

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 2025		Academic year of realisation of subject		2026/2027		
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. Mariusz Grinholc				
	Teachers						
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 possesses knowledge in the social sciences and humanities that is helpful in entrepreneurship and effective functioning in society, and understands 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 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 understands the ethical dilemmas and risks associated with conducting scientific research and introducing highly advanced technologies using biotechnology; appreciates the importance of intellectual property; and acts 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		

Subject contents	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		
Prerequisites and co-requisites			
Assessment methods and criteria	Subject passing criteria	Passing threshold	Percentage of the final grade
	Programme content	0.0%	100.0%
Recommended reading	Basic literature	A. Literature required for final course credit (passing the exam): A.1. used in class A.2. studied independently by the student	
	Supplementary literature	Materials provided in class by the instructor Supplementary literature will be provided during the class.	
	eResources addresses		
Example issues/ example questions/ tasks being completed			
Work placement	Not applicable		

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