PHARMA EDUCATION CENTER

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EUROPEAN PHARMACO VIGILANCE CONGRESS

MILAN, ITALY
NOVEMBER 29-30, 2018
2nd Edition

ABOUT

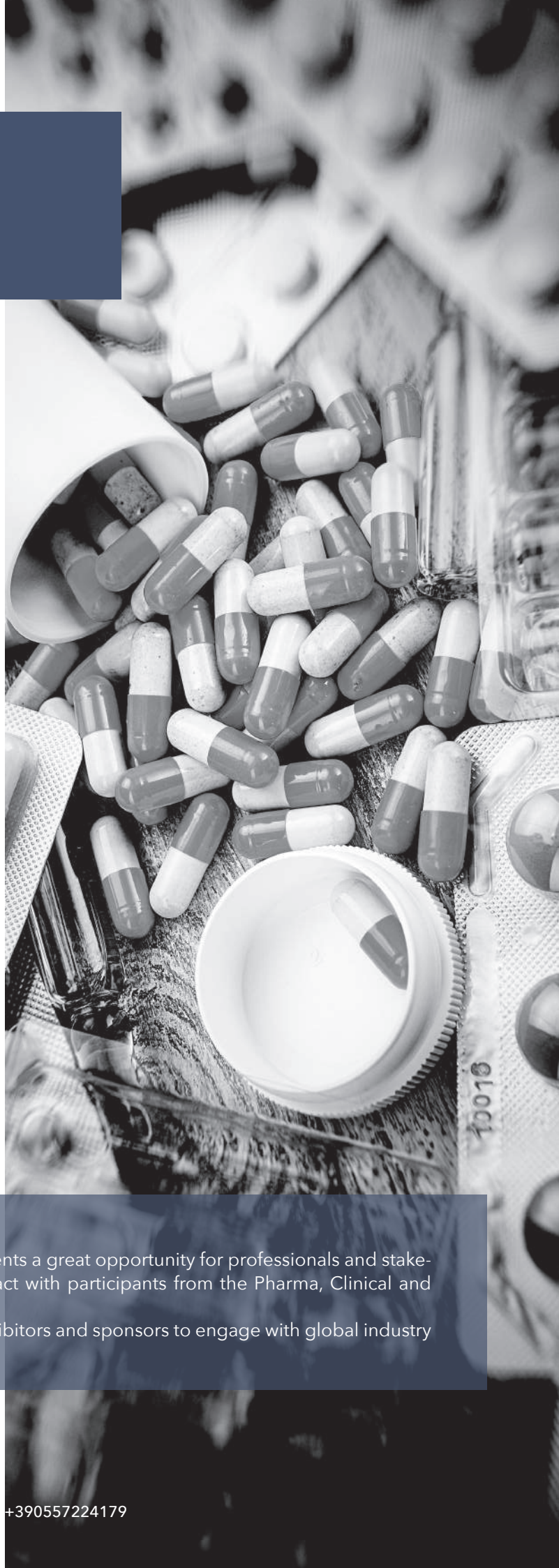
PEC – Pharma Education Center S.r.l. warmly invites PV professionals from the world to the **"European Pharmacovigilance Day – 2nd Edition"** which will be held on **November 29-30, 2018 in Milan, Italy.**

The field of Pharmacovigilance is growing rapidly and its development is making a tremendous impact in medical sciences and pharmaceuticals.

The 2nd European Pharmacovigilance congress is focused to the significant changes and challenges due to the EUDRAVIGILANCE implementation.

Key Speakers will give out updates about Eudravigilance at one-year from the implementation of the new requirements, how is changing the Signal Detection process, which is the impact of new requirements on the PV process as well as deepen PV quality system. Specific focus will be given on Patients Support Programmes (PSP) and engagement for the set up of appropriate risk management and risk minimization measures.

This 2 day Congress will offer 12 sessions of oral talks and keynotes presentations, including round-tables, networking lunch, exhibit area to showcase new and emerging technologies.



