

## Course Syllabus

### I. General Information

Course name in English	Experimental work methodology and quality management systems
Course name in Polish	Metodologia pracy doświadczalnej i systemy zarządzania jakością
Programme	Bioanalytical Technologies
Level of studies (BA, BSc, MA, MSc, long-cycle MA)	MSc
Form of studies (full-time, part-time)	full-time
Discipline	Biological sciences
Language of instruction	English

Course coordinator/person responsible	dr hab. Agnieszka Wolińska/dr Monika Jach
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Type of class ( <i>use only the types mentioned below</i> )	Number of teaching hours	Semester	ECTS Points
lecture	45	I	6
tutorial			
classes	15	I	
laboratory classes			
workshops			
seminar			
introductory seminar			
foreign language classes			
practical placement			
field work			
diploma laboratory			
translation classes			
study visit			

Course pre-requisites	Necessary skill in using a spreadsheet (Excel)
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### II. Course Objectives

C1 - To acquaint students with the principles of planning the laboratory experiments
C2 - Learning to use literature databases and the use of proper citation system works
C3 - To acquaint students with the most important statistical and bioinformatic packages
C4 - To acquaint students with the basics of measurement and analytical methods validation
C5 - To acquaint students with the classification of quality management systems and legislation
C6 - To acquaint students with requirements for non-sterile and special sterile production, and quality control
C7 - To acquaint students with good documentary practice in the field of: plant and laboratory documentation and quality control systems, standard operating procedure (SOP), specifications, certification

C8 - To acquaint students with creating documentation in the field of issues related to individual sections of quality control systems: SOP, standard testing procedures and specifications.

### III. Course learning outcomes with reference to programme learning outcomes

Symbol	Description of course learning outcome	Reference to programme learning outcome
<b>KNOWLEDGE</b>		
W_01	Student has knowledge in the field of research planning using the experimental methods used in biotechnology	K_W05
W_02	Knows the basics of bioinformatics, statistics and error theory	K_W04
W_03	Knows the fundamental principles of H&S	K_W07
W_04	The student knows and understands the need to implement quality assurance systems by maintaining a high standard at the stage of development, production and quality control of the biotechnology product	K_W07, K_W08, K_W03
<b>SKILLS</b>		
U_01	Student creates a scheme of the experience along with the work schedule (sets the priorities) on the topic of his choice and presents it to other students	K_U05, K_U18, K_U19
U_02	Performs basic statistical analyzes (one-way analysis of ANOVA variance, simple regression) and correctly interprets the obtained data	K_U04
U_03	Can write a report describing the laboratory experiment of the assumed limit of words and present it to the other students	K_U05
U_04	Is able to cite scientific papers correctly in footnotes and in the text of the work and prepares a short scientific speech with a multimedia presentation	K_U05
U_05	Shows responsibility for creating the H&S conditions in the laboratory, which includes planning a research experiment, is open to modern research techniques used in biotechnology	K_U15, K_U16, K_U17
U_06	The student demonstrates the ability to write a test procedure, specifying documents that describe the current mode of operation or the manner of performing various operations or activities	K_U02, K_U08
<b>SOCIAL COMPETENCIES</b>		
K_01	When planning a research experiment, it takes into account the principles of ethical behavior	K_K04
K_02	correctly identifies and resolves dilemmas associated with the profession and is aware of the need for ethical conduct during planning and carrying out research experiments	K_K04

### IV. Course Content

**Lecture:**

Familiarizing students with the course card and the rules of course passing  
 Searching for scientific literature. Scientific databases. Philadelphia list. Quoting and plagiarism.  
 Preparation of initial hypotheses. Sampling. Planning the experiment.  
 4: Structure of scientific work. Principles of writing scientific abstracts. Methods for presenting of

experimental results.

5: The basics of statistics (regression, analysis of variance) and error theory.

6: Basics of validation of measurement methods - data cleaning, distribution testing and verification of assumptions, evaluation of accuracy and stability. Validation of analytical methods - evaluation of accuracy, precision, repeatability, reproducibility, linearity, limit of quantification and detectability.

7: Introduction to bioinformatic analyzes - elements of the basic analysis of NGS data.

8: Classification of quality management systems. Legislation.

9: Quality management and quality control in an industrial plant and commercial laboratory. Quality policy.

10: Manufacturing: requirements for special sterile production and quality control.

11: Manufacturing requirements for non-sterile production and quality control.

12: Quality control systems: hygiene, validation, complaints.

