PEC PHARMA EDUCATION CENTER

EUROPEAN PHARMACO VIGILANCE DAY MILANO 30.11.2017

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First Edition

NEWS ON EUDRAVIGILANCE

SIMULTANEOUS TRANSLATION
ITALIAN - ENGLISH
ENGLISH- ITALIAN

Event Sponsor

SafetyDrugs
Pharmacovigilance Software System

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November 2017 – EudraVigilance Change Management

EMA will launch a new EudraVigilance system with enhanced functionalities for reporting and analysing suspected adverse reactions.

This conference will highlight how the use of the new EudraVigilance web application (EVWEB) can help Companies to achieve the effective safety system required by the law, especially under the new GVP guidance and EVWEB and EVDAS.

Conference Focus

- **EVDAS – How to manage and to integrate into the own Signal Evaluations?**
- **EVWEB system - Understand how it could improve the Signal detection process**
- **How to approach Signal Detection and Risk Management Today?**

Who Should Attend
The conference is aimed to users of EudraVigilance and to all professionals involved in the Signal detection.

Key Speakers

Dr. Glyn Belcher - Director of PV Consultancy Ltd - former Vice President of Biogen Head of International Drug Safety and Risk Management, EU QPPV
Dr. Carlo Ghiglione, Dr. Andrea Garlanda – Partners of Max Application-SafetyDrugs
Dr. Calin Lungu – EudraVigilance and XEVMPD Trainer for the EMA and former EVDAS Trainer for EMA - CEO of DDCS
Dr. Marco Sardella - Chief Pharmacovigilance Officer & EU QPPV ADIENNE Pharma & Biotech
Dr. Laura Sottosanti – Pharmacovigilance Department - Italian Medicines Agency

Moderator

Fernanda Ferrazin
Former Head of Pharmacovigilance Dept - Italian Medicines Agency

Agenda

08:30 – 9:30 **Registration**

09:30 – 09:40 **Chairperson's opening remarks** – Dr. Fernanda Ferrazin – Former Head Pharmacovigilance Dept - Italian Medicines Agency

09:40 –10:00 **Opening Keynote** - Complexity of Pharmacovigilance Management Today "Keep up with continuous changes in legislation and new technologies" Dr. Marco Sardella - Chief Pharmacovigilance Officer & EU QPPV ADIENNE Pharma & Biotech

10:00 – 11:00 **New EVWEB/ ISO-ICSR/ XEVMPD** - Major changes - Dr. Calin Lungu CEO DDCS - EV Trainer

11:00 – 11:20 **Morning Coffee/Tea & Networking**

11.20 – 12.10 **EVDAS and Download Manager** - Additional tools to assist MAHs in Signal Detection – Dr. Calin Lungu - CEO DDCS - EV Trainer

12:10 – 13:00 **Agency Perspective: News on Eudravigilance and PhV National System** Dr. Laura Sottosanti - PhV Department - Italian Medicines Agency

13:00 – 14:20 **Networking Luncheon**

14:20 – 15:20 **How to approach Signal Detection, Signal Assessment and Risk Management Today** - Dr. Glyn Belcher - Director of PV Consultancy Ltd former Vice President of Biogen Head of International Drug Safety and Risk Management, EU QPPV

15:20 – 15:40 **How to meet the worldwide PharmacoVigilance requirements with the safety database SafetyDrugs 6 –** Dr. Carlo Ghiglione Project manager, Dr. Andrea Garlanda Marketing manager - Max Application

15:40 – 16:30 **Round Table**
What impact will have the new Eudravigilance and Signal Detection Requirements on Pharmacovigilance activities?
What role will have the PhV National System after the go live of the new Eudravigilance system?
How to Best Address/Prioritize changes to PV Systems to maintain compliance with the new Eudravigilance and Signal Detection Requirements?
Moderator: Dr. F. Ferrazin
Round table: Meeting participants, Key Speakers and external members
Dr. Margherita D'Antuono - QPPV- Italfarmaco S.p.A.
Dr. Alessandra Del Porto – Farmacovigilanza Drug Safety Director MSD (Italia) S.r.l., Essex Italia S.r.l.
Dr. Valentina Mancini - Manager Pharmacovigilance Southern Europe Baxter S.p.A
Dr. Ugo Moretti - Responsible of Pharmacovigilance Regional Center of Veneto
Dr. Gianni Navalesi -Scientific Director Pharma D&

16:30 – 17:00 **Afternoon Refreshment Break** – Networking & Exhibit

17:00 – 17:20 **Chairperson's closing remarks and end of conference**

Glyn Belcher

Dr Glyn Belcher has over 30 years experience in clinical development and drug safety in the pharmaceutical industry. Dr Belcher qualified in medicine from Oxford and Cambridge universities and received his PhD in neuropharmacology from the latter. After a number of years in hospital internal medicine he joined Schering and worked in clinical research in the UK affiliate before moving to headquarters in Berlin, first as head of cardiovascular clinical research and later as head of a new safety department covering clinical development activities. Dr Belcher moved to Takeda European Research and Development Centre in London where he was Director of International Drug Safety and EU QPPV for nine years. He most recent full-time position was as Head of Drug Safety and Risk Management and EU QPPV at Biogen Idec in UK. In this position he took a lead role in the safety aspects of the European approval and post-marketing surveillance of Tysabri and other Biogen medicines. After retiring from this position, he has continued to consult for Pharmaceutical Industry companies as well as committing more time to teaching and mentoring in the areas of pre-marketing and post-marketing drug safety and benefit risk management.

