HL2014 Säkra medicintekniska produkter 7,5 hp

Safe Medical Devices

Fastställande

Kursplan för HL2014 gäller från och med HT08

Betygsskala

P, F

Utbildningsnivå

Avancerad nivå

Huvudområden

Medicinsk teknik

Särskild behörighet

At least two years of science studies at university level . Basic knowledge in medicine and medical engineering in accordance with the course HL1007 Medical engineering, basic course and knowledge in English corresponding to English B.

Undervisningsspråk

Undervisningsspråk anges i kurstillfällesinformationen i kurs- och programkatalogen.

Lärandemål

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.

Kursinnehåll

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.

Kurslitteratur

Course literature see literature list. Reference literature and internet sites will be informed on the course website before course start

Examination

- RED1 - Tentamen och projektarbete, 7,5 hp, betygsskala: P, F

Examinator beslutar, baserat på rekommendation från KTH:s handläggare av stöd till studenter med funktionsnedsättning, om eventuell anpassad examination för studenter med dokumenterad, varaktig funktionsnedsättning.

Examinator får medge annan examinationsform vid omexamination av enstaka studenter.

När kurs inte längre ges har student möjlighet att examineras under ytterligare två läsår.

Approved written examination and approved project work

Etiskt förhållningssätt

- Vid grupparbete har alla i gruppen ansvar för gruppens arbete.
- Vid examination ska varje student ärligt redovisa hjälp som erhållits och källor som använts.
- Vid muntlig examination ska varje student kunna redogöra för hela uppgiften och hela lösningen.