



Course syllabus

Medicinteknisk design Biomedical Design

EEMA01, 9 credits, G1 (First Cycle)

Valid for: 2023/24

Faculty: Faculty of Engineering, LTH

Decided by: PLED BME

Date of Decision: 2023-04-13

General Information

Main field: Technology.

Compulsory for: BME2

Language of instruction: The course will be given in Swedish

Aim

The purpose of the course is that the student shall develop an understanding of innovation and development processes of particular relevance to medical devices. This includes creating an understanding that medical devices often have a critical function and must be safe for patients, users and third parties. Also, the student needs to understand that, apart from demands from professionals and patients on safety, science and proven experience, there are also legal demands that make it necessary for the engineer to have deep knowledge about quality and government demands related to the development and management of medical devices.

Learning outcomes

Knowledge and understanding

For a passing grade the student must

- Describe and discuss different parts of the innovation process, such as needs analysis, trend and technology watch, and concept and prototype generation
- State the most important laws and regulations for medical devices
- Describe and discuss the process for achieving CE mark approval
- Discuss how a quality system is implemented and used
- Discuss how a risk system is implemented and used
- State how clinical evaluation can be performed

Competences and skills

For a passing grade the student must

- Explore and analyse needs, trends and technologies
- Create and evaluate ideas for how to address the identified needs
- Demonstrate and evaluate conceptual solution proposals
- Analyse the CE marking process for a biomedical product
- Propose a quality system based on the classification of the biomedical product
- Perform a basic risk analysis
- Propose how a clinical evaluation will be performed based on the classification of the biomedical product

Judgement and approach

For a passing grade the student must

- Be able to clearly present, verbally and in writing, the methods, experiences and conclusions from the project, and critically examine (based on scientific literature) and value the methods, experiences and conclusions presented by other students
- Be able to discuss medical device design with medtech companies and healthcare professionals

Contents

The course deals with innovation and development processes for medical devices in both lecture form and project form. The project starts at the course start, and will be performed in parallel with the lectures. The topics discussed at lectures shall be applied within the projects.

Medical devices play a crucial part in the diagnosis and treatment of patients in modern healthcare. An engineer working with medical technology and medical devices face particular demands, regardless if the person is an entrepreneur, works within research and development, service and maintenance, administration or law, in a small or large company, within the private or public sector; she/he needs to have patient safety as the number one priority – a safety mindset that is matched only in the aerospace sector.

Medical devices often have a critical function and must be safe for patients, users and third parties, and apart from demands from professionals and patients on safety, science and proven experience, there are also legal demands that make it necessary for the engineer to have deep knowledge about quality and government demands related to the development and management of medical devices.

The course will deal with needs analysis, trend and technology watch, concept and prototype generation, requirement specifications, patent issues, how a product is brought to market within (CE marking) and outside of Europe, laws and regulations, Medical Devices Regulation (MDR), standards, Notified Bodies, quality systems, risk analysis, clinical evaluation, and environmental management systems.

Examination details

Grading scale: TH - (U,3,4,5) - (Fail, Three, Four, Five)

Assessment: Written assignment, written exam (individual assessment), written

project report (team assessment) and individual written reflection.

The examiner, in consultation with Disability Support Services, may deviate from the regular form of examination in order to provide a permanently disabled student with a form of examination equivalent to that of a student without a disability.

Parts

Code: 0118. **Name:** Assignments.

Credits: 1,5. **Grading scale:** UG. **Assessment:** Written assignments.

Code: 0218. **Name:** Written Examination.

Credits: 3,5. **Grading scale:** TH. **Assessment:** Written test (individual assessment).

Code: 0318. **Name:** Project.

Credits: 3,5. **Grading scale:** TH. **Assessment:** Written project report (team assessment). Verbal presentation of the project (team assessment). **Contents:** The project is assessed by a written report.

Code: 0418. **Name:** Personal Reflection of Group Work .

Credits: 0,5. **Grading scale:** TH. **Assessment:** Individual written reflection.

Admission

The number of participants is limited to: No

Reading list

- Stefanos Zenios, Losh Makower, Paul Yock: Biodesign, The Process of Innovating Medical Technologies. Cambridge, 2010, ISBN: 978-0-521-51742-3,. Recommended for further study and additional reading.
- Peter Landvall: Medicintekniska produkter. SIS Förlag AB, 2010, ISBN: 978-91-7162-774-2. Recommended for further study and additional reading.
- Kumar, V. : 101 Design Methods. John Wiley & Sons, 2012, ISBN: 9781118083468. Recommended for further study and additional reading.
- Both. T.: D.School – bootcamp bootleg.
<https://dschool.stanford.edu/resources/the-bootcamp-bootleg>, 2010.
Recommended for further study and additional reading.

Contact and other information

Course coordinator: Universitetslektor Magnus Cinthio, magnus.cinthio@bme.lth.se

Course coordinator: Professor Anders Warell, anders.warell@design.lth.se

Course homepage: <http://bme.lth.se/course-pages/medicinteknisk-design/medicinteknisk-design/>

Further information: The course is given by the Departments of Biomedical Engineering and Design Sciences in collaboration.