



# HL2015 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.

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

## Establishment

Course syllabus for HL2015 valid from Spring 2009

## Grading scale

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

## Education cycle

Second cycle

## Main field of study

Electrical Engineering

## Specific prerequisites

Two years of undergraduate studies in Natural Sciences or Engineering, and knowledge of Medical Engineering corresponding to HL2006 Medical Engineering, Basic Course  
[http://www.kth.se/student/kurser/kurs/HL2006?l=en\\_UK](http://www.kth.se/student/kurser/kurs/HL2006?l=en_UK)

Documented proficiency in Swedish corresponding to Swedish B and English corresponding to English A.

## 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.

## 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.