WHY TO ATTEND

The European Pharmacovigilance Congress represents a great opportunity for professionals and stakeholders to meet targeted audience and fully interact with participants from the Pharma, Clinical and Regulatory community.

This European event is a unique opportunity for exhibitors and sponsors to engage with global industry partners.

FOCUS

EUROPEAN PHARMACOVIGILANCE CONGRESS 2018: CONFERENCE FOCUS

Eudravigilance updates-Experience gathered following one year from the implementation of the new Requirements

Signal Management

PV Quality System and impacts from the new Eudravigilance requirements

Brexit – Impact on Pharmacovigilance

Ethics in Pharmacovigilance

Patient Support Programmes

Advanced Therapies

Risk Management and Risk Minimization

Contracts & Outsourcing on PV

Digital Media on PV

Privacy in PV

Patient Engagement for Set up of more appropriate Risk Minimization Measures

WHO SHOULD ATTEND

- Pharmacovigilance Students and Scientists
- Pharmacovigilance Researchers and Trainers
- Medical Colleges
- Pharmaceutical Industries
- Pharmacovigilance Associations and Societies
- Software Developing Companies
- Medical Devices Manifacuring Companies
- Data Management Companies
- University Faculties scientists who are related to clinical and medical research (Senior, Associate and Assistant Professors, Research Scholars, Phd students) Also, Directors/Seniors Directors/Executive Directors and Vice Presidents /Senior Vice Presidents/Executive Vice Presidents and Heads/Leaders/Partners of:
- CROs and CMOs
- Clinical Research Sites
- Pharma, Biotech and Medical Devices Industries

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EUROPEAN PHARMACOVIGILANCE CONGRESS 2018: LIST of COMPANIES present as SPEAKERS
ADIENNE PHARMA & BIOTECH, AMGEN, ASTELLAS, BAXTER SPAIN, BIOGEN, CHIESI FARMACEUTICI, DOMPE' FARMACEUTICI, EMERGENT BIOSOLUTIONS, EUPATI, HELSINN HEALTHCARE SA, INSUD-PHARMA, ITALFARMACO, KITE PHARMA, PFIZER, PFIZER PHARMACEUTICALS, ROCHE, SHIONOGI LIMITED, TAKEDA ITALIA, VIFOR PHARMA

KEY SPEAKERS

Glyn Belcher, M.D.
Expert in Signal Detection/Risk Management - CEO of PV Consultancy Ltd - Former Vice President of Biogen - Head of International Drug Safety & Risk Management - EU QPPV

Mario Bertazzoli, M.D.
Director, Group Head of Drug Safety and Reference Physician to EU QPPV at Helsinn Healthcare SA

Laura Boga
QPPV - Dompé Farmaceutici Spa

Davide Bottalico, M.D.
Digital Healthcare & Innovation Director - Takeda Italia

Gian Nicola Castiglione, M.D.
EU QPPV & Director Global Pharmacovigilance - Chiesi Farmaceutici S.p.A

Filippo Cerruti
Legal Director & Senior Counsel Italy & Greece at Amgen

Fernanda Ferrazin
Former Head of Pharmacovigilance Dept. - Italian Medicines Agency Scientific Board - PEC (Pharma Education Center)

Mircea Ciuca, M.D.
Global Head Medical & Clinical Drug Safety - Vifor Pharma

David Chonzi
Vice President - Head of Patient Safety and Pharmacovigilance - Kite Pharma

Margherita D'Antuono
QPPV Italfarmaco Spa

Fabio De Gregorio, M.D.
Vice President, Head of Drug Safety Europe, EU QPPV Shionogi Limited

Philip Eichorn
Senior Director (Worldwide Safety & Regulatory) - Pfizer Pharmaceuticals

KEY SPEAKERS

Giovanni Furlan, M.D.
Safety Risk Lead, Director - Pfizer

Damon Green, M.D., MS
Medical Safety Surveillance Officer at Emergent BioSolutions. Former Medical Officer at FDA (CBER and CDER)

Paola Kruger
Expert Patient of EUPATI (European Patient's Academy for Therapeutic Innovation)

Calin A. Lungu, M.D.
MD, MRQA, BCMP
Eudravigilance and XEVMPD - EMA

Valentina Mancini
Associate Director Pharmacovigilance, Deputy European Qualified Person for PhV - Shionogi Limited

Raquel Martinez
Manager / EMEA Pharmacovigilance Agreements - Baxter S.L.

