

Subject card

Subject name and code	Quality management in non-clinical studies, PG_00207357						
Field of study	Medical Biology						
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	4		ECTS credits		2.0		
Learning profile	academic		Assessment form		credit		
Conducting unit	Department of Molecular Genetics of Bacteria -> Faculty of Biology -> Rector						
Name and surname of lecturer (lecturers)	Subject supervisor		dr Lidia Boss				
	Teachers						
Lesson types	Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
	Number of study hours	0.0	0.0	30.0	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		4.0		16.0	50
Subject objectives	The aim of the course is to prepare students to plan, conduct, and document non-clinical laboratory research in the fields of biology, medical biology, and microbiology. Students gain knowledge of the principles ensuring the reliability and reproducibility of results and learn how to apply the basic principles of Good Laboratory Practice (GLP), particularly those related to work organization, quality control, and proper management of research materials. In addition, during practical exercises, students develop ethical awareness and the ability to analyze results and identify errors, which forms the basis for working in accordance with high quality standards.						
Learning outcomes	Course outcome		Subject outcome		Method of verification		
	[BIOLMEDMU2_W04] knows the principles of planning research based on the achievements of biological and medical sciences, the principles of operation of equipment and apparatus used in medical biology research, and the principle of interpreting biological phenomena and processes based on empirical data in research work and practical activities		Knows the basic principles of good laboratory practice and good documentation practice		[SW4] test/exam - oral or written		
	[BIOLMEDMU2_U02] is able to plan and conduct experiments and measurements based on advanced research techniques and tools, is able to interpret the obtained results and draw conclusions		Can perform reliable research documentation on the basis of provided guidelines and obtained empirical data.		[SU3] text preparation/written work		
	[BIOLMEDMU2_U04] is able to identify errors and omissions in practice		Can verify compliance of prepared documentation with provided guidelines		[SU5] implementation of a problem task		
	[BIOLMEDMU2_K03] is ready to show concern for the prestige of the profession and properly understood professional solidarity		Demonstrates responsibility for high quality of experience and reliability of obtained data.		[SK8] observation of student's independent or team work		

Subject contents	The basic principles of quality management and evaluation in non-clinical research, the basic principles of good laboratory practice (DLP) and good documentation practice (DPD). Planning and organizing experiments based on specific guidelines (preparation of laboratory protocols based on selected European ISO standards). Preparation of reliable documentation in non-clinical studies (preparation of work cards, reports, case analysis). Assessment of the compliance of procedures with the guidelines contained in selected documents regulating the principles of work in non-clinical laboratories and elements of certification rules in such laboratories		
Prerequisites and co-requisites	Basic knowledge of chemistry and the ability to use it in the laboratory for the proper preparation of solutions, buffers and maintenance of work safety; ability to work sterile and to conduct bacterial cultures; basic knowledge of microbial identification		
Assessment methods and criteria	Subject passing criteria	Passing threshold	Percentage of the final grade
	Correct completion of assignments during classes	51.0%	30.0%
	The final grade also takes into account participation and attitude during class	51.0%	10.0%
	Mandatory attendance at classes (in accordance with the academic regulations)	80.0%	10.0%
	Grades on testes covering the material covered in the respective classes	51.0%	50.0%
Recommended reading	Basic literature	A.1. used in class: - The course is original and based on numerous publications (including original publications in scientific journals, guidelines contained in European ISO standards and other unpublished materials), the content of the classes is not included in any textbook - Instructions for exercises prepared by the trainer A.2. studied independently by a student Recommended by the ISO standards operator	
	Supplementary literature	Official guidelines published by the Organisation for Economic Cooperation and Development OECD, Organization for Economic Co-operation and Development)	
	eResources addresses		
Example issues/ example questions/ tasks being completed	A seminar-style lecture on the basic guidelines applied in conducting research in accordance with Good Laboratory Practice (GLP) and Good Documentation Practice (GDP), as well as the most important documents regulating these principles. Text analysis with discussion (selected ISO standards, examples of documentation compliant with GDP). Solving problems/conducting experiments based on the specified standards, along with maintaining documentation in accordance with the principles developed during the exercises. Case studies (based on obtained laboratory data) an attempt to interpret the results and prepare a report on the conducted study.		
Work placement	Not applicable		

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