PEC PHARMA EDUCATION CENTER

EUROPEAN PHARMACO VIGILANCE CONGRESS

WWW.EUPHARMACOVIGILANCE.COM

EUROPEAN PHARMACO VIGILANCE CONGRESS

MILAN, ITALY

NOVEMBER 28-29, 2019

3rd Edition

CONGRESS MEDIA PARTNER

Therapeutic Advances in Drug Safety

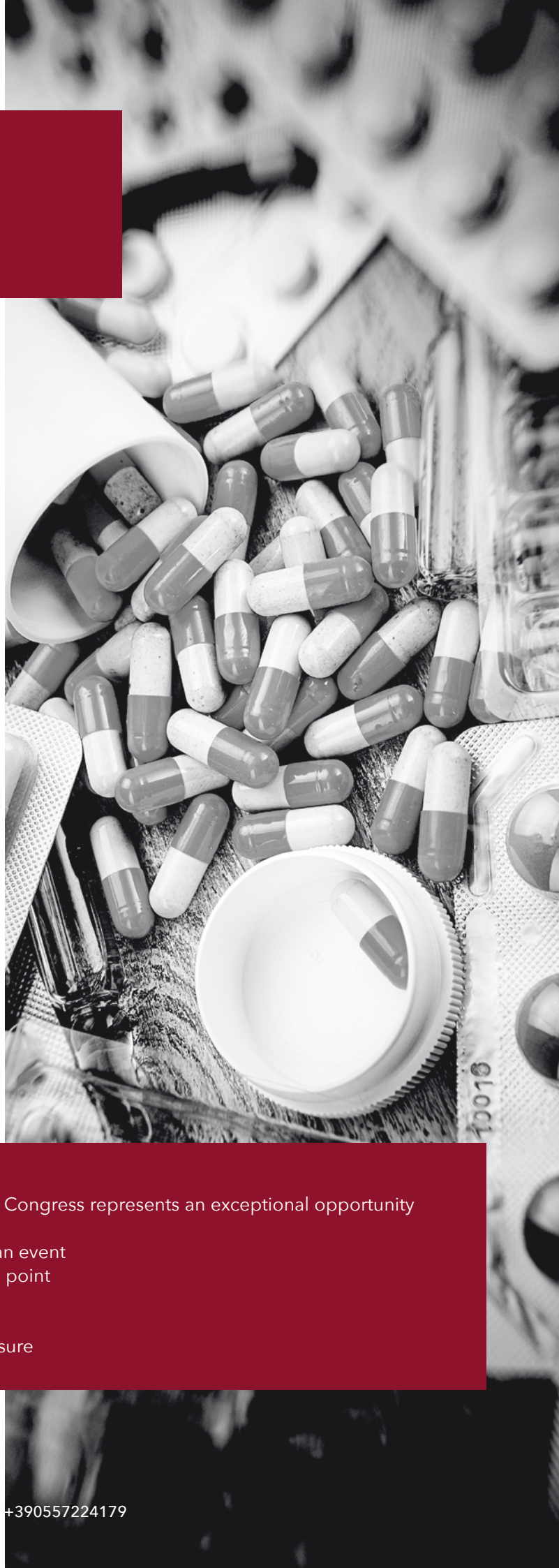
SAGE

PHARMA EDUCATION CENTER

ABOUT

PEC – Pharma Education Center S.r.l. warmly invites PV professionals from the world to the **"European Pharmacovigilance Congress – 3rd Edition"** which will be held on **November 28-29, 2019 in Milan, Italy.**

The 3rd edition of the European Pharmacovigilance Congress by PEC will offer a great opportunity for the different stakeholders to interact each other sharing their experiences concerning the implementation of the latest pharmacovigilance requirements, to learn more about the new legislations and to get insights by Valuable Experts from the field about possible strategies/solutions to address them.



