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 2024	Academic year of realisation of subject	2024/2025
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 polski
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	

Lesson types and methods 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

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 aspects of the tasks for a potential designer and manufacturer resulting from the regulations regarding the implementation and placing on the market of medical equipment.

Learning outcomes

Course outcome	Subject outcome	Method of verification
[K7_W06] Knows and understands, to an increased extent, the basic processes taking place in the life cycle of devices, facilities and technical systems.	Based on the acquired knowledge, the student knows and understands the principles and requirements for the proper process of designing, implementing, putting into use and monitoring a medical device.	[SW1] Assessment of factual knowledge [SW3] Assessment of knowledge contained in written work and projects
[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_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 actual conditions occurring during these trials. The student is able to select legal requirements relating to the certification process.	[SU4] Assessment of ability to use methods and tools
[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	Based on the acquired knowledge, the student understands the need to conduct properly designed clinical and market research and the need to use management systems that take into account appropriate legal regulations.	[SK5] Assessment of ability to solve problems that arise in practice

<table>
<tr><td>Subject contents</td><td>1. Discussion of the design, implementation and certification cycle of a medical product.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 obtaining funds for various stages of medical product development.</td></tr>
<tr><td>Prerequisites and co-requisites</td><td>Basics of electronics, physics and statistical methods in medical applications</td></tr>
<tr><td>Assessment methods and criteria</td><td>
<table>
<tr><th>Subject passing criteria</th><th>Passing threshold</th><th>Percentage of the final grade</th></tr>
<tr><td></td><td>55.0%</td><td>40.0%</td></tr>
<tr><td>umiejętności</td><td>55.0%</td><td>60.0%</td></tr>
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<tr><td>Recommended reading</td><td>
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<tr><td>Basic literature</td><td>Medical Devices Regulation (MDR)

ISO 14155 Clinical Investigation of Medical Device

Methodology for the clinical development of medical devices, French National Authority for Health</td></tr>
<tr><td>Supplementary literature</td><td>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</td></tr>
<tr><td>eResources addresses</td><td>Adresy na platformie eNauczanie:</td></tr>
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<tr><td>Example issues/ example questions/ tasks being completed</td><td>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.</td></tr>
<tr><td>Work placement</td><td>Not applicable</td></tr>
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