HL1000 Quality and Regulatory Aspects on Medical Devices 3.0 credits

Kvalitet och regelverk för medicintekniska produkter

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

Establishment

Course syllabus for HL1000 valid from Autumn 2007

Grading scale

A, B, C, D, E, FX, F

Education cycle

First cycle

Main field of study

Electrical Engineering

Specific prerequisites

Language of instruction

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

Intended learning outcomes

To give sufficient knowledge about the legal requirements for medical devices, and the methods used to safeguard the intention of these requirements to somebody, planning a career in the medical engineering field. To write a technical report.

Course contents

The quality assurance discussion includes quality systems like total quality management (TQM), the ISO 9000 series, Good laboratory practice (GLP), Good manufacturing practice (GMP) and Quality system regulation (QSR). Also methods to assess the reliability of medical devices and aspects on organization are addressed.

The regulatory aspects includes international standards, European and American directives and regulations, clinical trials, laboratory testing, and the certification and accreditation instruments.

The issues of responsibility, safety and ethics in health care and clinical trials are addressed specifically.

Course literature

Course material binder and documents distributed during the course.

Examination

- INL1 - Assignment, 3.0 credits, grading scale: A, B, C, D, E, FX, 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.

Other requirements for final grade

A written report.

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.