WHO SHOULD ATTEND

Pharma, Biotech and Medical Devices Industries
Pharmacovigilance Associations
Regulatory Bodies
CROs and CMOs
Clinical Research Sites
Data Management Companies
Software Development Companies
University Faculties
PV Consultant Societies

WHY TO PARTICIPATE

Partecipating at the 3rd European Pharmacovigilance Congress represents an exceptional opportunity for Companies to:

- Promote projects and solutions at a leading european event
- Reach a global audience at an international meeting point
- Forge new collaboration with key decision makers
- Network with Companies delegates
- Enhance Company's brand awarness and gain exposure

FOCUS

The development of the pharmacovigilance legislations based on the observation that too many cases of death from 'noxious and unintended' responses to medicines had been reported worldwide (only in EU around 197,000 cases).
It is now clear that through the adequate surveillance of the benefit/risk profile of medicinal products, and through the implementation of measures aimed at improving the correct use of drugs, complications can be managed and their occurrence reduced.
Also costs deriving from the management of complications consequence of treatments can be lowered by the mean of adequate surveillance and risk minimization measures.
All these aspects have thus led legislators to revise the pharmacovigilance legislation, wherever possible with the involvement of a wide range of stakeholders including Competent Authorities, Pharmaceutical Companies/Organizations, Patients and Healthcare Professionals so to ensure its effective implementation.
The experience gained over time, the technical and scientific progresses, the need for common standards in presence of several territorial/local differences and political evolutions must be taken into account by legislators while reviewing the pharmacovigilance requirements.
Keeping up with the evolving pharmacovigilance requirements could be indeed quite challenging, with no few difficulties for all the involved parties.

The 3rd edition of the European Pharmacovigilance Congress, will address all these aspects through direct experience shared by different stakeholders from the various fields (Competent Authorities, Pharmaceutical Companies/Organizations, Patients and Healthcare Professionals).

- UPDATE FROM INTERNATIONAL PHARMACOVIGILANCE ORGANIZATIONS
- PHARMACOVIGILANCE INSPECTIONS: THE CURRENT AND FUTURE LANDSCAPES
- EUDRAVIGILANCE/EVDAS UPDATES
- SIGNAL MANAGEMENT
- PATIENT EXPERT ENGAGEMENT: CENTRAL ROLE IN PHARMACOVIGILANCE FOR A BETTER AND SAFER USE OF MEDICINAL PRODUCT
- PHARMACOVIGILANCE IN SPECIAL POPULATIONS: GERIATRICS vs PEDIATRICS (THE NEW GVP MODULE), PREGNANCY AND BREASTFEEDING
- PHARMACOVIGILANCE IN THE FRAME OF ADVANCED THERAPIES/RARE DISEASES
- RISK MANAGEMENT & RISK MINIMIZATION
- PATIENT SUPPORT PROGRAMS AND MEDICAL INFORMATION
- PV SYSTEM: ORGANIZATION & QUALITY
- PHARMACOVIGILANCE IN CLINICAL TRIAL

CONGRESS MEDIA PARTNER

Published by SAGE, Therapeutic Advances in Drug Safety is an international peer-reviewed Open Access journal, delivering the highest quality original research articles, reviews, and scholarly comment on pioneering efforts and innovative studies pertaining to the safe use of drugs in patients. The journal has a strong clinical and pharmacological focus and is aimed at an international audience of clinicians and researchers in drug safety, providing an online forum for rapid dissemination of recent research and perspectives in this area.

As the official Media Partner of the 3rd edition of the European Pharmacovigilance Congress, Therapeutic Advances in Drug Safety will be publishing a congress abstract booklet which will be free to access online.

For more information about the journal:
https://journals.sagepub.com/home/taw
elena.conroy@sagepub.co.uk
@TADrugSafety

SPONSOR

HISTORY

EUROPEAN PHARMACOVIGILANCE CONGRESS 2018

EUROPEAN PHARMACO VIGILANCE CONGRESS

ABOUT THE CONFERENCE

The 2nd **European Pharmacovigilance Congress** was hosted on November 29 - 30th, 2018 in Milan, Italy.
Honourable Guests and Key Speakers supported this event with remarkable enthusiasm contributing to make the Conference a prominent success.

