

## Course Syllabus

### I. General Information

Course name	Quality management systems and procedures for protection of intellectual property
Programme	Biotechnology
Level of studies (BA, BSc, MA, MSc, long-cycle MA)	MSc
Form of studies (full-time, part-time)	part-time
Discipline	Biological sciences
Language of instruction	English

Course coordinator/person responsible	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	30	I	5
tutorial			
classes	30	I	
laboratory classes			
workshops			
seminar			
introductory seminar			
foreign language classes			
practical placement			
field work			
diploma laboratory			
translation classes			
study visit			

Course pre-requisites	Knowledge in the field of chemistry, biochemistry, microbiology, bioprocess technology
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### II. Course Objectives

Acquainting with the classification of quality management systems in biotechnology. Legislation
Getting to know the organizational location of the quality system in the company; quality management and quality assurance in an industrial plant; quality policy.
Discussion of issues related to the production: requirements for non-sterile and special sterile production, quality control
Determination of quality assurance systems in the scope of: hygiene, validation, complaints.
Acquainting with good documentary practice in the field of: plant documentation and quality control systems, SOPs, specifications, selected registration documents, certification
Acquiring the ability to create documentation in the field of issues related to individual sections of

quality assurance systems: standard operating procedures (SOP), standard testing procedures and specifications.
Acquainting with the concepts and principles of the scope of protection of industrial property and copyright. Intellectual property management
Acquiring the ability to search available patent databases.

### 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	The student knows the basic principles of occupational health and safety 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
W_02	The student knows and understands the basic concepts and principles in the field of industrial property and copyright protection and the need to manage intellectual property resources; can use patent information resources,	K_W09
<b>SKILLS</b>		
U_01	The student has the ability to critically analyze and select information, especially from electronic sources, in order to use them in industrial practice guaranteeing production in accordance with the requirements of law and the market,	K_U03
U_02	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
U_03	The student applies the procedures of protecting intellectual property, he is able to use patent information resources	K_U10
U_04	regularly updates the knowledge, knows its practical application in quality management systems, understands the need to follow regularly the scientific literature as well as to familiarize himself with scientific journals to deepen his knowledge	K_U16
<b>SOCIAL COMPETENCIES</b>		
K_01	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, he is ready to critically evaluate his knowledge and received content	K_K04

### IV. Course Content

Classification of quality management systems in biotechnology. Legislation. Organizational location of the quality system in the enterprise. Quality management and quality assurance in an industrial plant. Quality policy. Manufacturing: requirements for non-sterile and special sterile production, quality control. Quality assurance systems: hygiene, validation, complaints. Good documentary practice: plant documentation and quality control system, SOP standard operating procedures, specifications, selected registration documents, certification.
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Procedures for the protection of property - definitions and principles in the field of protection of industrial property and copyright. Intellectual property management.

#### 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 Conversational lecture Discussion	exam written test	Evaluated written paper Evaluated written test
W_02	Conventional lecture Conversational lecture Discussion	exam written test	Evaluated written paper Evaluated written test
<b>SKILLS</b>			
U_01	Practical exercises discussion Case study	paper	Paper printout Evaluated written paper Rating card
U_02	Practical exercises discussion	paper	Paper printout Evaluated written paper Rating card
U_03	Practical exercises	paper	Paper printout Evaluated written paper Rating card
U_04	Practical exercises	paper	Paper printout Evaluated written paper Rating card
<b>SOCIAL COMPETENCIES</b>			
K_01	Group work, discussion	paper	Paper printout Evaluated written paper Rating card

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

Exam: 100% mark from an exam

Classes: 40% mark from written test, 50% written essay, 10% evaluation of work during the classes

Mark	Evaluation criteria	
<b>verygood (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 91-100%
<b>overgood (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 86-90 %
<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 71-85%

<b>quitegood(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 66-70%
<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 51-65%
<b>insufficient (2)</b>	the student accomplishes the assumed learning outcomes at an insufficient level	the student demonstrates knowledge of the education content below the level of 51%

### VII. Student workload

Form of activity	Number of hours
Number of contact hours (with the teacher)	60
Number of hours of individual student work	65

### VIII. Literature

Basic literature
Good Manufacturing Practice - current legislation; Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application, Annex to CAC/RCP 1-1969 (Rev. 4 - 2003); Industrial property law - current law; current patent law
Additional literature
Good Manufacturing Practice Guide Guidelines for the examination of patent applications relating to pharmaceuticals