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PHVday

PHARMACOVIGILANCE 2015

Nordic Pharmacovigilance Day 2015
Hot Topics in Pharmacovigilance



media partner



Copenhagen, Denmark

Park Inn by Radisson Copenhagen Airport Hotel
Engvej 171 - Copenhagen

Tuesday, 6th October 2015 - 9.30 - 17.00

Hot Topics in Pharmacovigilance

Pharmacovigilance is evolving rapidly and is becoming ever-important in the pharmaceutical industry. Health Authorities are continuously focusing on the area and new legislation and policies from EU as well as globally are driving changes to processes and Technologies. Current PV trends include efficiency and performance of qualitative/empiric signal detection, joined activities in PASS and interdependencies in RMPs, complexities between company and EU or local QPPV, the growing relevance of audits and training at PV inspections and the adequate methods of the continuous benefit/risk assessment of medicinal products. In addition, the pertinent role of quality assurance and the respective methods to be developed for every subject as well as the legal aspects based on law and adjudgement will be addressed in order to support the right decision making. Well-known speakers in pharmacovigilance from authorities, pharma industry, law office and service provider will discuss together openly supporting appropriate solutions if applicable.

The Scientific Board, **Anne Gramkow**, *Head of Drug Safety, QPPV* at Pharmacosmos and **Martin Holm-Petersen**, *Senior Consultant* at Navitas Life Sciences, will share best practices, results and experiences in this field.

Who should attend?

The seminar is ideally suited for employees of small-, middle- and large-sized companies in the pharmaceutical sector especially concerned with the implementation and/or maintenance of pharmacovigilance (PV) systems, with its critical PV processes and quality system. Participants may come from various departments involved in fulfilling legal PV requirements.

Official language: English

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Agenda

- 09:00 - 09:30 *Registration and welcome coffee*
- 09:30 - 09:40 **Welcome from the Chair**
Anne Gramkow - Head of Drug Safety, QPPV at Pharmacosmos
Martin Holm-Petersen - Senior Consultant at Navitas Life Sciences
- 09:40 - 10:20 **Important Risks in the EU PV-Legislation and Guidance: Best Practices to allow optimised patient safety?**
Leonardo Ebeling - Managing Director, Dr. Ebeling & Assoc. GmbH
- 10:20 - 11:00 **ISO IDMP implementation: Stakeholders involved and the future in the organizations**
Rune Ringsholm Bergendorff - Managing Consultant, NNIT
- 11:00 - 11:30 *Coffee break*
- 11:30 - 12:10 **Inspections / Audit findings**
Thorsten Frank Jørgensen - Medicine Inspector, DHMA
- 12:10 - 12:50 **Affiliate PV Risk**
Jeffrey Ho - Life Sciences Management Consultant, Navitas Life Sciences
- 12:50 - 13:50 *Networking Lunch*
- 13:50 - 14:30 **Patient Support Programmes (PSPs) and Market Research Programmes (MRPs)**
Betina Østergaard Eriksen - Deputy QPPV, Novo Nordisk
- 14:30 - 15:10 **Pharmacovigilance & the scientific literature**
Daan De Jong - Director of Product Development, Elsevier
- 15:10 - 15:40 *Coffee break*
- 15:40 - 16:30 **Panel Discussion: Consumer Reporting, Patient Support Programme and Market Research Programme. Safety Communication**
- 16:30 - 16:40 **Conclusion**



How to reach the Park Inn by Radisson Copenhagen Airport Hotel
For further information, please visit
www.parkinn.com/hotel-copenhagen or www.pharmacovigilanceday.com

IN ORDER TO ATTEND THE NORDIC PHV DAY, PLEASE COMPLETE THE REGISTRATION FORM FOR EACH ATTENDEE AND SEND IT VIA E-MAIL: stefania.sarga@easy-b.it O VIA FAX: +39.035.4501262

- € 490,00 Early Bird fee extended until 25th September 2015
- € 610,00 ordinary fee (after 25th September 2015)
- € 440,00 Patronage members fee (association)
- € 360,00 for Academy, Public Administration and Freelancer
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The **fee includes**: seat at the conference, copy of presentations Speakers who allow the distribution, informative literature for the day, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.

For any additional information, please contact:

Stefania Sarga
stefania.sarga@easy-b.it
Phone: +39.035.515684 - Fax: +39.035.4501262

Methods of payment

The full amount must be paid on registration to EasyB s.r.l by bank transfer. If paying by bank transfer please attach proof of payment to the registration form.

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