University of Gdańsk

Subject card

Subject name and code	Monoclonal antibodies as drugs: from development to registration, PG_00153644		
Field of study	Biotechnology		
Date of commencement of studies	October 2024	Academic year of realisation of subject	2025/2026
Education level	Master's studies	Subject group	Optional subject group
Mode of study	full-time studies	Mode of delivery	at the university
Year of study	2	Language of instruction	Polish
Semester of study	3	ECTS credits	2.0
Learning profile	academic	Assessment form	credit
Conducting unit	Intercollegiate Faculty of Biotechnology UG-MUG -> Rector		
Name and surname of lecturer (lecturers)	Subject supervisor	dr hab. Andrea Lipińska	
	Teachers	dr hab. Andrea Lipińska	

Lesson types

Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
Number of study hours	30.0	0.0	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	5.0	15.0	50

Subject objectives

The aim of the training is to familiarise the student with the basic techniques and research tools used in biotechnology related to the production of biological drugs, in particular monoclonal antibodies. The student will also become acquainted with the basic methods of large-scale biosimilar drug development, legal regulations related to drug registration and methods of searching, selecting, verifying and presenting information related to the aforementioned issues.

Learning outcomes

Course outcome	Subject outcome	Method of verification
[BIOTECHMU2_W07] The graduate knows and understands social sciences and humanities, helpful in entrepreneurship and effective functioning in society as a human, citizen, employee, employer; the principles of responsibility in conducting scientific research.	Has knowledge in the fields of social sciences and humanities helpful for entrepreneurship and effective functioning in society, as a human being, citizen, employee, employer. Understands and applies the principles of responsibility in the conduct of scientific research.	[SW4] test/exam - oral or written
[BIOTECHMU2_W03] The graduate knows and understands general concepts of therapy and diagnostic methods of human diseases, including the mechanisms of action of selected drugs, immunotherapy and gene therapy	Is familiar with general concepts of therapy and diagnostic methods for human diseases, including mechanisms of action of selected drugs, immunotherapy and gene therapy	[SW4] test/exam - oral or written
[BIOTECHMU2_K04] The graduate is willing to understand ethical dilemmas and threats related to conducting scientific research and introducing advanced technologies using the achievements of biotechnology; appreciate the importance of intellectual property; behave ethically	Understands the ethical dilemmas and risks involved in conducting research and introducing advanced technologies using biotechnology advances; appreciates the importance of intellectual property; acts ethically	[SK4] test/exam - oral or written

<table>
<tr><td>Subject contents</td><td>Introduction to Polpharma Biologics and biologic medicines (basic definitions). Biological medicines, including biosimilars, and their impact on the healthcare system
healthcare system
Pharmacology of therapeutic monoclonal antibodies - introduction. Impact of critical quality parameters on PK/PD and clinical data
clinical
Development and validation of analytical methods
Antibodies as therapeutic agents. A case study
Generation of cell lines for biological production - general principles. Case study
Laboratory scale process development and optimisation - general principles. Case study
Finished product development - formulation development and selection of immediate packaging. Finished product process development
Large scale manufacturing - scaling up
Large scale manufacturing - upstream processes
Large scale manufacturing - downstream processes
Clinical trials - introduction and historical background. Clinical trials - methodology, strategies, design - including biosimilar medicines
Clinical trials - from plan to report
Registration - introduction. Health system regulators - guidelines and interactions
Registration pathway for biologic medicines
Technical development plan for a biological drug including biosimilar</td></tr>
<tr><td>Prerequisites and co-requisites</td><td></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>Programme content</td><td>0.0%</td><td>100.0%</td></tr>
</table></td></tr>
<tr><td>Recommended reading</td><td><table>
<tr><td>Basic literature</td><td>A. Literature required for final course credit (passing the exam):
A.1. used in class
A.2. studied independently by the student</td></tr>
<tr><td>Supplementary literature</td><td>Materials provided in class by the instructor
Supplementary literature will be provided during the class.</td></tr>
<tr><td>eResources addresses</td><td></td></tr>
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<tr><td>Example issues/ example questions/ tasks being completed</td><td></td></tr>
<tr><td>Work placement</td><td>Not applicable</td></tr>
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