Dr. Jorgen Matz
Head of Global Pharmacovigilance & Drug Safety - InsudPharma

José Alberto Ayala Ortiz
PVpharm CEO, EU QPPV, EudraVigilance EVWeb-XEVMPD Trainer, Pharmacovigilance Consultant, LCPPV Services Spain, GVP Audit

Patrizia Rotunno
Pharmacovigilance Consulting, Pharmacovigilance & Drug Safety Manager of Phast Consulting

Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV ADIENNE Pharma & Biotech
Chairperson for EU PV Congress

Francoise Dumas Sillan, M.D.
Vice President, Head Global QPPV office - Pfizer

Doris Irene Stenver, M.D.
Chief Medical Officer Danish Medicines Agency and member of Pharmacovigilance Risk Assessment Committee (PRAC), EMA

Bert Van Leeuwen, M.D.
Deputy-QPPV of Astellas Pharma

AGENDA - 29TH

08:15 Registration

09:10 **Opening Welcome & Chairperson's Opening Remarks**
Dr. Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV ADIENNE Pharma & Biotech

1- Eudravigilance updates-Experience gathered following one year from the implementation of the new Requirements

09:20 **EVDAS and Eudravigilance updates**
Dr. Calin Lungu
EudraVigilance and XEVMPD Trainer for EMA – CEO of DDCS

10:10 **Eudravigilance update: practical experience of a big pharma with the implementation of EVWEB and EVDAS**
Dr. Françoise Dumas Sillan
Vice President, Head Global QPPV office - Pfizer

10:40 **Q&A EudraVigilance**
10:50 **Morning Coffee/Tea & Networking**

11:20 **Roundtable: ICSR downloading & Management of Duplicates - Some MAH Experiences**

Moderator:
Dr. Mircea Ciuca, Global Head Medical & Clinical Drug Safety Vifor Pharma

Participants:
Dr. Valentina Mancini, Deputy QPPV Shionogi.
Dr. Laura Boga, QPPV, Dompé
Dr. Margherita D'Antuono QPPV - Italfarmaco
Dr. Patrizia Rotunno
Pharmacovigilance Consulting and Pharmacovigilance & Drug Safety Manager of Phast Consulting

2 - Signal Management

11:50 **Signal Detection and Signal Investigation**
Dr. Glyn Belcher
Expert in Signal Detection/Risk Management - PV Consultancy Ltd

12:20 **The new pilot process of Eudravigilance screening for adverse drug reactions by the MAH - practical aspects**
Dr. Mircea Ciuca
Global Head Medical & Clinical Drug Safety - Vifor Pharma

12:50 Q&A
13:00 Networking Lunch

3 - PV Quality System and impacts from the new Eudravigilance requirements

Co-Chair of the Session:
Dr Bert Van Leeuwen, Deputy QPPV of ASTELLAS Pharma

13:50 **The globalisation of the role of the EUQPPV: challenges of a complex PV regulatory environment**
Dr. Françoise Dumas Sillan
Vice President, Head Global QPPV office – Pfizer

14:20 **Pharmacovigilance System Master File**
Dr. Jorgen Matz
Head of Global Pharmacovigilance & Drug Safety - InsudPharma

14:50 **GVP - Module I - Quality System including the impacts from the new Eudravigilance requirements**
Dr. Jose Alberto Ayala Ortiz
PVpharm CEO, EU QPPV, EudraVigilance EVWeb-XEVMPD

AGENDA - 29TH

Trainer, Pharmacovigilance Consultant, LCPPV Services Spain, GVP Audit

15:20 Q&A

4 - Brexit – Impact on Pharmacovigilance

15:35 **Brexit Impact on PV**
Dr. Glyn Belcher
Expert in Signal Detection/Risk Management - PV Consultancy Ltd

