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Nordic Pharmacovigilance Day

Wednesday, **October 24th**, 2018

PHARMACOVIGILANCE CHALLENGES: HOT TOPICS IN 2018

📍 | Copenhagen, Denmark

Park Inn by Radisson Copenhagen Airport Hotel
Engvej 171

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PHARMACOVIGILANCE CHALLENGES:

HOT TOPICS IN 2018

The 5th Nordic Pharmacovigilance Day provides an opportunity to learn more about latest developments in Pharmacovigilance (PV) and engage with peer members of industry, regulators and service providers. The event focuses on major topics that are currently impacting or on the verge of change for PV departments: EU case processing and EVDAS since the EudraVigilance changes last November. PV in non-interventional studies. Perspectives on implementing General Data Protection Regulation and an outlook towards changes on handling combination products with the new Medical Device Regulation. Global regulatory intelligence in the past year. New, anticipated updates to GVP module VI regarding social media and understanding requirements, benefits and challenges of pervasive data such as social media and patient health records.

Like in previous years, the day will be an intense dive into areas that matters, to get inspiration and insights - and provides excellent networking opportunities with other passionate PV professionals.

Scientific Board



Martin Holm-Petersen

CEO at Insife



Betina Østergaard Eriksen

Vice President, Safety Surveillance at Novo Nordisk



Bina Kramhøft Schack

Deputy QPPV & Director at H. Lundbeck

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

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:

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

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

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PHARMACOVIGILANCE CHALLENGES: HOT TOPICS IN 2018

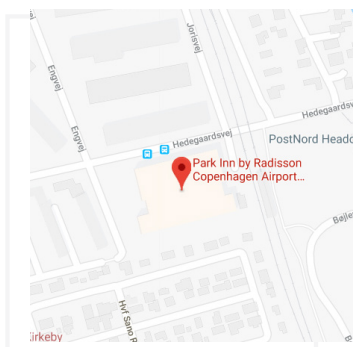
- 09:00 - 09:30 **Registration and Welcome Coffee**
- 09:30 - 09:40 **Welcome from the Chair**
Martin Holm-Petersen - *CEO* at Insife
Bina Kramhøft Schack - *Deputy QPPV & Director* at H. Lundbeck
Betina Østergaard Eriksen - *Vice President, Safety Surveillance* at Novo Nordisk
- 09:40 - 10:20 **Jabeen Ahmad - Regional Pharmacovigilance Director, Eastern Europe, Middle East & Africa (EEMEA) at AbbVie**
Pharmacovigilance in Low to Middle Income Countries: the role of “Right-size” PV
- 10:20 - 11:00 **Phil Tregunno - Vigilance, Intelligence and Research Group Manager at MHRA**
WEB-RADR – next steps
- 11:00 - 11:30 **Coffee break**
- 11:30 - 12:10 **Phil Tregunno - Vigilance, Intelligence and Research Group Manager at MHRA**
Brexit – an MHRA perspective
- 12:10 - 12:50 **Janne Malene Kampmann - Global QPPV, Sr. Director at H. Lundbeck A/S**
EVDAS (signal detection and data analysis – GVP module IX): practical examples, changes and SOP
- 12:50 - 13:50 **Networking Lunch**
- 13:50 - 14:30 **Lisbeth Bregnhøj - Medicines Inspector, GCP and PhV at DKMA**
Update on typical IT focus areas and deviations seen during PhV inspections and GCP inspections with drug safety references
- 14:30 - 15:10 **Nikolai Brun - Chief Medical Officer at Danish Medicines Agency**
HMA& EMA Big Data Task force initiative
- 15:10 - 15:40 **Coffee break**
- 15:40 - 16:20 **James Whitehead - Pharmacovigilance Scientist at AstraZeneca**
Real World Data: Analysing the Present to develop the Future
- 16:20 - 17:00 **Mikael Bygsøe - Senior safety surveillance advisor at Novo Nordisk**
Maria Murholm - Senior safety surveillance advisor at Novo Nordisk
The Medical Device Regulation in a post marketing surveillance perspective
- 17:00 - 17:10 **Final discussion and conclusion**

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HOW TO REACH THE CONFERENCE VENUE



