Module Description, available in: EN

Medical Device Market Access

General Information

Number of ECTS Credits

3

Module code

TSM_MedDMA

Valid for academic year

2020-2021

Last modification

2019-10-11

Responsible of 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.

	Berne	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 organic chemistry

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. 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 acquired competencies

The aim of this lecture is to

- know the important medical device design principles
- know all relevant aspects for the development of a medical device with respect to a successful market placement
- understand the regulation for medical devices in Europe (MDR) and USA (FDA)
- apply current standards for (software) design, risk management, usability and/or biological aspects

Contents of module with emphasis on teaching content

14 different topics related to the market access of a medical device will be presented each week as follows:

(1) From lab bench to bed side: medical device design principles.

(2) Understanding compatibility of materials according ISO 10993.

(3) Basic knowledge in microorganisms and pathogens (including ISO14644/clean room).

(4) Knowledge of cleaning and disinfection processes of medical products as well as sterilization procedures and methods. In addition, overview on the packaging of sterile products.

(5) Understanding the scientific language of medicine, the research culture as well as the ethical aspects in the context of medical devices.

(6) Knowledge of the classification of medical products and the requirements of EU-MDR and US-FDA.

(7) Insights into the quality management system EN ISO 13485:2016.

(8) Knowledge of the CE-labelling in Europe and registration procedure in the USA. Product labelling (ISO 15233) and UDI.

(9) 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).

(10) Knowledge of the legal requirements on producers of medical products in Europe and elsewhere.

(11) Introduction into the clinical testing of medical devices and basic knowledge of "good clinical practice" (including ISO 2859 and ISO 3951).

(12) Understanding the basics in the usability according EN 62366, validation of the usability.

(13) Understanding the risk management according ISO 14971 and having insights into the risk analysis.

(14) Overview on the markets, health systems and the decision makers when it comes to acquiring new medical products.

Teaching and learning methods

Lectures and practical work on computer

Literature

- Slides and lecture notes will be available in addition of recommended book chapters
- MDR
- EN ISO 13485:2016
- ISO 14971, 10993, 14644, 15233, 62304, 2859, 3951
- EN 62366

Assessment

Certification requirements

Module does not use certification requirements

Basic principle for exams

As a rule, all the standard final exams for modules and also all repetition exams are to be in written form

Standard final exam for a module and written repetition exam

Kind of exam

written

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

One A4 page (double side), hand written

Special case: Repetition exam as oral exam

Kind of exam

oral

Duration of exam

30 minutes

Permissible aids

No aids permitted