HL2014 Safe Medical Devices 7.5 credits

Säkra medicintekniska produkter

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

Establishment

Course syllabus for HL2014 valid from Autumn 2024

Grading scale

P, F

Education cycle

Second cycle

Main field of study

Medical Engineering

Specific prerequisites

120 ECTS in natural sciences or technology. 6 ECTS in medicine or medical devices/medical technology. English B/6.

Language of instruction

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

Intended learning outcomes

The main objective with this course is to give the student substantial understanding about the regulatory framework for medical devices and how personal protection and intended product performance can be assured by the medical device industry and the health care sector.

After passing the course, the student should be able to:

- Describe, explain and apply in practical use the regulatory demands for medical devices.
- Describe the difference between regulatory demands in different countries.
- Explain the interaction between authorities, regulatory bodies, standardization organizations and industry when placing a medical device on the market.
- Define quality and explain different methods for assuring quality in an organization or for products or services.
- Enlarge upon the essential role of risk analysis and quality assurance for the medical device industry.
- Explain and discuss how standardization development enhances the work in the medical device industry and the health care sector.

Course contents

Regulatory aspects: Legal prerequisites, safety, responsibilities, directives dealing with medical devices, standardization, clinical trials as a tool for demonstrating safety and efficacy, harmonization, certification and testing, product classes for devices and how to place a new product on the market. Quality: Quality as a working tool, total quality management (TQM), quality system. Safety and risk analysis. Development of quality system in industries/organizations, providing services/products for assurance that safe and efficient product reach the market.

Examination

- RED1 - Examination, 7.5 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.

Approved written examination and approved project work

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.