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# PHVday

## PHARMACOVIGILANCE 2016

Nordic Pharmacovigilance Day

*Pharmacovigilance challenges: hot topics in 2016*



media partner



Copenhagen, Denmark

Tuesday, October 25<sup>th</sup> 2016

*Park Inn by Radisson Copenhagen Airport Hotel  
Engvej 171 - Copenhagen*

## Pharmacovigilance challenges: hot topics in 2016

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

Further to the EMA-projects, we have to consider that compliance with regulatory guidance becomes much more complicated and pragmatic approaches are key. A taste of the Programme:

- **regulatory surveillance outside Europe.**
- **Signal Detection** with a look on the surrounding signal detection in large data sources and handing of big data.
- **New ICSR** handing with a focus on the electronic transmission in accordance to the ICH E2B (R3) message standard and on the legal requirements introduced by the Article 57(2) of Regulation (EC) 726/2004.

### Scientific Board

**Anne Gramkow**, *Head of Drug Safety, QPPV at Pharmacosmos*

**Martin Holm-Petersen**, *Head of pvtech® and Senior Consultant at Navitas Life Sciences*

**Betina Østergaard Eriksen**, *Director Global Safety Compliance & Deputy QPPV at Novo Nordisk*

### 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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Official language: English

START OF THE CONFERENCE: 9:30

END OF THE CONFERENCE: 16:40

## 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** - Head of pvtech® and Senior Consultant at Navitas Life Sciences  
**Betina Østergaard Eriksen** - Director Global Safety Compliance & Deputy QPPV at Novo Nordisk
- 09:40 - 10:15 **Martin J. Henzl** - Director PV Technology, Global Patient Safety at Baxter  
**ICSR (R3) implementation planning in Europe and Implementation guide**
- 10:15 - 10:50 **Berit Nautrup Andersen** - QPPV, Senior Director at Merck  
**Regulatory Surveillance outside EU - an EU QPPVs perspective**
- 10:50 - 11:20 **Coffee break**
- 11:20 - 11:55 **Dr. Tido Eger** - Managing Consultant at Navitas Life Sciences  
**Integrating medical devices into pharma PV and RA departments**
- 11:55 - 12:30 **Martin Dræbye Gantzhorn** - Equity Partner, Head of Life Science & Healthcare at Horten Law Firm  
**Benjamin Schulze Auster** - Senior Attorney at Horten Law Firm  
**The impact of the new Data Protection Regulation on Pharmacovigilance – some considerations**
- 12:30 - 12:40 **General Q&A**
- 12:40 - 13:40 **Networking lunch**
- 13:40 - 14:15 **Phil Tregunno** - Signal Management Unit Manager, and IMI WEB-RADR project lead at MHRA  
**Mobile Technologies and Social Media in Pharmacovigilance – a view from the WEB-RADR project**
- 14:15 - 14:50 **Helena Sköld** - Product Manager at UMC  
**VigiAccess: the door to VigiBase**
- 14:50 - 15:20 **Coffee break**
- 15:20 - 15:55 **Majken Berghuis** - Safety Compliance Specialist at Novo Nordisk  
**Patient Communication in Pharmacovigilance**
- 15:55 - 16:30 **Helle Virefeldt Sall** - MSc PV, Director, Pharmacovigilance Quality, PV & QA Specialist at INC Research  
**Analysis of the quantity and quality of cases in selected PSPs and MRPs and the value of cross-organisational collection and reporting of safety data from PSPs and MRPs**
- 16:30 - 16:40 **General Q&A and conclusions**

**How to reach the  
Park Inn by Radisson Copenhagen Airport Hotel**

For further information, please visit the conference website:  
<http://nordicpharmacovigilanceday2016.eventify.it/location>

## TWO WAYS TO REGISTER:

- **Online:** please register here <http://nordicpharmacovigilanceday2016.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](mailto:events@phvday.com) or by fax: +39(0)35.4501262  
In this case, you can pay by bank transfer.

### € 515,00 Early Bird fee until October 7th, 2016

€ 640,00 ordinary fee (after October 7th 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](mailto: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.

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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.