The 2nd **European Pharmacovigilance Congress** has brought together safety global experts from the pharmaceutical and healthcare industry:

- Pharma and Medical Devices Companies
- Biotech Companies
- Medicines Agencies
- Academic Research Institutes

SPEAKERS

Glyn Belcher, M.D.
CEO of PV Consultancy Ltd

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

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

Mircea Ciuca, M.D.
Global Therapeutic Area Head (Immunology & Neurology/Transplant), in Global Clinical Safety and PV at CSL Behring

David T Chonzi, M.D.
Vice President , Head of PV and Epidemiology , Allogene Therapeutics

Margherita D'Antuono, PharmD, PhD
Corporate PV Director, EU QPPV Italfarmaco

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

Philip Eichorn, M.D.
Senior Director Worldwide Safety & Regulatory - Pfizer Pharmaceuticals

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

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

Ilaria Grisoni
Sr. Director, EEA QPPV
Jazz Pharmaceutical

Sarah Hall
HonFPIPA,Managing Director
MIPSOL

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

Hervé Le Louët ,M.D., PhD
President of CIOMS, member of PRAC

Calin A. Lungu, M.D.
MRQA,BCPM, Eudravigilance and XEVMPD - EMA, CEO- DDCS

Arduino Mangoni,
MBBS, MD (Hons), PhD
Professor and Head, Department of Clinical Pharmacology,
School of Medicine, Flinders University, Australia

SPEAKERS

Valentina Mancini
Director Pharmacovigilance,
EU QPPV - Shionogi Europe

Daniela Marcozzi
Head of QA GCP & GVP,
Fidia Farmaceutici

Nele Matthijs
PV Inspector-DG Inspection -
FAMHP- Federal Agency for
Medicines and Health Products,
Brussels Area, Belgium

Giovanni Navalesi, MD
Scientific Director at
PHARMA D&S

José Alberto Ayala Ortiz
PVpharm CEO, EU QPPV,
PV Consultant,
LCPPV Services - Spain

Paola Pirovano
Head of Drug Safety & QPPV,
Recordati S.p.A.

Keya Pitts, MPH
Head, Quality, Standards and
Compliance, Global Patient Safety
and Risk Management at Alnylam
Pharmaceuticals - USA

Paolo Porcelli
GVP Senior Inspector, GCP and
GMP API Inspector in training,
Inspection and Certification
Department- AIFA (Italian Medici-
nes Agency)

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

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

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

Doris Irene Stenver , M.D., MPA
Indep. PV Adviser
Founder of Unique Advice, former
Chief Medical Officer Danish
Medicines Agency and former
member of PRAC

Barbara Testoni
Chief Operations Officer in Dueali
consulting srl

Alessandra Traversa
Independent Pharmacovigilance
expert

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

**Anne Ruth van Troostenburg De
Bruyn, tGP MD (Lond) FFPM,**
EU QPPV & VP, Pharmacovigi-
lance & Epidemiology, Gilead
Science

AGENDA - 28TH

07:40 - 08:45 **Registration**

08:55 - 09:05 **Welcome and Opening remarks by the Chairperson**
Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV ADIENNE Pharma & Biotech

09:05 **A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety (Media Partner)**
Arduino Mangoni, MBBS, MD, (Hons), PhD, FRCP (Lond, Glas, Edin), FRACP, FBPhS
Professor and Head, Dep. of Clinical Pharmacology, School of Medicine, Flinders University, Australia

1- UPDATE FROM INTERNATIONAL PHARMACOVIGILANCE ORGANIZATIONS

09:10 **Updates from CIOMS**
Hervé Le Louët,MD, PhD
President of CIOMS, member of PRAC

09:35 **Updates from PIPA**
Sarah Hall, PhD
HonFPIPA,Managing Director MIPSOL

09:50 **Q&A**

2 - PHARMACOVIGILANCE INSPECTIONS: THE CURRENT AND FUTURE LANDSCAPES

10:00 **PV inspections: Pitfalls in relation to company size & third parties**
Nele Matthijs
PV Inspector- DG Inspection - FAMHP – Federal Agency for Medicines and Health Products, Brussels Area, Belgium

10:25 **A GVP inspector in the Inspection and Certification Department: experiences in GXP, Product Quality & Counteracting of Pharmaceutical Crime**
Paolo Porcelli, GVP Senior Inspector, GCP and GMP API Inspector in training, Inspection and Certification Department AIFA (Italian Medicine Agency)

