# CM204V Quality Managment Systems and Regulatory Framework in Clinical Engineering 5.0 credits

**Kvalitetsledningssystem och regelverk inom medicinsk teknik**

This is a translation of the Swedish, legally binding, course syllabus.

## Establishment

Course syllabus for CM204V valid from Autumn 2023

## Grading scale

P, F

## Education cycle

Second cycle

## Main field of study

Medical Engineering

## Specific prerequisites

Bachelor's degree in biomedical science or at least 2 years work experience in healthcare.
English B/English 6

## Language of instruction

The language of instruction is specified in the course offering information in the course catalogue.

## Intended learning outcomes

After completion, the participant will be able to:

- analyse the current regulatory framework for medical technology operations in detail
- identify the necessary parts in a quality management system
- give details for developing a quality management system for medical technology operations
- identify critical risks in medical technology operations

## Course contents

The course includes a review of the following contents:

- applicable European directives, national laws, regulations and directions including MDR
- liability issues
- applicable standards
- the concept of quality
- quality management system for medical technology operations
- patient safety when using medical devices
- handling accidents and incidents
- adverse event analysis
- risk management in the use and handling of medical devices

## Examination

- TEN1 - Written exam, 5.0 credits, grading scale: P, F

Based on recommendation from KTH's coordinator for disabilities, the examiner will decide how to adapt an examination for students with documented disability.

The examiner may apply another examination format when re-examining individual students.

If the course is discontinued, students may request to be examined during the following two academic years.

## Ethical approach

- All members of a group are responsible for the group's work.
- In any assessment, every student shall honestly disclose any help received and sources used.
- In an oral assessment, every student shall be able to present and answer questions about the entire assignment and solution.