raffaella Pandini - Regulatory Affairs Operational Manager – Pharma D&S

10.55 **Q&A time**

11.10 **Coffee break**

SESSION VIII - PRICING AND REIMBURSEMENT OF PHARMACEUTICALS IN ITALY

11.30 **The new AIFA Pricing & Reimbursement guideline: overview and differencies with the previous dossier**
Alessandra Perini - Avv., LL.M. (UCL) - In-house Counsuel - Pharmaceutical Legal Expert

12.00 **Q&A time**

SESSION IX – ELECTRONIC COMMON TECHNICAL DOCUMENT – eCTD

12.15 **The electronic Common Technical Dossier (eCTD): experience with ASMF**
Lisa Milazzo - Regulatory Affairs Consultant - Pharma D&S

12.40 **The electronic Common Technical Dossier (eCTD) and important regional differences**
Hans Rensland - Managing Director - Racon Regulatory Affairs Consulting GmbH

13.05 **Panel discussion**

13.20 **Closure of the Forum**

SPEAKERS

Stefano Accorsi
MSc EMBA - Head of Regulatory Affairs "China and International", Global Regulatory Affairs – Chiesi Farmaceurtici S.p.A.

Roberto Ascione
CEO – Healthware Group

Mihai Bilanin
Director, Global Regulatory CMC - GSK Biopharmaceuticals

Ilaria Brocchi
RA Senior Project Manager - Pharma D&S

Phil Brown
Director, Regulatory & Compliance - Association of British HealthTech Industries

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Priya Tiwari
Associate Director, Regulatory Affairs Digital Health, Medical Devices & Combination Products – Biogen

ENTRY FEE
600 €

500 € until March 15
550 € until April 12

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 (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

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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.

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