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PHVday

PHARMACOVIGILANCE 2016

Benelux Pharmacovigilance Day
Risk Management Strategy and innovation in Pharmacovigilance



Amsterdam, The Netherlands

Tuesday, October 11th 2016

Hyatt Place Amsterdam Airport
Rijnlanderweg 800, Hoofddorp
Amsterdam, The Netherlands

media partner



Risk Management Strategy and Innovation in Pharmacovigilance

2016 will be a very challenging year for all people dealing with safety of drugs, biologics and devices.

Further to the EMA-projects the compliance with regulatory guidance becomes much more complicated and pragmatic approaches are key.

The conference will take you through the implementation of a Risk management strategy with a particular focus on technologies and tools. Session dedicated to Innovation in Pharmacovigilance, Quality & Compliance in PV; Risk management plans; Inspections/Audit Findings will also be foreseen.

Scientific Board

Joyce de Langen, *Senior Solution Manager Pharmacovigilance* at Elsevier

Official language: English

Who should attend the conference?

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/Vigilance Systems, with its critical processes and quality system. Participants may come from various departments involved in fulfilling Pharmacovigilance/Vigilance requirements as legal Medical Affairs and Regulatory Affairs.

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Risk Management Strategy and Innovation in Pharmacovigilance

Official language: English

START OF THE CONFERENCE: 10:00 AM

END OF THE CONFERENCE: 4:00 PM

Agenda

- 09:30 - 10:00 **Registration and welcome coffee**
- 10:00 - 10:15 ***Welcome from the Chair***
Joyce de Langen, *Senior Solution Manager Pharmacovigilance at Elsevier*
- 10:15 - 10:50 **What is IDMP and why is it important for pharmacovigilance?**
Hans Van Bruggen - *Regulatory Affairs Scientist, eCTDconsultancy B.V.*
- 10:50 - 11:25 **Patient Support Programmes**
Anthony Amoureux - *Director Pharmaceutical & Medical Affairs / QP / RP / QPPV, Eurocept Pharmaceuticals*
- 11:25 - 11:55 **Coffee break**
- 11:55 - 12:25 **Risk management Life cycle approach – KEY POINTS**
Essam Ghanem - *Head of Drug Safety and Pharmacovigilance (DSPV), Keyrus Biopharma Belgium*
- 12:25 - 12:55 **Risk Management Plans and Risk Minimization Measures**
Francien Rotteveel - *Manager Regulatory Affairs & Quality Assurance, AbbVie*
- 12:55 - 14:00 **Networking lunch**
- 14:00 - 14.35 **Social Media screening in Pharmacovigilance**
Marc Zittartz - *Chief Quality Officer, pharmaSOL*
- 14:35 - 15:10 **Auditing/Quality management systems of computerized systems in Pharmacovigilance**
Michael von Essen - *Senior Compliance Consultant, NNIT*
- 15:10 - 15:45 **Best practices for pharmacovigilance & the scientific literature monitoring**
Ivan Krstic - *Senior Product Development Manager Embase, R&D Solutions, Elsevier*
- 15:45 - 16:00 **Q&A and conclusions**

TWO WAYS TO REGISTER:

- **Online:** please register here <http://beneluxpharmacovigilanceday2016.eventify.it/orders/new>
In this case, you can choose to pay by credit card or by bank transfer.
- **By email or fax:** please fill the registration form below for each attendee and send it by email: events@phvday.com or by fax: +39(0)35.4501262
In this case, you can pay by bank transfer.

€ 515,00 Early Bird fee, extended until September 30th, 2016

€ 640,00 ordinary fee (after September 30th, 2016)

€ 460,00 Patronage members fee (association)

€ 370,00 for Academy, Public Administration and Freelancer
(please specify)

*The **fee includes:** seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, welcome coffee, networking lunch, coffee break, organisational office assistance, certificate of attendance.*

For further information, please contact:

Stefania Sarga
events@phvday.com
Phone: +39(0)35.515684 - Fax: +39(0)35.4501262

Payment by bank transfer

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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Terms of payment

The registration fee must be paid at the time of registration. Confirmation of event admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants or registrations of roles that are not included in the target of the event.

Cancellation

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the event date. Cancellations will only be valid if made in writing (by email). Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

Information collection and use

Participants information is collected and utilised by EasyB S.r.l. and sponsor companies in accordance with Italian Legislative Decree 196/2003. Data collected will be used and communicated to third parties for the purposes of event organisation and may be used to communicate future similar initiatives. Participants may at any time verify the accuracy of the information and request changes or deletion.