10:50 **Q&A**

11:00 **Morning Coffee/Tea & Networking**

3 - EUDRAVIGILANCE/EVDAS UPDATES

11:20 **Eudravigilance/EVDAS Updates (e.g. What we have learned from the extended pilot phase period)**
Calin Lungu, M.D.
MRQA, BCPM, Eudravigilance and XEVMPD - EMA,CEO - DDCS

11:50 **Q&A**

4 - SIGNAL MANAGEMENT

12:00 **Signal management: theoretical and practical considerations**
Fabio De Gregorio
Vice President, Head of Drug Safety Europe, Shionogi Europe

12:25 **Round Table:**
"Weight of different sources for the identification/confirmation of safety signals (e.g. Big Databases vs other sources) - some experiences"

Moderator: Fabio De Gregorio
Vice President, Head of Drug Safety Europe. Shionogi Europe.

Participants:
L. Boga, QPPV
Dompé Pharmaceutical
M. D'Antuono, Corporate PV Director, EU QPPV- Italfarmaco
C. Lungu, MRQA, BCPM, Eudravigilance and XEVMPD - EMA,CEO – DDCS
G.Navalesi, MD Scientific Director at PHARMA D&S
J. A. Ayala Ortiz, PVpharm CEO,EU QPPV, EudraVigilance EVWeb-XEVM PD Trainer, PV Consultant, LCPPV Services Spain, GVP Audit
P. Pirovano, Head of Drug Safety & QPPV, Recordati
P. Rotunno, Drug Safety Manager of Phast Consulting, PV Consulting

13:00 **Lunch**

AGENDA - 28TH

5 - PATIENT EXPERT ENGAGEMENT: CENTRAL ROLE IN PHARMACOVIGILANCE FOR A BETTER AND SAFER USE OF MEDICINAL PRODUCT

14:00 **PRAC experiences with patient engagement**
Doris Irene Stenver, MD, MPA
Indep. PV Adviser, Founder of Unique Advice, former Chief Medical Officer Danish Medicines Agency and former member of PRAC

14:25 **Round table: "The impact of direct patient reporting on PV"**
Introduction by the moderator:
Kruger Paola, Expert Patient - EUPATI
Participants:
P. Eichorn, M.D. Senior Director Worldwide Safety & Regulatory - Pfizer Pharmaceuticals
I. Grisoni, Sr. Director, EEA QPPV, Jazz Pharmaceutical
V. Mancini, Director Pharmacovigilance, EU QPPV - Shionogi Europe
D.Marcozzi, Head of QA GCP & GVP Fidia Farmaceutici
D.I. Stenver, MD, MPA, Indep. PV Adviser, Founder of Unique Advice, former Chief Medical Officer Danish Medicines Agency and former member of PRAC

6 - PHARMACOVIGILANCE IN SPECIAL POPULATIONS: GERIATRICS vs PEDIATRICS (THE NEW GVP MODULE), PREGNANCY AND BREASTFEEDING

Chairperson of the session: **Valentina Mancini**, Director Pharmacovigilance, EU QPPV - Shionogi Europe

15:10 **Drug safety in older patients: current status and way forward**
Furlan Giovanni, Pharm D
Safety Risk Lead, Director- Pfizer

15:35 **PV in paediatrics patients**
Laura Boga
QPPV - Dompé Pharmaceutical

16:00 **PV in Pregnancy and Breastfeeding**
Margherita D'Antuono,
Pharm D, Ph D
Corporate Pharmacovigilance Director, EU QPPV, Italfarmaco

16:25 **Q&A**
16:35 **Coffee break**

7 - PHARMACOVIGILANCE IN THE FRAME OF ADVANCED THERAPIES/RARE DISEASES

Chairperson of the session: Mircea Ciuca, M.D.
Global Therapeutic Area Head (Immunology & Neurology/Transplant), in Global Clinical Safety and Pharmacovigilance at CSL Behring

17:00 **Pharmacovigilance of medicines for rare and ultrarare diseases**
Glyn Belcher, M.D.
CEO of PV Consultancy Ltd

17:25 **PV and risk management in CAR-T cell therapy**
Anna Ruth van Troostenburg De Bruyn
tGP MD(Lond) FFPM,EU QPPV & VP, Pharmacovigilance & Epidemiology, Gilead Sciences

