

Nordic Pharmacovigilance Day

Sharing Current Best Practices and Strategic Approaches within Pharmacovigilance Regulated Activities

Data
09 November 2021

Lingua

Inglese

Location
Copenhagen, Denmark

SPONSORS

DialogSolutions
Literature · Technology · Services

MEDIA PARTNERS

Pharma
VOICE

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INTRODUZIONE

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.



PROGRAMMA

| 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 |



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|----------------|---|
| 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



Scientific Board
Doris Stenver
Independent Pharmacovigilance
Adviser, Founder of Unique Advice



Speaker
Ib Alstrup
IT Medicines Inspector at Danish
Medicines Agency



Speaker
Mikael Juul Bygsø
Senior safety surveillance
specialist at NovoNordisk



Speaker
Marie Fogh Hansen
Principal Pharmacovigilance
Professional at Lundbeck





Speaker
Martin Holm-Petersen
CEO at Insife



Speaker
Ea Marie Holst
Partner and Director of
Pharmacovigilance at Pharma IT



Speaker
Kiernan Trevett
Expert GpVp Inspector at MHRA

QUOTE ISCRIZIONE

€ 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.

DURATA E INFORMAZIONI UTILI

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)

SEDE DELLA CONFERENZA





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