GDAŃSK UNIVERSITY OF TECHNOLOGY

Subject card

Subject name and code	Aspects of implementation and certification of medical products, PG_00053349		
Field of study	Biomedical Engineering, Biomedical Engineering, Biomedical Engineering		
Date of commencement of studies	February 2022	Academic year of realisation of subject	2022/2023
Education level	second-cycle studies	Subject group	Optional subject group Subject group related to scientific research in the field of study
Mode of study	Full-time studies	Mode of delivery	at the university
Year of study	2	Language of instruction	Polish Polish
Semester of study	3	ECTS credits	2.0
Learning profile	general academic profile	Assessment form	assessment
Conducting unit	Department of Biomedical Engineering -> Faculty of Electronics, Telecommunications and Informatics		
Name and surname of lecturer (lecturers)	Subject supervisor	prof. dr hab. inż. Jerzy Wtorek	
	Teachers	prof. dr hab. inż. Jerzy Wtorek dr inż. Adam Bujnowski mgr inż. Kamil Osiński	

Lesson type and method of instruction

Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
Number of study hours	15.0	15.0	0.0	0.0	0.0	30

E-learning hours included: 0.0

Aspekty wdrażania i certyfikacji produktów medycznych - Moodle ID: 29770
https://enauczanie.pg.edu.pl/moodle/course/view.php?id=29770

Learning activity and number of study hours

Learning activity	Participation in didactic classes included in study plan	Participation in consultation hours	Self-study	SUM
Number of study hours	30	2.0	18.0	50

Subject objectives

The subject introduces the aspects of tasks for a potential designer and manufacturer resulting from the regulations on the implementation and marketing of medical equipment.

Learning outcomes

Course outcome	Subject outcome	Method of verification
[K7_W09] Knows and understands, to an increased extent, the economic, legal and other conditions of various types of activities related to the given qualification, including the principles of protection of industrial property and copyright.	The student knows the regulations governing the admission of medical products to the market and the related requirements for the design, production and quality assurance management system.	[SW1] Assessment of factual knowledge
[K7_K71] is able to explain the need to apply knowledge from humanistic, social, economic or legal sciences in order to function in a social environment	On the basis of the acquired knowledge, the student understands the need to conduct properly designed clinical and market trials and the need to use management systems that take into account the relevant legal regulations.	[SK5] Assessment of ability to solve problems that arise in practice
[K7_U71] is able to apply knowledge from humanistic, social, economic or legal sciences in order to solve problems	The student is able to design clinical trials taking into account the aspect of their credibility, taking into account the real conditions occurring during these trials. The student knows how to select the legal requirements relating to the certification process.	[SU4] Assessment of ability to use methods and tools
[K7_W06] Knows and understands, to an increased extent, the basic processes taking place in the life cycle of devices, facilities and technical systems.	On the basis of the acquired knowledge, the student knows and understands the rules and requirements for the correct process of designing, implementing, putting into service and monitoring a medical device.	[SW3] Assessment of knowledge contained in written work and projects [SW1] Assessment of factual knowledge

Subject contents	1. Overview of the medical product design, implementation and certification cycle.2. Importance and basic requirements for the prototype, MVP and final product.3. Certification process.4. Clinical trials at various stages of product development.5. Designing clinical trials.6. Market research and raising funds for various stages of the development of a medical product.
Prerequisites and co-requisites	Basics of electronics, physics and statistical methods in medical applications

Assessment methods and criteria

Subject passing criteria	Passing threshold	Percentage of the final grade
umiejętności	55.0%	60.0%
wiedza	55.0%	40.0%

Recommended reading

Basic literature	Medical Devices Regulation (MDR) ISO 14155 Clinical Investigation of Medical Device Methodology for the clinical development of medical devices, French National Authority for Health
Supplementary literature	https://single-market-economy.ec.europa.eu/sectors/electrical-and-electronic-engineering-industries-eei/radio-equipment-directive-red_en https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=celex%3A32014L0035
eResources addresses	Podstawowe https://eur-lex.europa.eu/legal-content/PL/ALL/?uri=CELEX:32017R0745 - Medical Devices Regulation (MDR)

Example issues/ example questions/ tasks being completed	1. Discuss the concept of MVP2. Based on the design documentation, carry out a simulated device certification procedure.3. Principles and requirements for designing clinical trials.
Work placement	Not applicable