17:50 **Beyond autologous cellular therapies: PV for Allogeneic CAR T therapies**
David T Chonzi, M.D.
Vice President , Head of Pharmacovigilance and Epidemiology , Allogene Therapeutics

18:15 **Q&A**

18:30 **Chairperson's closing remarks**
Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV, ADIENNE Pharma & Biotech

18:40 **Networking Buffet and drinks**

AGENDA - 29TH

08:00 - 08:40 **Registration**

08:45 **Welcome and Opening remarks by the Chairperson of the European Pharmacovigilance Congress**
Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV, ADIENNE Pharma & Biotech

8:55 **A word from the Editor-in-Chief of Therapeutic Advances in Drug Safety (Media Partner)**
Arduino Mangoni, MBBS, MD, (Hons), PhD, FRCP (Lond, Glas, Edin), FRACP, FBPhS
Professor and Head, Dep. of Clinical Pharmacology, School of Medicine, Flinders University, Australia

8 – RISK MANAGEMENT & RISK MINIMIZATION

Chairperson of the session:
Hervé Le Louët ,MD, PhD,
President of CIOMS, member of PRAC

09:00 **Risk Management Plans post GPV module V revision 2: the way forward**
Francoise Dumas Sillan, M.D.
Vice President, Head Global QPPV office at Pfizer

09:25 **PRAC, risk management and experiences with referral procedures**
Doris Irene Stenver, MD, MPA
Independent PV Adviser, Founder of Unique Advice, former Chief Medical Officer Danish Medicines Agency and former member of PRAC

09:45 **Risk Management in pre-marketing phase**
Mircea Ciuca, M.D. ,
Global Therapeutic Area Head (Immunology & Neurology/ Transplant), in Global Clinical Safety and Pharmacovigilance at CSL Behring

10:05 **Effectiveness of Risk minimization measures**
Glyn Belcher, M.D.
CEO of PV Consultancy Ltd

10:25 **Q&A**

10:35 **Coffee Break**

9 - PATIENT SUPPORT PROGRAMS AND MEDICAL INFORMATION

Chairperson of the session:
Gian Nicola Castiglione, M.D.
EU QPPV & Director Global PV – Chiesi Farmaceutici

10:55 **Safety considerations for Patient Support and Market Research Programmes**
Phillip Eichorn, M.D.
Senior Director Worldwide Safety & Regulatory – Pfizer Pharmaceuticals

11:15 **Medical information and Pharmaco vigilance working together**
Sarah Hall, PhD
HonFPIPA, Managing Director MIPSOL

11:35 **Q&A**

10 - PV SYSTEM: ORGANIZATION & QUALITY

Chairperson of the session:
Francoise Dumas Sillan, M.D. Vice President, Head Global QPPV office at Pfizer

11:45 **Quality for the QPPV**
Bert Van Leewen, M.D.
Deputy-QPPV of Astellas Pharma

12:10 **Ensuring Quality Oversight in Pharmacovigilance (PV) Vendor Management**
Keya Pitts, MPH
Head, Quality, Standards and Compliance, Global Patient Safety and Risk Management at Alnylam Pharmaceuticals - USA

12:35 **EU QPPV: role evolution and future challenges**
Ilaria Grisoni
Sr. Director, EEA QPPV at Jazz Pharmaceutical

AGENDA - 29TH

12:55 **Lunch**

14:10 **Follow up period post PV Inspection**
Gian Nicola Castiglione, M.D.
EU QPPV & Director Global PV – Chiesi Farmaceutici

14:35 **Data Integrity in PV**
Guerrina Barbara Testoni
Chief Operations Officer in Dueali consulting srl

15:00 **Q&A**

11 - PHARMACOVIGILANCE IN CLINICAL TRIAL

Chairperson of the session: Patrizia Rotunno, Drug Safety Manager of Phast Consulting, PV Consulting

15:20 **Therapeutic strategies targeting nitric oxide pathways and drug repurposing for cardiovascular risk management: from drug discovery to clinical studies"**
Arduino Mangoni, MBBS, MD (Hons), PhD, FRCP (Lond, Glas, Edin), FRACP, FBPhS
Professor and Head, Department of Clinical Pharmacology, School of Medicine,Flinders University, Australia

