Course: Engineering rules for medical devices — credits: 5

Course code	ELVH18GERMD
Name	Engineering rules for medical devices
Study year	2024-2025
ECTS credits	5
Language	English
Coordinator	J. Zijlstra
Modes of delivery	Education
Assessments	Engineering rules for medical devices - Assignment

Learning outcomes

The course deals with (not necessarily technical) aspects which are of specific importance for engineering and bringing to the market of medical products. It consists of 3 parts: Medical Ethics, Ergonomics of Human Factors and Medical Device Regulation.

1.4.1 Medical Ethics

Student can:

*** recognize the different ethical theories and apply them to an arbitrary case**
*** deal with the ethical aspects associated with the professional and research practice**
*** compose an information and informed consent form in accordance with the regulations of the medical ethical committee**
*** analyze a medical-ethical or research-ethical problem, using a six-step process**
*** present a well-argued viewpoint on a medical-ethical or research-ethical case**

1.4.2 Ergonomics of Human Factors

Student can:
*** On a basic level identify, explain, and evaluate the impact of various personal attributes (physical, sensory, and cognitive HF aspects)**
*** Analyse the effect of physical environment factors on comfort and performance**
*** Apply addressed human factors principles in design**

1.4.3 Medical Device Regulation MDR

Student
*** understands the regulatory environment for the development of a medical device**
*** knows impact of MDR and CE for product design and use**
*** knows the route to obtain product conformity and approval by notified body**
*** knows the different risk classes of medical products**
*** is familiar with Safety Requirements and Technical Construction File**
*** can apply the Medical Device Regulation in medical product design**

Content

Medical Ethics
The Ethics course gives an introduction to the theory of medical and research-ethics. The student takes note of a number of classical ethical approaches and can argue them on a medical-ethical and research-ethical case.

Ergonomics of Human Factors
* An introduction to the scope of Human Factors (HF) and ergonomics
* Sensory HF: Physical environmental factors, heat, light and vibration and their measurement
* Physical HF: Anthropometrics as related to product and environment use
* Task analysis including all HF aspects, as tool for research and design
* Anatomy and biomechanics in relation to Human Factors

Medical Device Regulation MDR
Create awareness of dedicated legislation, concerning safety and quality, when designing and using medical devices.

Included in programme(s)
Exchange Biomedical Engineering (autumn)
Minor Biomedical Engineering

School(s)
Institute of Engineering

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