13: Good documentary practice: plant documentation and quality control system, SOP standard operating procedures, specifications, certification.

14: Hazard Analysis and Critical Control Points as a preventative food safety system.

15: Review of lectures and preparations for final exam

Classes:

1: Update of the state of knowledge for the selected research area - literature search rules (online databases). Setting hypotheses and research goals.

2: Planning a research experiment - setting a work schedule, number of samples for analyzes, repetitions, rules for taking environmental tests.

3: The structure of the scientific papers - review articles, original, methodical, short communications. Principles of abstract preparing.

4: Preparation of data for publication - graphic presentation of results (Excel), correct table construction, learning how to interpret results.

5: Rules for the preparation of multimedia presentations and public appearances. The rules of correct citation of scientific papers.

6: Introduction to statistical analysis methods (ANOVA, simple regression) using Statgraphics and/or Statistica software.

7: Writing rules of a specification as a document that provides critical defining information about a product and a list of test and acceptance criteria.

8: Writing rules of a test standard procedure, specifying documents that describe the current mode of operation or the manner of performing various operations or activities,

## V. Didactic methods used and forms of assessment of learning outcomes

Symbol	Didactic methods <i>(choose from the list)</i>	Forms of assessment <i>(choose from the list)</i>	Documentation type <i>(choose from the list)</i>
<b>KNOWLEDGE</b>			
W_01	Conventional lecture	Written test	Evaluated written test/test
W_02	Conventional lecture	Written test	Evaluated written test/test
W_03	Conventional lecture	Written test	Evaluated written test/test
W_04	Conventional lecture	Written test	Evaluated written test/test
<b>SKILLS</b>			

U_01	Practical classes	Presentation	Presentation rating card
U_02	Practical classes	Test of practical skills	Rating card/Observation report
U_03	Textual analysis	Test of practical skills	Evaluated written paper
U_04	Textual analysis / Practical exercises	Test of practical skills	Evaluated written paper / Presentation rating card
U_05	Practical classes	Test of practical skills	Rating card
U_06	Practical exercises Discussion Case study	Papers	Paper printout Evaluated written paper Rating card
<b>SOCIAL COMPETENCIES</b>			
K_01	Practical classes	Observation	Observation report
K_02	Practical classes	Observation	Observation report

#### VI. Grading criteria, weighting factors.....Student workload

**Lecture:** Written exam in the form of a single choice test - 90%, participation in lectures - 10%

**Classes:** Evaluation for the preparation of the scheme of experience and its presentation to other students (25%) and evaluation for the preparation of the scientific abstract (25%). Assessment for preparing a multimedia presentation and presenting it to other students (25%) and evaluation for preparing a short scientific text in which the literature is correctly quoted together with proper references (25%)

Mark	Evaluation criteria	
<b>very good (5)</b>	the student realizes the assumed learning outcomes at a very good level	the student demonstrates knowledge of the education content at the level of 95-100%
<b>over good (4.5)</b>	the student accomplishes the assumed learning outcomes an over good level	the student demonstrates knowledge of the education content at the level of 85-94 %
<b>good (4)</b>	the student accomplishes the assumed learning outcomes at a good level	the student demonstrates knowledge of the education content at the level of 75-84%
<b>quite good (3.5)</b>	the student accomplishes the assumed learning outcomes at a quite good level	the student demonstrates knowledge of the education content at the level of 65-74%
<b>sufficient (3)</b>	the student accomplishes the assumed learning outcomes at a sufficient level	the student demonstrates knowledge of the education content at the level of 55-64%
<b>insufficient (2)</b>	the student accomplishes the assumed learning	the student demonstrates knowledge of the education content below the level of

	outcomes at an insufficient level	55%
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Form of activity	Number of hours
Number of contact hours (with the teacher)	69 (60 + 9 individual consultation)
Number of hours of individual student work	<b>81</b>

## VII. Literature

Basic literature
Laake P., Benestad H.B., Olsen B. R. 2015. Research in Medical and Biological Sciences. Academic Press-Elsevier
Natarajan, Dhanasekharan. 2017. ISO 9001 Quality Management Systems. Springer
Additional literature
Godwil E.A. 2015. Fundamentals of Research Methodology: A Holistic Guide for Research Completion, Management, Validation and Ethics. Nova Science Publisher
Luis R.L., Jose A.G.R., Vikas K. 2013. Building Quality Management Systems: Selecting the Right Methods and Tools. CRC Press Taylor&Francis