

Design and Implementation of Quality Management System (QMS)

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

Gain insight into the regulatory requirements for Quality Management Systems for pharmaceuticals, medical devices, and combination products, and be introduced to practical examples of Quality Management Systems in organisations of different sizes and levels of complexity.

About the course

It is a regulatory requirement to have a QMS (Quality Management System) in place before initiating clinical trials. A well-designed QMS ensures clarity, improves efficiency, and applies risk management principles 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 pharmaceuticals (drugs and biologics), medical devices, and combination products.

You will see examples of a QMS in 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.

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.

What you gain

Sign-up

Course

Design and Implementation of Quality Management System (QMS)

Format

1 day

Price next year

6.100 kr. excl. VAT

Choose date and sign up

Hillerød 15. mar – 15. mar. 2027

Your benefit

- 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 benefit

- Your employee will understand the regulatory requirements for the QMS.
- Your employee will be able to design and implement a new QMS or improve your existing QMS.
- Your employee will know what to focus on when selecting an IT system for the electronic QMS.

Course program

09:00 – 16:00

- 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.