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Nordic Pharmacovigilance Day

Thursday, **October 24th**, 2019

“HOT TOPICS”- INCREASING AWARENESS OF SIGNIFICANT AND ESSENTIAL NEEDS IN PHARMACOVIGILANCE

📍 | **Copenhagen**

Park Inn by Radisson Copenhagen Airport Hotel

Engvej 171

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“HOT TOPICS”- INCREASING AWARENESS OF SIGNIFICANT AND ESSENTIAL NEEDS IN PHARMACOVIGILANCE

After the great success of the 5th Nordic Pharmacovigilance Day in 2018, the 6th edition will be another opportunity to discuss, deliberate and debate the latest operational and technological challenges in the Pharmacovigilance field. Recent advances and perspectives in Pharmacovigilance (PV) will be shared during the meeting, with an emphasis on practical aspects and how-tos. The meeting brings together the major experts to share their knowledge with practical examples triggering engaging discussions and guiding participants' efforts in the jungle of methods now available. The objective is to help and find solutions to the many challenges that, as a cross-functional development team in PV, must solve to maximize the new opportunities ahead of us. This year's event focuses on topics that currently have major impact on Pharmacovigilance related processes and activities such as, but not limited to:

- Industry experiences from latest PV inspections
- SDEAs and good pharmacovigilance outsourcing practices,
- New technologies to improve PV related processes,
- QPPV challenges and real-life experiences,
- Reference Safety Information and Risk Management Plans.
- PRAC Strategies to measure the Impact Factor of Pharmacovigilance
- Signal detection in pharmacovigilance using EVDAS

Moreover, we will present perspectives on implementing General Data Protection Regulation and Clinical Trial Regulation. During this one-day forum we will provide and discuss the best solutions for ensuring a patient focused future and to help drive success in your organization.

Scientific Board

Caroline Susanne Sandström Msc PhD
Senior Specialist GCP/GLP/GVP Compliance
Global QA R&D at Ferring Pharmaceuticals A/S

Doris Irene Stenver, MD, MPA
Independent Pharmacovigilance Adviser,
Founder of Unique Advice

Martin Holm-Petersen
CEO at Insife

Who should attend?

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

- Safety and Pharmacovigilance dept.
- Clinical operation dept.
- Statistic dept.
- Medical Affairs dept.
- Medical Information dept.
- Regulatory Affairs dept.
- Quality & Compliance dept.
- Legal dept.
- Software Developing dept.
- Medical Devices Manufacturing Companies
- University Faculties scientists who are related to clinical and medical research (Senior, Associate and Assistant Professors, Research Scholars, Phd students).

Also, Directors/Seniors Directors/Executive Directors and Vice Presidents /Senior Vice Presidents/Executive Vice Presidents and Heads/Leaders/Partners of: CROs and CMOs, Clinical Research Sites, Pharma, Biotech and Medical Devices Industries.

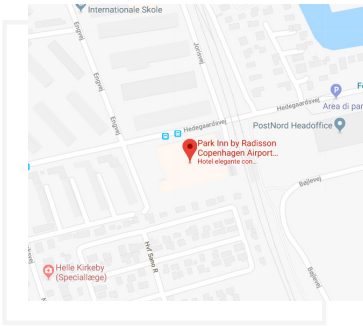
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“HOT TOPICS”- INCREASING AWARENESS OF SIGNIFICANT AND ESSENTIAL NEEDS IN PHARMACOVIGILANCE

- 08:30 - 09:00 **Registration and welcome coffee**
- 09:00 - 09:10 **Welcome**
- 09:10 - 09:50 **PRAC strategies to measure impact of pharmacovigilance**
Doris Irene Stenver, MD, MPA - *Independent Pharmacovigilance Adviser, Founder of Unique Advice*
- 09:50 - 10:30 **Building a PV Strategy 2025**
Lykke Bjerglund Graff - *VP, Head of Global Safety at LEO Pharma*
- 10:30 - 11:00 **Coffee break**
- 11:00 - 11:40 **Signal detection in pharmacovigilance using EVDAS**
Jose Ortiz - *CEO at PVpharm*
- 11:40 - 12:20 **AI and Machine Learning literature monitoring: improve quality and save time!**
Mark Drinkwater - *Co-founder of Pi2 Solutions at ProQuest*
- 12:20 - 13:20 **Networking Lunch**
- 13:20 - 14:00 **QPPV related topics: real life experiences and challenges**
Pilar Carrero - *QPPV Office Vice President at Novo Nordisk A/S*
- 14:00 - 14:40 **Safety Data Exchange Agreements (SDEA)**
Katrine Dragsbæk Møller - *Senior Drug Safety Specialist at MSD*
- 14:40 - 15:10 **Coffee break**
- 15:10 - 15:50 **Are you GDPR compliant?**
Julia Appelskog - *Head of PV Strategy Office at Merck*
- 15:50 - 16:30 **PV Inspections – experiences from a company perspective**
Caroline Susanne Sandström Msc PhD - *Senior Specialist GCP/GLP/GVP Compliance Global QA R&D at Ferring Pharmaceuticals A/S*
- 16:30 - 16:40 **Conclusions**

HOW TO REACH THE CONFERENCE 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 website



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[Download the Events Summary 2019](#)



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Please visit [the conference website](#) or contact the organisational offices:

Federica Bertoli Phone: +39 (0)35.4123594 | federica.bertoli@lsacademy.com

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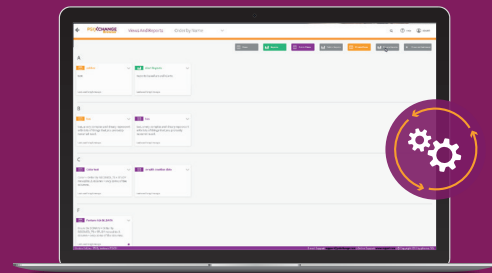


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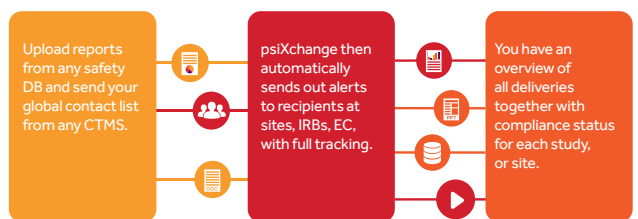
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• Online

please register here

<https://nordicpharmacovigilanceday2019.lscademyevents.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: federica.bertoli@lscademy.com** or by **fax: +39(0)35.4501262**

In this case, you can pay by bank transfer.

■ **€ 655,00 Early Bird fee extended until Octoberber 11th, 2019**

■ **€ 765,00 Ordinary fee** (after October 11th, 2019)

■ **€ 570,00 Patronage members fee** (Association _____)

■ **€ 430,00 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.

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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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For any additional information, please contact:

Federica Bertoli | federica.bertoli@LSacademy.it **Phone:** +39 (0)35.4123594

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