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PHARMACOVIGILANCE 2017

Nordic Pharmacovigilance Day

Pharmacovigilance Challenges: Hot Topics in 2017



Copenhagen, Denmark

Wednesday, October 25th, 2017

Park Inn by Radisson Copenhagen Airport Hotel

Engvej 171 - Copenhagen

Event Managed by



Nordic Pharmacovigilance Day

Pharmacovigilance Challenges: Hot Topics in 2017

The proactive role of pharmacovigilance is a key part of the life cycle of the drug to ensure safety of the patients. The 4th Nordic Pharmacovigilance Day will focus on new PV challenges related to systems (e.g. ICSR handling and signal detection in the new Eudravigilance database), new and updated legislation inside and outside Europe, and new areas like social media. With increasing regulatory expectations and innovative initiatives in and outside Europe, it becomes imperative to collate the thoughts of all stakeholders of pharmacovigilance. The conference looks forward to accomplishing this task with a great deal of passion and commitment.

The Scientific Board:

Anne Gramkow, Head of Drug Safety, QPPV at Pharmacosmos

Martin Holm-Petersen, CEO at Insite

Betina Østergaard Eriksen, Vice President, Safety Surveillance at Novo Nordisk

will lead a panel of experts to share best practices, knowledge and experience in this field.

Official language: English

Who should attend?

This one-day conference is designed to benefit functional/technical professionals working in the pharmaceutical and health care system dealing with the Pharmacovigilance system, such as:

- Pharmacovigilance dept.
- Clinical operation dept.
- Statistic dept.
- Medical Affairs dept.
- Regulatory Affairs dept.
- Quality & Compliance dept.

in pharmaceutical and Biotech companies, Clinical Research Organizations (CROs) and public health centers.

Nordic Pharmacovigilance Day

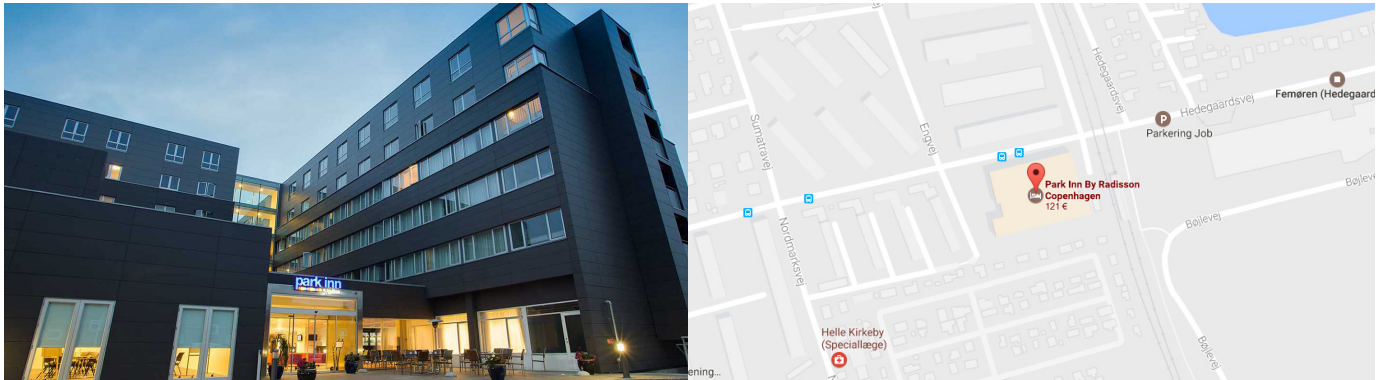
Pharmacovigilance Challenges: Hot Topics in 2017

Agenda

- 08:50 - 09:20 **Registration and welcome coffee**
- 09:20 - 09:30 **Welcome from the Chair**
Anne Gramkow - Head of Drug Safety, QPPV at Pharmacosmos
Martin Holm-Petersen - CEO at Insife
Betina Østergaard Eriksen - Vice President, Safety Surveillance at Novo Nordisk
- 09:30 - 10:10 **Birgitte Scharling** - Pharmacovigilance Policy Expert at Novo Nordisk
EU Pharmacovigilance Legislation – EU key regulatory Pharmacovigilance updates
- 10:10 - 10:50 **Esteban Herrero-Martinez** - Director, Regulatory Policy and Intelligence at AbbVie
Emerging market pharmacovigilance, industry activity to improve engagement, legislative consistency and support compliance
- 10:50 - 11:20 **Coffee break**
- 11:20 - 11:50 **Martin Holm-Petersen** - CEO at Insife
Changes to the Health Agency PV technology landscape and expected impacts
- 11:50 - 12:30 **Michael Kristensen** - Head of GPCD Systems & Applications at ALK
ALK's voyage to meet E2b(R3) – considerations about upgrading/migrating the safety database and preparing for the EudraVigilance launch
- 12:30 - 13:30 **Lunch**
- 13:30 - 14:10 **Ona Kinduryte** - Lead Risk Management Physician at Boehringer Ingelheim
Are MAHs prepared to perform signal detection in EudraVigilance?
- 14:10 - 14:50 **Lykke Bjerglund Graff** - Head of Global Pharmacovigilance at LEO Pharma
Initiating a new product portfolio and PV implications to enable a successful launch into market
- 14:50 - 15:20 **Coffee break**
- 15:20 - 16:00 **Marnix Wieffer** - Biomedical information specialist at Elsevier
Literature Management for Pharmacovigilance: Outsource or in-house solution?
- 16:00 - 16:20 **Panel discussion**
- 16:20 - 16:30 **Conclusions**

How to reach the conference venue

Venue | **Park Inn by Radisson Copenhagen Airport Hotel** | Engvej 171 - Copenhagen, Denmark



Situated near both the Copenhagen Airport and the city centre, the Park Inn is an ideal place to stay while traveling for business and leisure. If you arrive by car, this hotel's location in Copenhagen, Denmark provides free parking. The nearby metro and train stations are convenient for cyclists and guests without cars.

Transport options

Metro station Femøren (two stops to airport and six to city centre) - beside hotel

Copenhagen International Airport - 3 km (5 min by metro)

Copenhagen Central Station - 7 km (10 - 15 min by car)

For further information please visit the conference [website](#) or contact the organization offices:

Stefania Sarga

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stefania.sarga@LSacademy.it

Sponsorship opportunities

Sponsor the event and take the chance to network with all attendees. Exclusive benefits and high impact branding before, during and after the conference.

If you are interested in sponsoring the event, please write an email to events@LSacademy.it or call us: +39(0)35.515684

[Download the Events Summary 2017](#)

TWO WAYS TO REGISTER:

- **Online:** please register here <https://nordicpharmacovigilanceday2017.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:
stefania.sarga@LSAcademy.it or by fax: **+39(0)35.4501262** In this case, you can pay by bank transfer.

- **€ 595,00 Early Bird fee extended until October 11th, 2017**
- € 710,00 Ordinary fee (after October 11th, 2017)
- € 540,00 Patronage members fee (Association _____)
- € 390,00 for Academy, Public Administration, Freelance (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 any additional information, please contact:

Stefania Sarga
stefania.sarga@LSAcademy.it
Phone +39 (0)35.4123594

Payment by bank transfer

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

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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

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