16:00 **Q&A**

16.10 **Afternoon Refreshments**

5 - Ethics in Pharmacovigilance

16:30 **Ethics in Pharmacovigilance**
Dr. Damon Green
Medical Safety Surveillance Officer at Emergent BioSolutions.
Former Medical Officer at FDA (CBER and CDER)

17:00 Q&A

6 - Patient Support Programmes

17:10 **PV considerations in Patient Support Programmes (PSPs), Market Research and other Externally-facing Engagement Activities**
Dr. Phillipp Eichorn
Senior Director - Worldwide Safety and Regulatory - Pfizer

17:40 **PV agreements with vendors conducting PSP or MRP**
Dr. Raquel Martinez
Manager / EMEA Pharmacovigilance Agreements - Baxter S.L – Spain

18:20 **Chairperson's closing remarks**
Dr. Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV - ADIENNE Pharma & Biotech

18:30 **Networking, Buffet and drinks**

AGENDA - 30TH

08:30 **Registration**

09:00 **Chairperson's Opening Remarks**
Dr. Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV - ADIENNE Pharma & Biotech

7 – Advanced Therapies

09:10 **Advanced therapies; An overview on cellular therapies including Chimeric Antigen receptor (CAR-T)**
Dr. David Chonzi
Vice President- Head of Patient Safety and Pharmacovigilance - Kite Pharma

09.35 **Q&A**

8 - Risk Management and Risk Minimization

09:40 **EU Pharmacovigilance 2018: An update on activities in the Pharmacovigilance Risk Assessment Committee.**
Dr. Doris Irene Stenver
Chief Medical Officer Danish Medicines Agency and member of Pharmacovigilance Risk Assessment Committee (PRAC), EMA

10:10 **New Requirements: What is a successful R.M. planning?**
Dr. Glyn Belcher
Expert in Signal Detection/Risk Management - PV Consultancy Ltd

10:40 **Q&A**
10:50 **Morning Coffee/Tea & Networking**

11:10 **PASS implementation in Risk Management processes**
Dr. Fabio De Gregorio
Vice President, Head of Drug Safety Europe, EU QPPV at Shionogi

11:35 **Safety Communication**
Dr. Gian Nicola Castiglione
EU QPPV & Director Global Pharmacovigilance
Chiesi Farmaceutici S.p.A.

12:00 **Q&A**

9 - Contracts & Outsourcing on PV

12:10 **PV agreements with external parties**
Dr. Raquel Martinez
Manager / EMEA Pharmacovigilance Agreements - Baxter S.L – Spain

12:35 **Proposals for good pharmacovigilance outsourcing practices**
Dr. Giovanni Furlan
Safety Risk Lead, Director - Pfizer

13:10 **Lunch**

10 - Digital Media on PV

14:10 **How we can match healthcare innovation and PV rules?**
Dr. Davide Bottalico
Digital Healthcare & Innovation Director - Takeda Italia
Dr. Valentina Mancini
Associate Director Pharmacovigilance, Deputy European Qualified Person for PV Shionogi.

11 - Privacy in PV

15:00 **Impact of New Privacy Regulation on PV**
Dr. Filippo Cerruti
Country Counsel Italy & Greece Amgen

15:30 **Q&A**

AGENDA - 30TH

12 - Patient Engagement for Set up of more appropriate Risk Minimization Measures

