University of Gdańsk

Subject card

Subject name and code	Quality management in non-clinical studies, PG_00207357		
Field of study	Biology		
Date of commencement of studies	October 2026	Academic year of realisation of subject	2026/2027
Education level	Master's studies	Subject group	Obligatory subject group in the field of study Optional subject group Subject group related to scientific research in the field of study
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	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
[BIOLMU2_U06] is able to use the acquired specialist knowledge in the field of biological sciences to interpret the collected empirical data and draw conclusions	Can verify compliance of prepared documentation with provided guidelines	[SU5] implementation of a problem task
[BIOLMU2_U04] is able to plan and carry out complex research tasks or expert opinions in the field of the biological specialty studied, independently or in a team, also in changing and unforeseen conditions	Can perform reliable research documentation on the basis of provided guidelines and obtained empirical data.	[SU3] text preparation/written work
[BIOLMU2_K02] is ready to work effectively as a team member and to comply with the rules of teamwork and take responsibility for the tasks carried out	Demonstrates responsibility for high quality of experience and reliability of obtained data.	[SK8] observation of student's independent or team work
[BIOLMU2_W02] has a thorough knowledge and applies the principle of rigorous, empirically based interpretation of biological phenomena and processes in research and practical activities	Knows the basic principles of good laboratory practice and good documentation practice	[SW4] test/exam - oral or written

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%
Grades on testes covering the material covered in the respective classes	51.0%	50.0%
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%

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

Document generated electronically. Does not require a seal or signature.