GDAŃSK UNIVERSITY OF TECHNOLOGY

Subject card

Subject name and code	Outline of the process of creating a new drug, PG_00069252		
Field of study	Biotechnology		
Date of commencement of studies	February 2025	Academic year of realisation of subject	2025/2026
Education level	second-cycle studies	Subject group	
Mode of study	Full-time studies	Mode of delivery	at the university
Year of study	1	Language of instruction	Polish
Semester of study	2	ECTS credits	3.0
Learning profile	general academic profile	Assessment form	assessment
Conducting unit	Department of Pharmaceutical Technology and Biochemistry -> Faculty of Chemistry -> Wydziały Politechniki Gdańskiej		
Name and surname of lecturer (lecturers)	Subject supervisor	dr hab. inż. Iwona Gabriel	
	Teachers		

Lesson types and methods of instruction

Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
Number of study hours	15.0	0.0	30.0	0.0	0.0	45

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	45	5.0	25.0	75

Subject objectives

Expanding knowledge on the subject of preclinical and clinical research.

Learning outcomes

Course outcome	Subject outcome	Method of verification
[K7_K01] understands the need to constantly update knowledge based on the state of the art in accordance with the latest scientific literature, improve professional skills and the importance of teamwork	The student is able to work in a group to develop a plan and schedule for the implementation of a multi-stage research task. The student is able to propose a plan for the synthesis of a biologically active compound and methods for determining its antimicrobial activity.	[SK1] Assessment of group work skills [SK5] Assessment of ability to solve problems that arise in practice [SK3] Assessment of ability to organize work
[K7_U07] evaluates the possibility of commercialization of a product or technology based on the analysis of scientific publications and patents	The student is able to use the acquired knowledge to assess the commercialization possibilities of a product.	[SU2] Assessment of ability to analyse information [SU3] Assessment of ability to use knowledge gained from the subject
[K7_W05] identifies crucial developments in research, apparatus and technology in biotechnology and related fields	The student is able to propose a plan for a biologically active compound synthesis, determine the relationship between structure and biological activity, and conduct selected tests used at preclinical trials.	[SW1] Assessment of factual knowledge
[K7_W03] selects methods using living organisms and biomolecules to produce and process consumer goods	The student knows bioethical problems and regulations in planning preclinical and clinical trials.	[SW1] Assessment of factual knowledge

Subject contents

Lecture: The stages of the formation of a new drug. Preclinical testing. Phases of clinical trials. Terms & Methodology. Ethics in biomedical research. Legal regulations: ICH GCP, Declaration of Helsinki, the Nuremberg Code. Roles and responsibilities in clinical trials. Informed Consent. The safety of drugs in clinical trial. Pharmacovigilance - pharmacological vigilance.

Laboratory classes: the course of action for a potential antibacterial compound from the stage of synthesis through testing its in vitro properties using tests used in preclinical studies.

<table>
<tr><td>Prerequisites and co-requisites</td><td colspan="3">Basic knowledge of organic synthesis, microbiology, biochemistry and drug technology.</td></tr>
<tr><td>Assessment methods and criteria</td><td colspan="3"><table>
<tr><th>Subject passing criteria</th><th>Passing threshold</th><th>Percentage of the final grade</th></tr>
<tr><td>test</td><td>50.0%</td><td>50.0%</td></tr>
<tr><td>tests and reports from laboratory classes</td><td>50.0%</td><td>50.0%</td></tr>
</table></td></tr>
<tr><td rowspan="3">Recommended reading</td><td>Basic literature</td><td colspan="2">Badania kliniczne - wyzwania i perspektywy rozwoju. Autor: Hanna Preus, Artur Preus Rok wydania 2022 Wyd. CeDeWu ISBN 978-83-8102-566-9</td></tr>
<tr><td>Supplementary literature</td><td colspan="2">None</td></tr>
<tr><td>eResources addresses</td><td colspan="2"></td></tr>
<tr><td>Example issues/ example questions/ tasks being completed</td><td colspan="3">What are the differences between Phase I and II of Clinical Trials. Describe the Fixed Dose Method for determining acute toxicity. What is ICH GCP. List the classes of sulfonamides.</td></tr>
<tr><td>Work placement</td><td colspan="3">Not applicable</td></tr>
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