Course Syllabus

I. General Information

Course name in English	Pharmaceutical biotechnology
Course name in Polish	Biotechnologia farmaceutyczna
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	Asst. Prof. Dr. Altijana Hromic-Jahjefendic

Type of class *(use only the types mentioned below)*	Number of teaching hours	Semester	ECTS
Lecture	30	III	6
Tutorial			
Classes	30	III	
laboratory classes			
Workshops			
Seminar			
introductory seminar			
foreign language classes			
practical placement			
field work			
diploma laboratory			
translation classes			
study visit			

Course pre-requisites	Knowledge in biochemistry, basic biotechnology and bioprocess technologies, enzymology and microbiology

II. Course Objectives

C1 -To facilitate an understanding of major concepts of pharmaceutical biotechnology including preclinical and clinical drug development
C2 - To understand significance of use of microbial synthesis of biological molecules
C3 - To identify the regulatory issues related to the biopharmaceutical approval process
C4 - To understand the ethical and social implications of modern biotechnology
C5 - To facilitate an understanding of major concepts of pharmaceutical biotechnology in the evaluation of novel drug targets

III. Course learning outcomes with reference to programme learning outcomes

Symbol	Description of course learning outcome	Reference to programme learning outcome
KNOWLEDGE		
W_01	The students describe technologies used in industry and evaluate the dependence of efficiency of the obtained bioproduct regarding the applied method.	K_W02, K_W08
W_02	The student evaluates the type and characteristics of microorganisms useful for bioprocess technologies, synthesis of biological molecules and identifies microbiological contaminations occurring in fermentation industry	K_W02, K_W06
W_03	The student possesses knowledge concerning developments in industrial production of biomolecules as well as regulatory issues behind those processes. The student explains the mechanisms leading to the overproduction of economically important metabolites.	K_W05,K_W08, K_W03
W_04	The student knows the ethics and social implications of biomolecules production.	K_W09
SKILLS		
U_01	The student applies mibrobiological techniques preparing inoculum for microbial cultures.	K_U01
U_02	The student operates basic laboratory equipment.	K_U07
U_03	The student chooses respective culture conditions and culture method as well as analyses the final product.	K_U09
U_04	The student reports obtained experimental results, analyses and draws conclusions and interpretations.	K_U05, K_U06
COMPETENCIES		
K_01	The student is aware of the value of modern research techniques.	K_K01
K_02	The student is taking care of laboratory equipment.	K_K03
K_03	The student proceeds according to good practice regulations in the production of pharmaceutical substances and acts in accordance with the principles of occupational health and safety.	K_K05, K_K04

IV. Course Content

Lecture:

1: Introduction to pharmaceutical biotechnology

2: Review of the major techniques used to detect specific proteins or determine protein structure/amount

3: Production of biotech compounds - major principles and procedures

4: Formulation of biotech products, including their delivery strategies

5: General concepts in pharmacology, including pharmacokinetics and pharmacodynamics of therapeutic proteins

6: Importance of genomics and other `Omics` technologies in biomarkers development

7: Pharmacogenomics and personalized therapy

8: Major applications and issues associated with gene therapy
9: Principles of gene silencing and its potential therapeutic applications
10: The major application of cell therapy in pharmaceutical biotechnology
11: Significance of industrial microbiology in modern pharmaceutical biotechnology
12: Biotech products: Insulin/Vaccines
13: Bioethical and regulatory issues related to applications of pharmaceutical biotechnology
14: Selected topics in pharmaceutical biotechnology
Lab classes:
Lactic acid bacteria – structure, characteristics lactic acid fermentation
Yeast (Baker's, winery, distillery) - structure, characteristics, alcoholic fermentation
Production of vitamins by microorganisms, biosynthesis of glucose oxidase

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

Symbol	Didactic methods *(choose from the list)*	Forms of assessment *(choose from the list)*	Documentation type *(choose from the list)*
KNOWLEDGE			
W_01	Conventional lecture Discussion	Written test	Evaluated written test/test
W_02	Conventional lecture Discussion	Written test	Evaluated written test/test
W_03	Conventional lecture Discussion	Written test	Evaluated written test/test
W_04	Conventional lecture Discussion	Written test	Evaluated written test/test
SKILLS			
U_01	Laboratory classes	Observation and Report	Report printout
U_02	Laboratory classes	Observation and Report	Observation report
U_03	Practical classes	Test of practical skills	Rating card
U_04	Laboratory classes	Report	Report printout
COMPETENCIES			
K_01 K_02 K_03	Laboratory classes Problem based learning Discussion group	Observation Literature review Implementation of project	Observation report Observation report Rating card

VI. Grading criteria, weighting factors

WRITTEN TEST TO PASS THE LECTURE: 100%
LAB CLASSES:
80% GRADES FROM WRITTEN TESTS
10% REPORTS
10% PRACTICAL SKILLS

Mark	**Evaluation criteria**	
Very good (5)	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%

overgood (4.5)	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 %
Good (4)	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%
Quite good (3.5)	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%
sufficient (3)	the student accomplishes the assumed learning outcomes necessary as prerequisite	the student demonstrates knowledge of the education content at the level of 55-64%
insufficient (2)	the student accomplishes the assumed learning outcomes at an insufficient level	the student demonstrates knowledge of the education content below the level of 55%

VII. Student workload

Form of activity	Number of hours
Number of contact hours (with the teacher)	70 (60 + 10 individual consultation)
Number of hours of individual student work	80

VIII. Literature

Basic literature
1) Crommelin, Daan J. A., Sindelar, Robert, Meibohm, Bernd: Pharmaceutical Biotechnology: Fundamentals and Applications, Springer (2019)
2) Gary Walsh: Pharmaceutical Biotechnology: Concepts and Applications, Wiley (2013)