15:35 **Early Access Program (EAP): a practical approach**
Mario Bertazzoli, M.D.
Director, Group Head of Drug Safety and Reference Physician to EU QPPV at Helsinn Healthcare SA

16:00 **Pragmatic approaches for PV in Clinical Trials**
Jose Alberto Ayala Ortiz
PVpharm CEO, EU QPPV, EudraVigilance EVWeb-XEVMPD Trainer, PV
Consultant, LCPPV Services Spain, GVP Audit

16:20 **Challenges of RSI Management – a non-commercial sponsor perspective**
Alessandra Traversa
Independent Pharmacovigilance expert

16:40 **Q&A**

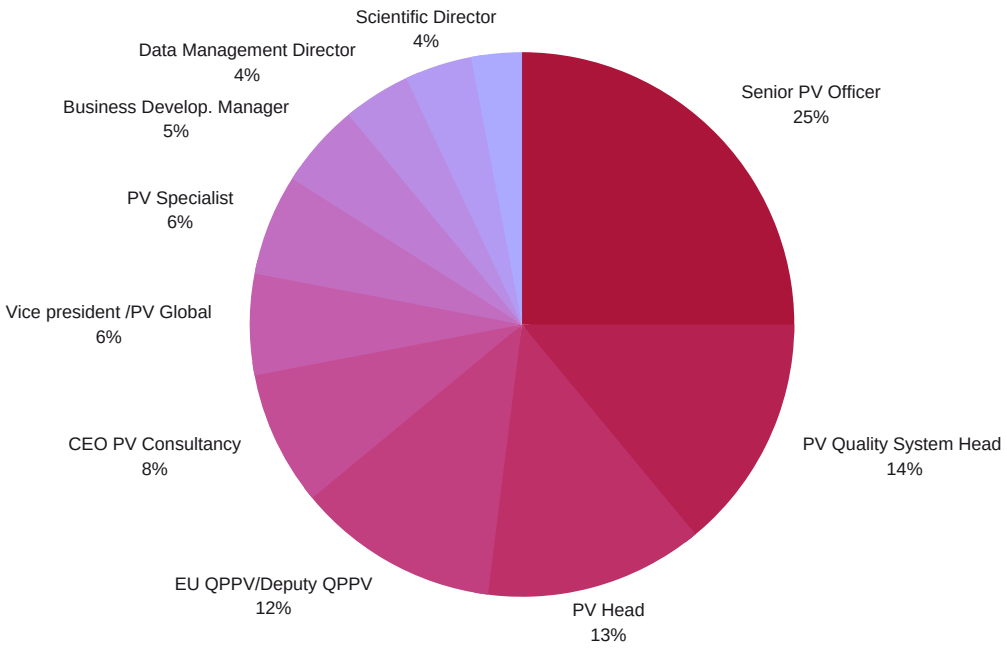
16:50 **End of Chairperson's Closure Remarks and coffee break**
Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV ADIENNE Pharma & Biotech

17:00 **End of the Congress**

PEC PHARMA EDUCATION CENTER

EUROPEAN PHARMACO VIGILANCE CONGRESS

ATTENDANCE



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PEC PHARMA EDUCATION CENTER

EUROPEAN PHARMACOVIGILANCE CONGRESS 2018: LIST of COMPANIES

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- Desk in the foyer within F&B area
- Company logo over our marketing materials - website, event brochure, NL (about 8000 contacts), educational material distributed during the conference
- 1Free Conference Pass
- List of participants

SILVER SPONSOR
- Desk in the foyer within F&B area
- Company logo over our marketing materials - website, event brochure, NL (about 8000 contacts), educational material distributed during the conference
- 2 Free Conference Pass
- List of participants

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- Recognition as event Gold Sponsor
- Desk in the foyer within F&B area
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- Company logo slideshare during the breaks