Fernanda Ferrazin

Fernanda Ferrazin, former GMP inspector, has gained long experience as GMP inspector and director, first in the Ministry of Health where he served from 1984 to 2004, and later at the Italian Agency for Medicines (established in 2004). From 2009 to 2013 she has been involved in the safety of medicines (as Director of the Pharmacovigilance Office and alternate member of the PRAC - Committee for Pharmacovigilance Risk Assessment of the European Medicines Agency EMA in London). From 2013 to 2015 has verified regulatory compliance due to the updating of the registration dossiers and CTDs of the medicines by MAH companies, in particular in case of GMP production API production delays and semi-finished/finished products. Teacher on GMP and Pharmacovigilance issues in several University Masters and Training Courses. Speaker at numerous scientific congresses.

Calin Lungu

Calin is the Chief Executive Officer of Drug Development Consulting Services (DDCS), established in 1999, a pharmacovigilance quality assurance consulting firm located Luxembourg. He has worked for 15 years in drug development, clinical research, pharmacovigilance and quality assurance. He is a medical doctor. Calin has conducted more than 140 pharmacovigilance systems audits for various pharmaceutical companies, has audited transfer of safety databases and MedDRA recoding, PSUR processes, CCSI processes, signal detection, has participated in the preparation, conduct and follow-up of various regulatory inspections in the area of pharmacovigilance in Europe, has advised several EU and non-EU pharmaceutical companies in establishing/improving a pharmacovigilance system in conformity with current regulatory requirements.
Calin has been a Eudraviglance Trainer since 2004 and has trained more than 250 Eudravigilance and XEVMPD courses and has been a professional trainer in the use of the EudraVigilance Data Analysis System for European National Competent Authorities and the European Medicines Agency between 2008 and 2013.

Marco Sardella

Marco Sardella, Chief Pharmacovigilance Officer EU-QPPV-ADIENNE Pharma & Biotech Dr. Marco Sardella is a PV Person with significant experience in setting up pharmacovigilance and risk management systems worldwide (experience with EMA, USA, Canada, Switzerland, Russian Federation, ASIA, Middle East). Former European QPPV of Gentium S.p.A/Jazz Pharma. Today, overall Responsible for Global Safety and Pharmacovigilance for the Group ADIENNE Pharma and Biotech in the position of Chief Pharmacovigilance Officer & European QPPV. Experience with development of CTD safety modules for hemato-oncological products [successful approval in US, Canada, (New Drug Applications) and EMA (Marketing Authorization Applications)].
Responsible for Safety in international pre-approval and post-approval safety studies.

Laura Sottosanti

From 2000 to present, dr. Laura Sottosanti is the Scientific Administrator at the Pharmacovigilance Office of the Italian Medicines Agency – (AIFA).
Member of various national and international commissions , most significant:
Italian Representative in several meetings of the European Commissions for the discussions on new pharmacovigilance legislation of the Expert Group on the delegates acts, Coordinator of the Signal Analysis Working Group between AIFA and the Regional Center for Pharmacovigilance, Italian member of the signal management review technical working group (SMART WG) at EMA, reference at national level for BEMA (benchmarking of AIFA) activity, Italian Trusted deputy for Eudravigilance.
Teacher on Pharmacovigilance issues in several University Masters on Pharmacovigilance. Speaker at numerous scientific congresses. Author of various publications on topics related to pharmacovigilance.

Max Application

Max Application develops solutions for the pharmaceutical world and, in particular, manages the pharmacovigilance processes thanks to SafetyDrugs, its safety database.
SafetyDrugs supports the capture, management, reporting and analysis of adverse events from clinical trials and from post marketing surveillance, including cases from literature, of all medical products: from drug to devices, from vaccines to cosmetics. SafetyDrugs 6 is compliant with ICSR ICH E2B (R3), EMA and FDA rules. It is available both On Premises and in SaaS modality on Oracle® Cloud Platform with disaster recovery protection.
The Signal Detection analysis is included in the Business Intelligence module and provides statistics that show the evidence of adverse events with disproportionally high statistical scores.
With SDConverter tool, SafetyDrugs is able to directly import the ADR(s) from PDF file provided by Italian National Authority "Rete Nazionale di FarmacoVigilanza".
Max Application provides direct assistance through its internal assistance team.

SafetyDrugs
Pharmacovigilance Software System

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THE REGISTRATION FEE INCLUDES
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HOW TO PAY THE REGISTRATION FEE
Payment is required before the date of conference by back transfer to:
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SWIFT: BPMIITM1323 headed to Pharma Education Center S.r.l. Via dei Pratoni 16 – 50018 Scandicci (FI). VAT number 02173670486 indicating the participant's name and the name of the event.

CANCELLATION FEES
You have to communicate any cancellation to the conference until the 25th October 2017. After that time will be charged the full fee. Registration is trasferable to another participant of the same company in any moment. Cancellations or replace must be received in writing by email to info@pharmaeducationcenter.it
Pharma Education Center can postpone EUPhv Day or delete it if the event does not reach the minimum number of participants prefixed. Pharma Education Center will have to return the amount already paid or can release a bonus usable by the company within the year to participate in another course or event.

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