

Nordic Pharmacovigilance Day 2014

**Tuesday, 7th October 2014 - Carlsberg Museum & Business Centre
COPENHAGEN - Valby Langgade 1 - 1799 - 09:30 - 17:10**

Pharmacovigilance is an extremely important function of public health. It is defined as the science and the process, applied to the monitoring of medicines' safety, thus allowing action to be taken in reducing their risks and increasing their benefit risk ratio.

In the EU all medicinal products must undergo severe tests and be assessed for safety, quality and efficacy. Only then their use can be authorised. The monitoring continues even when the medications are distributed on the market, so as to detect and assess all possible factors that could affect their safety and to allow for corrective measures to be taken.

The careful monitoring of pharmaceutical products means that the Marketing Authorization Holders must invest considerable resources – financial, operational and structured – to ensure their safety.

This conference will highlight how streamline your pharmacovigilance and safety processes use to meet the new GVP guidances.

The Scientific Board, **Aili Chong**, Pharmacovigilance Consultant, i-Li Consulting and **Bertrand Le Bourgeois**, Consultant, EasyB will share best practices, results and experiences in this field.

Who should attend?

The seminar is aimed to companies of all sizes who need understand best practices in pharmacovigilance and safety processes.

Official language: English

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PROGRAMME



09:00 - 09:30 **Registration and welcome coffee**

09:30 - 09:40 **Welcome from the Chair**
Aili Chong - Pharmacovigilance Consultant, i-Li Consulting
Bertrand Le Bourgeois - Consultant, EasyB



09:40 - 10:20 **From pre-clinical to post-marketing: the lifecycle of pharmacovigilance**
Peter Schüler - Senior Vice President, Medical & Safety Services, ICON Clinical Research



10:20 - 11:00 **Safety Data Exchange Agreements (SDEAs) and Training of personnel for pharmacovigilance**
Anne Gramkow - Head of Drug Safety, QPPV, Pharmacosmos A/S



11:00 - 11:40 **Coffee Break**



11:40 - 12:20 **Pharmacovigilance and Social Media - Time to embrace the change**
Marc Zittartz - Chief Quality Officer, pharmaSOL

12:20 - 13:00 **Upcoming demands from the new GVP guidelines: A challenge to PV systems and how to address them (case study)**
Laurent Perrin - Managing Director and Owner, Perrin Consulting
Peter Jackstadt - Drug Safety Systems Manager, Actelion
Serge Strubel - Drug Safety Business Intelligence Manager, Actelion



13:00 - 14:00 **Networking Lunch and Exhibitor Area**

14:00 - 14:40 **From a number of ADRs to product withdrawal from the EU market – the consequence of a PRAC recommendation (referral under Article 107i of Directive 2001/83/EC)**
Hanne Damgaard Jensen - Chief Development Officer, Azanta A/S

MEDIA PARTNER:



14:40 - 15:20 **Realising a long-term Safety IT strategy by short-term initiatives**
Martin Holm-Petersen - Director of IT & Projects, Novo Nordisk



15:20 - 16:00 **Coffee Break**



16:00 - 17:00 **PANEL DISCUSSION**
MODERATOR: *Bertrand Le Bourgeois - Consultant, EasyB*

17:00 - 17:10 **Conclusion/Discussion**



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THE LEADING NORDIC LIFE SCIENCE BUSINESS MAGAZINE

Registration

In order to attend the Nordic Pharmacovigilance Day, the registration form should be completed and faxed to: **(+39) 035 4501262**
or emailed to: **info@easy-b.it**
or register and pay online: <http://events.lsacademy.it/conferences>

REGISTRATION FEE

€ 360,00 **Early Bird** fee by 3rd October 2014

€ 420,00 ordinary fee after 3rd October 2014

€ 250,00 for Academy, Public Administration, Freelance

*The **fee includes**: seat at the conference, copy of presentations will be made available by Speakers, informative literature for the day, networking lunch, coffee breaks, organisational assistance from registration to event day (travel, accommodation, etc..), certificate of attendance.*

Payment

Payment should be made **online**, or by **bank transfer** (please see details below), or by mailing a **cheque**, along with the registration form. Upon receipt of payment, the registration will be confirmed. Invoice will be sent following receipt of payment. We couldn't accept late registrations or due to limited conference place available or registrations of roles that are not included in the target of the event.

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (BERGAMO) P.IVA 03633040161

Banca Popolare di Vicenza - Filiale di Nese

IBAN: IT27H0572852521820570697999

SWIFT: BPVIIT21820

How to reach the Carlsberg Museum & Business Centre - Copenhagen

For further information, please visit the website:

<http://nordic-pharmacovigilanceday.eventify.it/location> or:

<http://www.visitcarlsberg.dk/business/Pages/Beautifulsettings.aspx>

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. 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.



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For any additional information, please contact:

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Terms of payment

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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.

Date **Signature.....**