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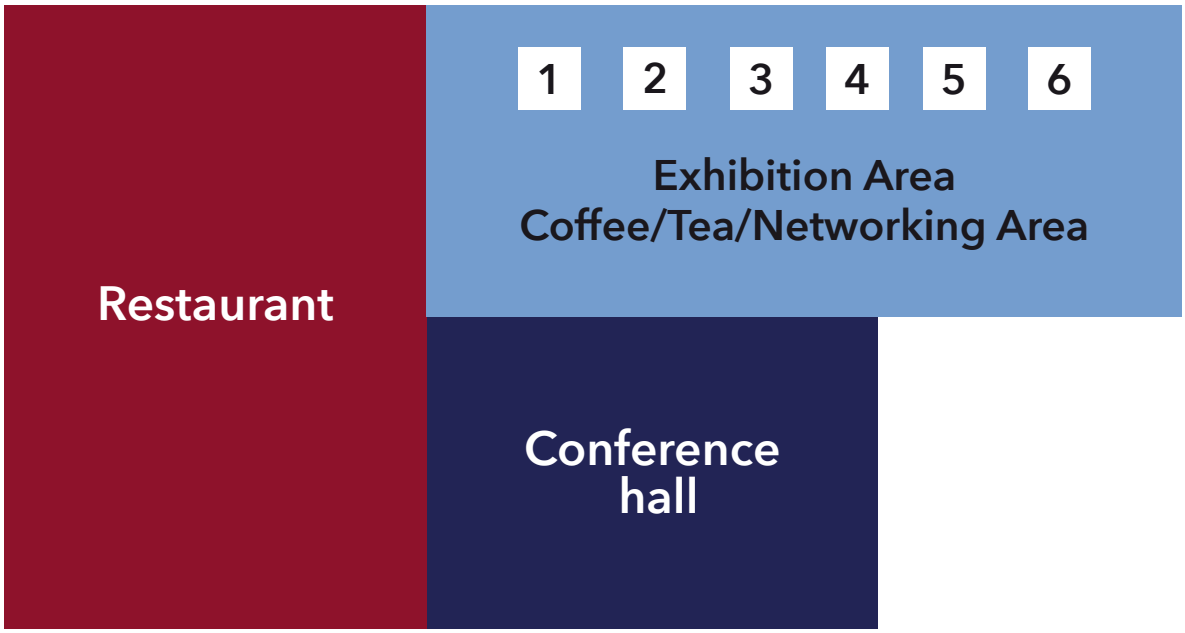
- Desk in the foyer within F&B area
- Company logo over our marketing materials - website, event brochure, NL (about 8000 contacts), educational material distributed during the conference
- 5 Free Conference Pass
- List of participants
- Company logo slideshare during the breaks
- Banner Roll up at the top of the Congress Room
- Coffee break sponsorized by your Company

FLOOR PLAN

Book your stalls now before they run out!!!



For further information on Sponsorship Opportunities, please contact

Matteo Gentili, Ph.D
Project Manager
email: mgentili@pharmaeducationcenter.it
mobile: +39 347 049 2499

Dr. Lucia Costanzo,
Senior Conference Manager PEC
email: lcostanzo@pharmaeducationcenter.it
mobile: +39 3319658839- + 39 3480094076

Note: The floorplan is subject to change at the discretion of the organisers

CONGRESS VENUE

BUSINESS HOTEL IN MILAN, NEAR STAZIONE ROGOREDO

The Starhotels Business Palace is strategically located in the east of Milan, a few subway stops from the historic centre, near the Linate airport, the Rogoredo railway station and the motorway.

Address
Via Privata Pietro Gaggia, 3
20139 Milano
Italia

T:+39 02 535451
F:+39 02 57307550

From the Milano Centrale Train
Station (10km), take metro line 3 to the Porto di Mare stop (10 metro stops).
From the Milano Rogoredo Train Station (800 meters) you can either walk to the hotel or take the metro line 3 for one stop to Porto di Mare (1 metro stop).

PEC Staff will organize in the relaxing area of Starhotels Business Palace at the end of first day course, a free refreshment and aperitif for Speakers and delegates!!
Don't forget to book your seat for evening Aperitif!!

ENTRY FEE

EUROPEAN PHARMACO VIGILANCE CONGRESS

PEC PHARMA EDUCATION CENTER

ENTRY FEE
€ 1750
10% discount for registrations within 2 months from the congress
vat not included
Multiple registrations
15% discount on the 2nd member
20% discount on the 3rd member
Discounts are not cumulative

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.

CONGRESS VENUE

Address
Business Hotel
Via Privata Pietro Gaggia, 3
Milan

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.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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