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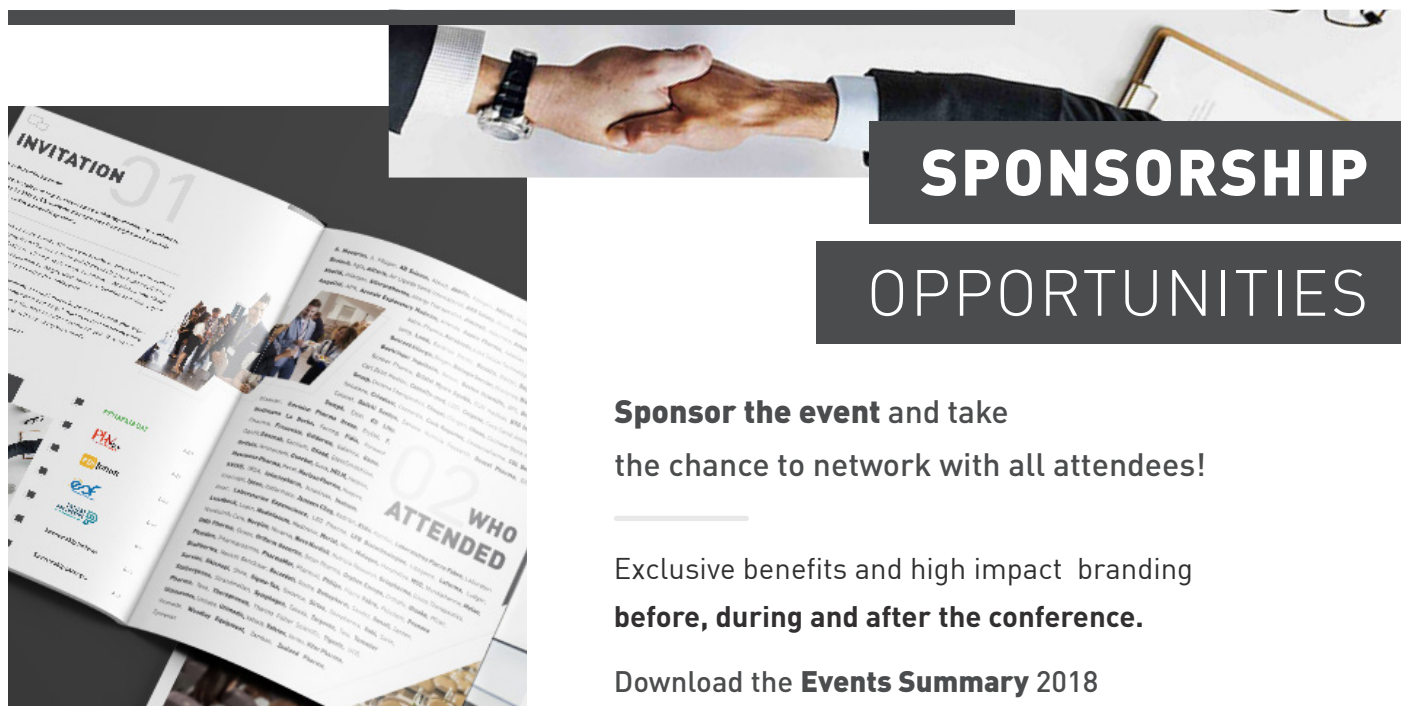
Situated near both the Copenhagen Airport and the city centre, the Park Inn is an ideal place to stay while traveling for business and leisure. If you arrive by car, this hotel's location in Copenhagen, Denmark provides free parking. The nearby metro and train stations are convenient for cyclists and 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)



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Download the **Events Summary 2018**



For further information

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

Ilaria Butta Phone +39 (0)35.4123594 | ilaria.butta@LSacademy.com

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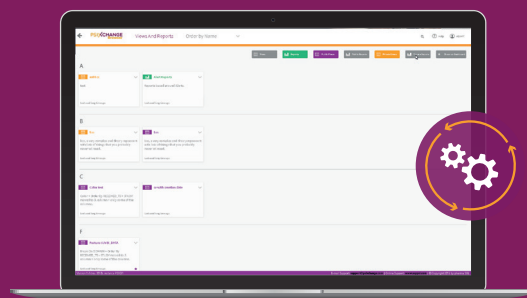


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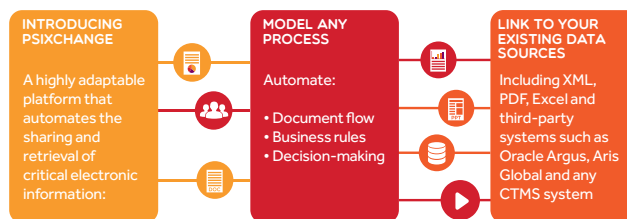
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Two ways to register

• Online

please register here

<https://nordicpharmacovigilanceday2018.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: ilaria.butta@LSacademy.com** or by **fax +39(0)35.4501262**

In this case, you can pay by bank transfer.

■ **€ 655,00** Early Bird fee extended until October 10th, 2018

■ **€ 765,00** Ordinary fee (after October 10th, 2018)

■ **€ 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.

For any additional information, please contact:

Ilaria Butta | ilaria.butta@LSacademy.com **Phone:** +39 (0)35.4123594

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Date _____ Signature _____