Pharmakon

Pharmacovigilance - an introduction

What you need to know

You will learn about pharmacovigilance for medicinal products for human use, the current requirements in EU and Denmark, and how they are handled by life science, the competent authorities, and European Medicines Agency.

Today's requirements and awareness of safety on medicinal products is an important task at any life science company; a solid and robust pharmacovigilance system with effective and efficient procedures and processes are needed, to ensure that the benefits of the medicinal product exceed the risks by the greatest achievable margin.

You will be introduced to core elements within the pharmacovigilance system and its quality system and how these elements are described and documented in the Pharmacovigilance System Master File. You will learn how adverse events received from spontaneous sources, clinical trial sources and other solicited sources are handled. This includes, among other things, the assessment, evaluation and reporting to competent authorities of Individual Case Safety Reports, signal detection and management, safety risk management and benefit-risk evaluation of a medicinal product.

The role and responsibilities of the marketing authorisation holder towards the pharmacovigilance system and the Qualified Person responsible for Pharmacovigilance (QPPV) will also be covered as well as how audits and inspections of the pharmacovigilance system are conducted.

You will be able to explain the purpose and objectives of pharmacovigilance, state important elements of a pharmacovigilance system and demonstrate their connections and interactions.

The course consists of presentations from experts, discussions based on your own experiences and group work.

At the course you will meet:

Jette H. Lindgren, Senior Database Manager at ALK-Abello A/S

Klaus Bitsch-Jensen, Deputy EU-QPPV, Head of QPPV Office at ALK-Abello A/S

Tina Maria Greve, Principal Drug Safety Advisor at ALK-Abello A/S

Fida Issa, Safety Surveillance Specialist at Novo Nordisk A/S

Mai Frederiksen Raun, Professional Coordinator at Danish Medicines Agency

Kursusfakta

NIVEAU
Specialiserede

FORMAT
2 dage

VURDERING
4,89 ud af 5

PRIS I ÅR
9.900 kr. ekskl. moms, overnatning ikke inkluderet

Tilmeldingsdatoer

Hillerød
9. mar. — 10. mar.
2022

Hillerød
1. nov. — 2. nov.
2022

Har du spørgsmål til kurset?

Kontakt
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Målgruppe

The course is aimed at healthcare professionals and others who have either just started working within pharmacovigilance or as part of their role is having interfaces with pharmacovigilance.

Dit udbytte

Your benefits:

- You know the current requirements for Pharmacovigilance
- You have a fundamental knowledge of the practical handling of Pharmacovigilance
- You are aware of the responsibilities of both the MAH and the sponsor.

Din virksomheds udbytte

The company's benefits:

- Your employee ensures that the Pharmacovigilance system is in compliance with the requirements
- Your employee demonstrates the connections and interactions of the elements in the pharmacovigilance system
- Your employee reports the required information to the competent authorities.

Kursusagenda

The course duration is two days. Accommodation is not included.

Day 1: 09.00 – 16.15
- Pharmacovigilance and the legislation
- Practical experience with Pharmacovigilance in clinical trials
- Pharmacovigilance – Quality system
- Practical experience with Pharmacovigilance Post marketing – Part 1

Day 2: 09.00 – 15.15
- Practical experience with Pharmacovigilance Post marketing – Part 2
- EU QPPV and PSMF
- Audits and Inspections

The course consists of presentations from experts, discussions based on your own experiences and group work.