PHVday PharmacoVigilance 2021

LIFE SCIENCE ACADEMY

Nordic Pharmacovigilance Day

Sharing Current Best Practices and Strategic Approaches within Pharmacovigilance Regulated Activities

Date
09 November 2021

Language
English

Location
Copenhagen, Denmark

SPONSORS

DialogSolutions
Literature · Technology · Services

MEDIA PARTNERS

PharmaVOICE

CREATIONKnowledge
HCP insights for leaders in healthcare

ABOUT

Sharing Current Best Practices and Strategic Approaches within Pharmacovigilance Regulated Activities

The Nordic Pharmacovigilance Day has become a very popular forum for a broad range of professionals engaged in strengthening the safety of medicinal products and medical devices.

The 8th edition will build on the experiences from previous successful conferences presenting a program covering the current most important topics and challenges encountered within the pharmacovigilance area. Knowledgeable experts will provide excellent updates in key areas, covering recent advances in technology, science and legislation, as well as practical aspects. Sessions will be interactive and participants will be able to ask questions, engage in a dialogue and also share their own experiences.

Among others, we will cover the following topics:

- Inspections
    - Industry and regulatory perspectives, including IT perspective
    - Current trends including special features during the pandemic
- Medical device and combination product – the PSUR document
- Pharmacovigilance requirements post-Brexit (e.g. PSMF)
- Artificial Intelligence
    - AI & Machine Learning
    - AI applied in signal detection and safety data analysis
- Outsourcing of pharmacovigilance tasks
- Pharmacovigilance operations in Headquarters vs. Affiliate

Who should attend?
The conference program is designed for healthcare professionals or pharmacists in safety surveillance units in the pharmaceutical industry or regulatory agencies, either as specialists or managers, QPPVs, inspectors and QA personnel including auditors, employees in regulatory affairs units with close relations to pharmacovigilance, sponsors, vendors and CROs, representatives from patient organizations.

Scientific Board
Wasim Anwar, *Vice President & Deputy QPPV - Head of QPPV Office, Global Safety at Novo Nordisk A/S*
Caroline Sandstroem*, Senior Specialist GCP/GLP/GVP, Compliance Global QA R&D at Ferring Pharmaceuticals*
Doris Irene Stenver, *Independent Pharmacovigilance Adviser, Founder of Unique Advice*

The Conference is planned to be a one-day on-site event located in Copenhagen, unless the current state-of-play of the Covid-19 pandemic only allows for a on-line event.

PROGRAMME

09 November 2021	
08:30 **09:00**	**Registration**
09:00 **09:10**	**Welcome by the Scientific Board**
09:10 **09:50**	**Using AI/ML Algorithms in Critical GVP Applications - Points to Consider** **Ib Alstrup** IT Medicines Inspector at Danish Medicines Agency
09:50 **10:10**	**Coffee break**
10:10 **11:00**	**Digital Landscape in PV – How to apply artificial intelligence effectively?** **Martin Holm-Petersen** CEO at Insife
11:00 **11:30**	**Panel Discussion and Q&A Session** **Wasim Anwar** Vice President & Deputy QPPV - Head of QPPV Office, Global Safety at Novo Nordisk A/S **Ib Alstrup** IT Medicines Inspector at Danish Medicines Agency **Martin Holm-Petersen** CEO at Insife
11:30 **12:30**	**Lunch**
12:30 **13:15**	**Medical device and combination product – the PSUR document** **Mikael Juul Bygsø** Senior safety surveillance specialist at NovoNordisk
13:15 **14:00**	**Pharmacovigilance requirements post-Brexit** **Kiernan Trevett** Expert GpVp Inspector at MHRA
14:00 **14:30**	**Coffee break**

14:30 **15:10**	**Outsourcing of Pharmacovigilance Activities** **Ea Marie Holst** Partner and Director of Pharmacovigilance at Pharma IT
15:10 **15:50**	**PV Operations in Headquarter vs. Affiliate –Collaboration and oversight** **Marie Fogh Hansen** Principal Pharmacovigilance Professional at Lundbeck
15:50 **16:10**	**Q&A session** **Marie Fogh Hansen** Principal Pharmacovigilance Professional at Lundbeck **Ea Marie Holst** Partner and Director of Pharmacovigilance at Pharma IT
16:10 **16:20**	**Conclusions by the Scientific Board**

SPEAKERS

Scientific Board
Wasim Anwar
Vice President & Deputy QPPV - Head of QPPV Office, Global Safety at Novo Nordisk A/S

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

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Doris Stenver
Independent Pharmacovigilance Adviser, Founder of Unique Advice

Speaker
Ib Alstrup
IT Medicines Inspector at Danish Medicines Agency

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Senior safety surveillance specialist at NovoNordisk

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Martin Holm-Petersen
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Speaker
Ea Marie Holst
Partner and Director of
Pharmacovigilance at Pharma IT

Speaker
Kiernan Trevett
Expert GpVp Inspector at MHRA

REGISTRATION FEE

€ 670,00* Early Bird fee until October 29th, 2021
€ 790,00* Ordinary fee
€ 430,00* Freelance, Academy, Public Administration

* *for Italian companies: +22% VAT*

Fee includes: seat at the conference, copy of presentations of Speakers who allow the distribution, networking lunch, 2 coffee breaks, organisational office assistance, certificate of attendance.

USEFUL INFORMATION

Park Inn by Radisson Copenhagen Airport
Engvej 171, 2300 Copenhagen S, Denmark

Park Inn by Radisson Copenhagen Airport is situated near both the Copenhagen Airport and the city centre. 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)

CONFERENCE VENUE

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