pharmakon

Design and Implementation of Quality Management System (QMS)

Learn how to build a compliant and user-friendly QMS – with practical tools

Gain insights into the regulatory requirements for Quality Management Systems for pharmaceuticals, medical devices and combination products, and be introduced to practical examples of Quality Managements Systems for organisations of different sizes and complexities.

It is a regulatory requirement to have a QMS (Quality Management Systems) in place before initiating clinical trials. A well-designed QMS ensures clarity, improves efficiency and applies risk management to ensure safe and effective products.

In this course you will get an overview of the regulatory requirements for a QMS. You will learn about the requirements for both pharmaceuticals (drugs and biologics), medical devices and combination products.

You will see examples of a QMS for both a small early-stage biotech/medtech company and a large multi-product global company involved in both clinical trials and marketed products.

Furthermore, we will discuss how to write SOPs (Standard Operating Procedures) that are compliant and user-friendly.

Finally, you will learn what to consider when selecting the IT system that is best suited for your QMS and your organisation.

The course language is English.

At the course you will meet:
Erik Steffensen, Managing Partner and Principal Consultant, Spot-on Pharma Consulting

Course facts

FORMAT
1 day

PRICE THIS YEAR
5.900 DKK excl. VAT

Sign-up dates

Hillerød
5. nov.
2026

Do you have questions about this course?

Kontakt
Kursuskoordinator
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Target group

This course is for managers and employees who work with the design or implementation of a Quality Management System. It is also relevant if you write SOPs or take part in evaluating or selecting electronic QMS solutions.

Your benefits

• You will understand the regulatory QMS requirements for pharmaceuticals, medical devices and combination products
• You will be able to design a new QMS or improve your existing QMS
• You will learn what to consider when selecting the IT system that is best suited for your QMS and your organisation.

Your company's benefits

• Your employee understands the regulatory requirements for the QMS
• Your employee can design and implement a new QMS or improve your existing QMS
• Your employee will know what to focus on when selecting the IT system for the electronic QMS.

Course agenda

09.00 - 16.30

• Overview of regulatory requirements for QMS for pharmaceuticals, medical devices and combination products, respectively
• Examples of QMS for small and large companies
• Guidance for writing compliant and user-friendly SOPs
• Important considerations when selecting the IT system for electronic QMS

The course will be a combination of interactive lectures and group work
The course language is English.

The tutor are Danish i.e. questions can be asked both in Danish and in English.

Sign up online at
www.pharmakon.dk