COURSE DESCRIPTION CARD - SYLLABUS

Course name
Clinical trials of medicinal products and medical devices [S2IBio1E>BKPL]

Course

Field of study
Biomedical Engineering

Year/Semester
1/2

Area of study (specialization)
Bionics and Virtual Engineering

Profile of study
general academic

Level of study
second-cycle

Course offered in
english

Form of study
full-time

Requirements
compulsory

Number of hours

Lecture
15

Laboratory classes
0

Other (e.g. online)
0

Tutorials
0

Projects/seminars
0

Number of credit points

1,00

Coordinators

Lecturers

Prerequisites

First-cycle studies in engineering in the field of bioengineering, medical apparatus, implants, bioethics.

Course objective

To familiarize students with the basic knowledge and terminology of clinical trials of medicinal products and medical devices, the methodology of scientific research in biological and medical sciences, the certification process of medical devices under Polish and European law, legal regulations concerning the above-mentioned areas.

Course-related learning outcomes

Knowledge:
The student is able to properly classify a medicinal product and a medical device and define the legal regulations applicable to its placing on the market.
the student understands the essence, purpose and method of conducting clinical trials of medicinal products and medical devices. The student knows the basic terms used in the field of clinical trials.
Has knowledge of the ethical aspects of conducting biomedical research and the methods of monitoring the safety and effectiveness of medicinal products and medical devices.
Has a basic knowledge of the life cycle of technical devices, facilities and systems.
He has basic knowledge of management, including quality management and running a business, in the

field of biomedical engineering.

Skills:
Logical thinking, using information obtained from the library, the Internet and other sources.
Is able to obtain information from specialist literature, databases on clinical trials and other properly selected sources (also in English) in the area of critical evaluation and to draw conclusions, to formulate and exhaustively justify engineering opinions; is able to integrate and interpretet the obtained information.

Social competences:
1. Understanding the need to learn and acquire new knowledge.
2. Awareness of the benefits of combining engineering and biomedical knowledge for society.
3. Is aware of the importance and understanding of non-technical aspects and effects of engineering activities, including its impact on the environment, and the responsibility for the decisions made.

Methods for verifying learning outcomes and assessment criteria

Learning outcomes presented above are verified as follows:

Learning outcomes presented above are verified as follows:
Lecture - final test.
Depending on the percentage of the student"s performance on the tests, the following scores are awarded:
2 (not enough) <0 points; 50 points>
3 (sufficient) (50 points; 60 points>
3+ (positive plus) (60 points; 70 points>
4 (good) (70 points; 80 points>
4+ (good plus) (80 points; 90 points >
5 (very good) (90 points; 100 points>

Programme content

Lecture:
1. Outline of the process of developing a new drug / medical device. Obtaining the required permits and opinions before starting a clinical trial.
2. Certification of a medical device under Polish and European law
2. Monitoring clinical trials and managing the trial in the research site.
3. Methodology of scientific research - types of research in biological and medical sciences
4. Legal aspects of conducting medical research
5. Ethical aspects of scientific research
5. Reporting the results of a clinical trial.

Teaching methods

Lecture: multimedia presentation supported by examples on the blackboard.

Bibliography

Basic
1. Badania kliniczne, opracowanie zbiorowe pod redakcją Teresy Brodniewicz, GCP.pl, CeDeWu Sp. z o.o., 2016
2. Badania kliniczne produktów leczniczych i wyrobów medycznych. Zagadnienia prawne, Tomasz Kuczur, Damian Wąsik, Wolters Kluwer Polska, 2016
1.W. Jędrychowski. Zasady planowania i prowadzenia badań naukowych w medycynie. Wydawnictwo Uniwersytetu Jagiellońskiego, Kraków, 2004.
2.John W. Creswell, Projektowanie badań naukowych. Metody jakościowe, ilościowe i mieszane, Wydawnictwo Uniwersytetu Jagiellońskiego., 2013.
Additional
1. Ustawa z dnia 6 września 2001 r. Prawo farmaceutyczne. (Dz. U. 2001 nr 126 poz. 1381)
2. Ustawa z dnia 5 grudnia 1966 r. o zawodach lekarza i lekarza dentysty. (Dz. U. 1997 nr 28 poz. 152)
3. Ustawa z dnia 20 maja 2010 r. o wyrobach medycznych (Dz.U.2020.0.186)
4. Deklaracja Helsińska Światowego Stowarzyszenia Lekarzy (WMA): etyczne zasady prowadzenia badań

medycznych z udziałem ludzi.

Breakdown of average student's workload

	Hours	ECTS
Total workload	25	1,00
Classes requiring direct contact with the teacher	15	0,50
Student's own work (literature studies, preparation for laboratory classes/ tutorials, preparation for tests/exam, project preparation)	10	0,50