Module Description, available in: EN

Medical Device Market Access

General Information

Number of ECTS Credits

3

Module code

TSM_MedDMA

Valid for academic year

2024-25

Last modification

2023-09-27

Coordinator of the module

Jens Ulmer (OST, jens.ulmer@ost.ch)

Explanations regarding the language definitions for each location:

- Instruction is given in the language defined below for each location/each time the module is held.
- Documentation is available in the languages defined below. Where documents are in several languages, the percentage distribution is shown (100% = all the documentation).
- The examination is available 100% in the languages shown for each location/each time it is held.

	Lausanne			Lugano	Zurich		
Instruction					**X** E 100%		
Documentation					**X** E 100%		
Examination					**X** E 100%		

Module Category

TSM Technical scientific module

Lessons

2 lecture periods and 1 tutorial period per week

Entry level competences

Prerequisites, previous knowledge

This course requires knowledge about

- technical design methods
- mathematical statistics/data analysis
- basic knowledge about standardization

Brief course description of module objectives and content

The course provides an in-depth overview on necessary aspects for implementing a medical device into the market. You will work on real products and improve the device by reviewing the clinical need and update the concept. For this you will be guided through the first steps of the Stanford biodesign principle. Besides concept improvement you will learn how to go through the mandatory regulatory aspects. In addition, you will get insights into market analysis techniques and fundamentals of the health care system.

Aims, content, methods

Learning objectives and competencies to be acquired

Aims:

The aim of this module is to:

- Know and apply the first steps of the Stanford Biodesign principle to develop a medical device.
- Understand the regulatory aspects within EU (MDR) and US (FDA)
- Know the current standards used for designing and developing medical devices according to MDR
- Understand the basic aspects of the health care system and know the relevant market aspects.

Module content with weighting of different components

- Stage 1: Defining the clinical need
  - From bench to bed side. Understand the clinical need and make use of knowledge about disease fundamentals and observation/clinical problem identification.
  - Understanding the scientific language of medicine, the research culture as well as the ethical aspects in the context of medical devices.
  - Introduction into the medical device regulation.
- Stage 2: Screening and concept improvement
  - Knowledge of the classification of medical devices and the corresponding regulatory pathway within EU-MDR and US-FDA
  - Overview of the legal requirements on the design and construction of medical products. This includes the requirement engineering as well as the general safety and performance requirements.
  - Insights into the quality management system EN ISO 13485:2016 including testing, verification, and validation principles.
- Stage 3: Product concept and business strategy
  - Understanding the basics in usability engineering according EN 62366 and the validation of usability
  - Understanding the risk management according to ISO 14971 and having insights into the risk analysis.
  - Knowledge in market evaluation, current health care systems and developing a reimbursement strategy.
  - Introduction into the clinical testing of medical devices and basic knowledge of "good clinical practice".

Teaching and learning methods

During the course you will directly apply the theoretical aspects of the module by working with your colleagues on real medical devices. The provided documents will help you to navigate through the regulatory approval process.

Literature

- Medical device design: Innovation from concept to market, Peter Ogrodik, Academic Press (2020). ISBN 978-0-12-814962-1
- Biodesign – The Process of Innovating Medical Technologies, Paul Yock, Stefanos Zenios, Josh Makower, Todd Brinton, Uday Kumar, Cambridge Academic (2015). ISBN 978-1-107-08735-4
- EU-MDR, US-FDA
- Various standards

Assessment

Certification requirements

Module uses certification requirements

Certification requirements for final examinations (conditions for attestation)

Practical aspects will be covered by a written and orally presented group work, duration 30 min.

Counting:1/3 of the total grade

Basic principle for exams

As a rule, all standard final exams are conducted in written form. For resit exams, lecturers will communicate the exam format (written/oral) together with the exam schedule.

Standard final exam for a module and written resit exam

Kind of exam

Written exam

Duration of exam

120 minutes

Permissible aids

Aids permitted as specified below:

Permissible electronic aids

Principally none - if required, regulations will be handed out

Other permissible aids

2 pages (DIN A4), single sided, handwritten

Special case: Resit exam as oral exam

Kind of exam

Oral exam

Duration of exam

30 minutes

Permissible aids

No aids permitted