#### Pharmakon

## Complaint Handling and Recall Management

# Be inspection ready by having robust processes for complaint handling and product recalls

Learn how to establish robust processes for investigating customer complaints and performing product recalls.

Gain insights into regulatory requirements and practical examples to enhance compliance and inspection readiness of your organisation.

Patients and health authorities expect medicinal products and medical devices to be of high quality.

However, quality issues do occur, and it is important to have robust systems in place for investigating customer complaints and recalling products.

During GMP inspections health authorities always focus on scrutinizing these processes as they are essential components of ensuring patient safety.

During this course you will learn how to establish robust and compliant processes for the handling of customer and product recalls.

We will look at the complete process from the first customer contact until completion of investigation and possible market action.

You will learn how to triage customer contacts into product inquiries, adverse events and product complaints.

Furthermore, you will see examples of how to investigate specific customer complaints and recall products.

The course language is English.

At the course you will meet:

Erik Steffensen, Managing Partner and Principal Consultant, Spot-on Pharma Consulting.

#### Sign-up dates

Hillerød 11. sep. 2025

#### **Course facts**

FORMAT 1 day

**PRICE THIS YEAR** 5.600 DKK excl. VAT

### Do you have questions about this course?

Kontakt

Kursuskoordinator Andreas Goldschadt +45 48 20 62 63 ag@pharmakon.dk

#### **Target group**

- Customer Service employees receiving customer complaints
- Responsible Person (RP) in the affiliate
- Qualified Person (QP)
- QA and production employees involved in investigating customer complaints
- QA and production employees involved in product recalls

#### Your benefits

• you will understand the regulatory requirements for the handling of customer complaints and product recalls

• you will see specific examples of the handling of customer complaints and product recalls

• you can implement compliant and robust processes for complaint handling and recalls within your organisation.

#### Your company's benefits

- your employee understands the regulatory requirements for customer complaints and recalls
- your employee can help establish/improve the processes for customer complaints and recalls within the organisation
- your employee can explain the processes for customer complaints and recalls during authority inspections.

#### **Course agenda**

The course covers the following topics, among other:

- Regulatory requirements for customer complaints and recalls
- Examples of customer complaint handling and product recalls
- How to establish robust and compliant processes for customer complaint handling and product recalls

The course will be a combination of interactive lectures and group work with cases.

#### Sign up online at

www.pharmakon.dk