Master's Department of Engineering Sciences

MSc in Automation Engineering and Robotics

Name of the unit: Safety, evaluation, and economic development of medical devices

Lecturer: Ludovic Saint-Bauzel (saintbauzel@isir.upmc.fr)
Course code: UM5RBM31
Student workload: 24 h of lectures
Credits: 3 ECTS
Specialization tracks: ☐ ROBOT ☐ SI ☒ MeDH
Semester offered: ☐ S1 ☐ S2 ☒ S3 ☐ S4
Language of instruction: ☐ French ☒ English
Targeted audience: ☒ Engineering Sciences students ☐ Other (specify):
Localization : ☒ PMC Campus ☐ Other (specify):

Course Overview

The objective of this course is to give an overview of the societal and economic constraints of medical devices. It examines several central aspects with respect to the safety and the acceptability of assistive and rehabilitation technologies. It also presents risk management concepts and techniques for the development of medical robots, more specifically of rehabilitation robots. Study of the economic viability of a project. Medical economic development: study of the various stages of the development of a device with medical use, the proof of concept in the launch on the market.
Keywords: TRL, Ergonomics, UX design, Clinical trial, Medical devices, Risk plan

Prerequisites

Students should have previously acquired the following prerequisites to follow this course:

- None

Intended Learning Outcomes

By the end of this course, students will be able to:

1. Definition and application of basic concepts for risk management: risk, harm, safety, hazard, hazardous situation, safety integrity, safety integrity level, etc.
2. Risk analysis methods based on system modeling. Risk reduction techniques for medical devices (Hardware and software fault avoidance techniques, fault tolerance mechanisms, etc.)
3. Acceptability and ergonomics of the assistive technologies. Relationship between Assistive Technology and Inclusive Design.
4. Clinical trials methodology and protocol design.
5. Engineers, designers and technicians collaboration methodology / Evaluation of a medical product / Certification principles and regulations

Indicative Teaching Sequence and Methods

Week	C/TD/TP*	Content	Preparation	Learn. outc.
S1	3/0/0	Definition basic concepts of risk		AAV1
S2	3/0/0	Acceptability and ergonomics		AAV2
S3	3/0/0	Clinical trials methodology and		AAV3
S4	3/0/0	Certification principle and regulation		AAV4
S5	3/0/0	Medtech seminaries		AAV1,2,3,4,5
S6	3/0/0	Medtech seminaries		AAV1,2,3,4,5
S7	3/0/0	Medtech seminaries		AAV1,2,3,4,5
S8	3/0/0	Medtech seminaries		AAV1,2,3,4,5

* C/TD/TP respectively corresponds to lectures, tutorials and lab sessions.

Indicative Assessment of Intended Learning Outcomes (1st session)

Week	Individ./group	In-person/remote	Type of exam	Evaluated outcomes	Scale %
S6	Group	In-person	Other	AAV1-7	50 %
S8	Individual	In-person	Other	AAV1-7	50 %

2nde session of exam

Session	Individ./group	In-person/remote	Type of exam	Evaluated outcomes	Scale %

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