Module Description, available in: EN

Medical Device Market Access

General Information

Number of ECTS Credits

3

Module code

TSM_MedDMA

Valid for academic year

2022-23

Last modification

2022-01-14

Coordinator of the module

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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 all relevant aspects for successfully introducing a medical device into the market. It will make use of the Stanford biodesign principle to evaluate the clinical need and concept development with respect to regulation and the specific medical device market restrictions. The corresponding topics include the important tasks during the development of a medical device (prior market access) as well as after its placement on the market.

Aims, content, methods

Learning objectives and competencies to be acquired

The aim of this lecture is to

- Know the important medical device design principle
- Know all relevant aspects for the development of a medical device
- Know and apply the Stanford biodesign principle to design and develop a commercially successful 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 relevant aspects of the health system and business aspects within medical device market sector

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 development

- Knowledge of the classification of medical devices and the corresponding regulatory pathway within EU-MDR and US-FDA
- Prototyping, concept screening and generating a MVP.
- Overview on the legal requirements on the design and construction of medical products. This includes the requirement management as well as the verification and validation of development results including the Software Life Cycle (ISO 62304).
- 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 the usability according EN 62366, validation of the usability
- Understanding the risk management according to ISO 14971 and having insights into the risk analysis.
- Understanding biological safety according to ISO 10993 and some technical safety aspects (ISO 60601)
- Knowledge of the CE-labelling in Europe and registration procedure in the USA. Product labelling (ISO 15233) and UDI.
- Knowledge in current health 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

Theoretical lectures combined with group-work

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