

# PHVday

PHARMACOVIGILANCE 2024



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## Nordic Pharmacovigilance Day

Harmonizing Perspectives to Support  
Implementation of Common Objectives in  
Pharmacovigilance: Insights from the Nordic  
Region

Date

13 November 2024

Language



Inglese

Location

Copenhagen

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## ABOUT

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It is our pleasure to announce that the well-known Nordic Pharmacovigilance Day conference is taking place on 13 November 2024, in Copenhagen, Denmark. The conference offers a full day of engagement for professionals deeply involved in pharmacovigilance and related activities, as well as being a valuable platform to delve into current and compelling topics including fostering collaboration across various departments and companies.

The primary objective of the conference is to provide delegates with a friendly environment for learning, interaction, active participation, and inspiration. Given the rapidly evolving expectations in pharmacovigilance across diverse areas, the conference agenda will encompass multiple perspectives. This includes viewpoints from regulators, insights from partners and service providers, and case studies from both small and large pharmaceutical companies.

The program will be focused on concrete presentations, real life experiences and useful “take-home” messages, covering “hot topics”, such as PV oversight, digital media listening, implementation of RMP and RMM, signal analytical tools, combination products, PV system governance and responsibilities from both local and global point of views.

Looking forward to meeting you in Copenhagen for a wonderful day of sharing, training, and networking! See you there!

### 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.

## PROGRAMME

13 November 2024	
08.30 09:00	<b>Registration</b>
09:00 09:10	<b>Welcome by the Scientific Board</b>
09:10 09:50	<b>Handling Safety Data from Digital Media</b>  <b>Maria Laustsen Murholm</b> Compliance Specialist for Digital Health at Novo Nordisk
09:50 10:30	<b>Graph Theory in Pharmacovigilance: Enhancing Drug Safety Analysis</b>  <b>Peter Nowicki</b> Senior Director of Innovation Lab & PV Products at RxLogix
10:30 11:10	<b>Coffee break</b>
11:10 11:50	<b>PV Supplier Oversight by MAH - Learning from Inspection</b>  <b>Jeanette Johansson</b> Pharmacovigilance Inspector at the Swedish Medical Products Agency  <b>Henrik Bengtsson</b> Pharmaceutical Inspector, pharmacovigilance, Drug inspectorate - Industry and Hospital Department at Swedish Medical Products Agency
11:50 12:30	<b>Pre-Qualification of a PV Supplier: Process and Expectations</b>  <b>Patricia Jiménez Vasquez</b> Country Pharmacovigilance Lead Sweden, MSD AB
12:30 13:30	<b>Lunch</b>



13:30 14:30	<b>Workshop in groups - Navigating the Governance of Global Pharmacovigilance Systems</b>
14:30 15:10	<p><b>Post-Market Reporting for Drug-Device Combination Products in the EU versus US: Challenges faced during Implementation when Device Specific Requirements meet the Pharmacovigilance System</b></p> <p><b>Juan Paolo Granada</b> Senior Pharmacovigilance Physician at Ferring Pharmaceuticals A/S</p> <p><b>Maj-Britt Schmidt Andersen</b> Medical Devices Intelligence and Compliance Manager in Global Safety at Ferring Pharmaceuticals A/S</p>
15:10 15:40	<b>Coffee break</b>
15:40 16:20	<p><b>Assessing and Enhancing the Effectiveness of Risk Minimisation Measures - Authority's Perspective</b></p> <p><b>Per Sindahl</b> Senior Pharmacovigilance Assessor at Danish Medicines Agency</p>
16:20 16:30	<b>Closing Remarks by the Scientific Board</b>

## SPEAKERS



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



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



*Scientific Board*  
**Caroline Susanne Sandström**  
Head of Global Clinical Quality at  
Ferring Pharmaceuticals A/S



*Speaker*  
**Henrik Bengtsson**  
Pharmaceutical Inspector,  
pharmacovigilance, Drug  
inspectorate - Industry and  
Hospital Department at Swedish  
Medical Products Agency





*Speaker*  
**Patricia Jiménez Vasquez**  
Country Pharmacovigilance Lead  
Sweden, MSD AB



*Speaker*  
**Jeanette Johansson**  
Pharmacovigilance Inspector at  
the Swedish Medical Products  
Agency



*Speaker*  
**Juan Paolo Granada**  
Senior Pharmacovigilance  
Physician at Ferring  
Pharmaceuticals A/S



*Speaker*  
**Maria Laustsen Murholm**  
Compliance Specialist for Digital  
Health at Novo Nordisk



*Speaker*  
**Peter Nowicki**  
Senior Director of Innovation Lab  
& PV Products at RxLogix



*Speaker*  
**Maj-Britt Schmidt Andersen**  
Medical Devices Intelligence and  
Compliance Manager in Global  
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*Speaker*  
**Per Sindahl**  
Senior Pharmacovigilance  
Assessor at Danish Medicines  
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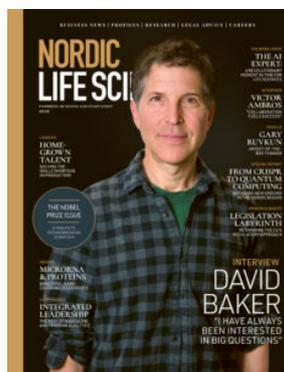


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## Media Partner

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In collaboration with Nordic Life Science, all the participants will receive a digital copy of their latest issue free of charge at the end of the conference.

## REGISTRATION FEE

€ 680,00 Early Bird fee until 14 October 2024

€ 790,00 Ordinary fee

€ 490,00 Freelance, Individual, 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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## USEFUL INFORMATION

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The conference will take place at:

### **Hotel Scandic CPH Strandpark**

Amager Strandvej 401 - 2770 Kastrup

The hotel is located next to Oresund with fantastic views of the water, bridge and city skyline. The area offers a wide selection of recreational outdoor activities, and you can reach downtown Copenhagen in 12 minutes. Copenhagen airport is only 1 metro stop (Kastrup Station) away.

## CONFERENCE VENUE

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### **Hotel Scandic CPH Strandpark**

Amager Strandvej 401 - 2770 Kastrup

