

# Pharmacovigilance - an introduction

## What you need to know.

The course is applicable for new employees within the pharmacovigilance area. Learn about pharmacovigilance for medicinal products for human use, the current requirements in EU and Denmark, and how they are handled by the pharmaceutical industry, by the authorities and European Medicines Agency (EMA).

The participants will be provided with a basic introduction to the current pharmacovigilance requirements, highlighting responsibilities applicable for both the marketing authorisation holder and the sponsor for clinical trials. Using interactive learning, the participants will be able to explain the purpose and objectives of pharmacovigilance, state important elements of a pharmacovigilance system and demonstrate their connections and interactions to each other.

In this course you will be introduced to:

Senior Database Manager, Diploma in Pharmacovigilance Jette H. Lindgren, ALK-Abello A/S

Deputy EU-QPPV & Drug Safety Adviser Klaus Bitsch-Jensen, ALK-Abello A/S

### Kursusfakta

#### NIVEAU

Specialiserede

#### FORMAT

Flerdageskursus

#### VURDERING

4,7 ud af 5

#### PRIS

9.500 kr. ekskl. moms, overnatning ikke inkluderet

## Tilmeldingsdatoer

Hillerød		Hillerød	
<b>18. mar.</b>	—	<b>6. okt.</b>	—
09:00 -	19. mar.	09:00 -	7. okt.
16:00	09:00 -	16:00	09:00 -
	16:00		16:00
	2020		2020

## Har du spørgsmål til kurset?

### Kontakt

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## Dit udbytte

- Basic introduction to the current legal requirements.
- Fundamental knowledge of practical handling of pharmacovigilance.
- Knowledge of responsibilities of the marketing authorisation holder and the sponsor.

## Din virksomheds udbytte

- Share knowledge of the current legal requirements.
- Possess knowledge of responsibilities of the marketing authorisation holder and the sponsor.
- Ensure compliance within Pharmacovigilance requirements.

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# Målgruppe

Healthcare professionals and others who have either just started working within pharmacovigilance or as part of their role is having an interfaces with pharmacovigilance.

**Tilmelding kan ske online på**

[www.pharmakon.dk](http://www.pharmakon.dk)