

Nordic Pharmacovigilance Day

Different Perspectives and New Challenges within
Pharmacovigilance Regulated Activities

Data
16 November 2023

Lingua

Inglese

Location
Copenhagen, Denmark

SPONSORS

Pharma IT **Veeva**
A ProductLifeGroup Company

 **insife**

 **ARITHMOS**



INTRODUZIONE

 10th ANNIVERSARY

Different Perspectives and New Challenges within Pharmacovigilance Regulated Activities

2023 is a special year for the yearly conference “Nordic Pharmacovigilance Day”, as it has successfully reached the 10th edition which will be held in Copenhagen on November 16th 2023.

It will be a full day event focused on the current and interesting topics for people working in depth with pharmacovigilance regulated activities or with any interlinking activities in e.g. related departments, in northern Europe.

Knowledgeable experts coming from pharma industry, health authorities, service providers and CROs, will share their experiences and will be available for discussion and questions.

The aim of this conference is to bring the learning opportunity for pharmacovigilance professionals to discuss, interact, actively participate and get inspired from the speakers as well as from each other.

Considering that the expectation covering pharmacovigilance is quickly evolving within several different areas, the agenda of the conference will offer different perspectives from e.g. regulators, insights from partners and providers, and presenting examples from both small and big pharma companies.

The talks will focus on:

- Regulatory processes in pharmacovigilance activities
- Early experiences of the EU CTR n.536/2014
- Optimization of pharmacovigilance processes
- Handling of new sources of safety information
- Globalization of PSMF
- Learnings from PV audits – internal activities and external vendors
- Medical Devices: vigilance and signal detection
- Combination products: challenges and solutions

Would you like to attend? Don't forget to register in advance to secure your seat at the Early Bird fee. It will be a pleasure to celebrate the 10th anniversary of the Nordic Pharmacovigilance Day together.

Scientific Board

- *Wasim Anwar* - Vice President & Deputy QPPV - Head of QPPV Office, Global Safety at Novo Nordisk A/S
- *Caroline Susanne Sandström* - Head of Global Clinical Quality at Ferring Pharmaceuticals A/S
- *Mette Stie Kallesøe* - Head of Pharmacovigilance, QPPV at Hansa Biopharma AB

Who should attend?

The conference program is designed for healthcare professionals or pharmacists working in the pharmacovigilance 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, vendors and CROs working with patient safety data.

PROGRAMMA

08:30 09:00	Registration
09:00 09:10	Welcome by the Scientific Board
09:10 09:50	Regulatory processes in pharmacovigilance activities, the authority perspective on interfacing departments involved in a PV inspection Jeanette Johansson Pharmacovigilance Inspector at the Swedish Medical Products Agency
09:50 10:30	Learnings from Pharmacovigilance Audits Bilal Ghazal Senior Manager Pharmacovigilance and GDP Audits, Quality Audits at Novo Nordisk
10:30 11:00	Coffee Break
11:00 11:40	Using one platform across the pharma value chain Pilar Carrero Vice president Global Safety at LEO Pharma A/S



11:40 12:20	Harnessing the power of social media to promote medicines safety Shannen Young Social Media Coordinator at Uppsala Monitoring Centre
12:20 13:20	Networking Lunch
13:20 14:00	Medical device and combination products: Vigilance and post market surveillance (PMS) Linda Matti Associate Director, Deputy QPPV, PV operations at Ascendis Pharma
14:00 14:40	Early experience of the EU CTR Søren Nilaus Præstegaard PV Compliance Specialist at Novo Nordisk
14:40 15:10	Coffee Break
15:10 15:50	Optimization of case processing through AI and data science Michael Braun-Boghos Senior Director Safety Strategy at Oracle Health Applications & Infrastructure
15:50 16:30	Globalization of PSMF Klaus Bitsch-Jensen Director, Head QPPV Office & EU-QPPV - Global Pharmacovigilance & Clinical Development at Alk Gitte Eiersholt PV Specialist, PV Europe at Alk
16:30 16:40	Conclusions

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
Head of Global Clinical Quality at
Ferring Pharmaceuticals A/S





Scientific Board
Mette Stie Kallesøe
Head of Pharmacovigilance,
QPPV at Hansa Biopharma AB



Speaker
Klaus Bitsch-Jensen
Director, Head QPPV Office & EU-
QPPV - Global Pharmacovigilance
& Clinical Development at Alk



Speaker
Michael Braun-Boghos
Senior Director Safety Strategy
at Oracle Health Applications &
Infrastructure



Speaker
Pilar Carrero
Vice president Global Safety at
LEO Pharma A/S



Speaker
Gitte Eiersholt
PV Specialist, PV Europe at Alk



Speaker
Bilal Ghazal
Senior Manager
Pharmacovigilance and GDP
Audits, Quality Audits at Novo
Nordisk



Speaker
Jeanette Johansson
Pharmacovigilance Inspector at
the Swedish Medical Products
Agency



Speaker
Linda Matti
Associate Director, Deputy QPPV,
PV operations at Ascendis Pharma



Speaker
**Søren Nilas
Præstegaard**
PV Compliance Specialist at Novo
Nordisk



Speaker
Shannen Young
Social Media Coordinator at
Uppsala Monitoring Centre

QUOTE ISCRIZIONE

€ 680,00 Early Bird fee until 16 October 2023

€ 790,00 Ordinary fee

€ 440,00 Freelance, Academy, Public Administration

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



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DURATA E INFORMAZIONI UTILI

The conference will take place at:

Park Inn by Radisson Copenhagen Airport

Engvej 171 - 2300 Copenhagen

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



Park Inn by Radisson Copenhagen Airport

Engvej 171 - 2300 Copenhagen - Denmark