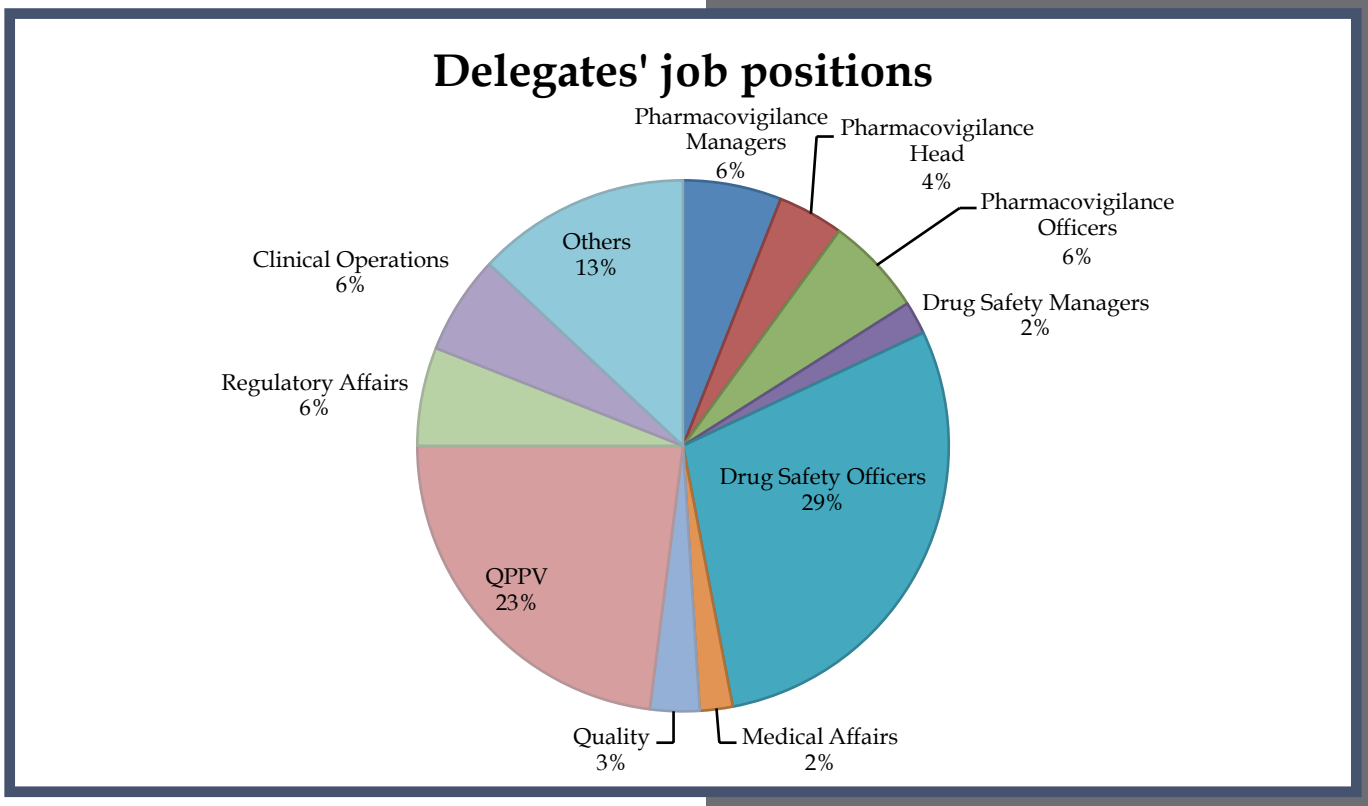
15:35 **How to manage a drug stopped in Clinical Phase I for safety reasons**
Dr. Mario Bertazzoli
Director, Group Head of Drug Safety and Reference Physician to EU QPPV at Helsinn Healthcare SA

16:00 **The evolving role of patients in Risk Communication and partnership with Industry: a potential gamechanger in PV?**
Dr. Paola Kruger
Patient Expert, EUPATI Fellow
EUPATI – Italy

16:30 Q&A & Afternoon Refreshments

16:45 **Chairperson's Closure Remarks**
Dr. Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV ADIENNE Pharma & Biotech

ATTENDANCE



The 1st European Pharmacovigilance Congress has brought together safety global experts from the pharmaceutical and healthcare industry:

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TERMS OF PAYMENT
Advance payment is required with respect to the event date by bank transfer to Banca Popolare di Milano – Agency n.323 – Florence (Italy), IBAN: IT85J0558402802000000001400, SWIFT: BPMIITM1223 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.

CONGRESS VENUE

Ritz Hotel
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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.eupharmacovigilance.com/, or fill the form and submits by email to info@pharmaeducationcenter.it.
A confirmation email will be sent to confirm the registration.

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