



# Biomedical product technologies

## Syllabus of the academic discipline ( Syllabus )

### Academic discipline requirements

|  |   |
|--|---|
| Level of higher education                    | <i>First (bachelor's)</i>   |
| Discipline                                   | <i>Chemical and Bioengineering</i>  |
| Specialty                                    | <i>163 Biomedical Engineering</i>   |
| Educational program                          | <i>Medical Engineering</i>  |
| Discipline status                            | <i>Elective</i>   |
| Form of study                                | <i>full-time/distance learning</i>  |
| Year of training, semester                   | <i>3rd year, fall semester</i>  |
| Scope of the discipline                      | <i>4 ECTS credits (120 hours)</i>   |
| Semester control/control measures            | <i>Test/essay, modular test</i>   |
| Class schedule                               | <i>26 hours – lectures , 28 hours – practical , 66 hours – independent work.<br/>According to schedule on the website : <a href="https://schedule.kpi.ua/">https://schedule.kpi.ua/</a></i>   |
| Language of instruction                      | <i>Ukrainian</i>  |
| Information about the course leader/teachers | <b>Lecturer:</b> Candidate of Technical Sciences, Associate Professor Lutsenko Tetiana Mykolayivna, <a href="tel:+380976830955">+380976830955</a> , <a href="mailto:lutsenko.tetiana@iit.kpi.ua">lutsenko.tetiana@iit.kpi.ua</a><br><b>Practical:</b> Candidate of Technical Sciences, Associate Professor Lutsenko Tetiana Mykolayivna, <a href="tel:+380976830955">+380976830955</a> , <a href="mailto:lutsenko.tetiana@iit.kpi.ua">lutsenko.tetiana@iit.kpi.ua</a> |
| Teacher profile                              | <b>Lecturer / practical:</b> <a href="https://bi.fbmi.kpi.ua/uk/lutsenkoua/">https://bi.fbmi.kpi.ua/uk/lutsenkoua/</a>  |
| Course placement                             | Link to a remote resource on Google Classroom :<br><a href="https://classroom.google.com/u/1/c/ODAxMjEwMzA3NTMz">https://classroom.google.com/u/1/c/ODAxMjEwMzA3NTMz</a>  |

### Academic discipline program

#### 1. Description of the academic discipline, its purpose, subject of study and learning outcomes

##### What will be studied?

Theoretical foundations concerning the rules and requirements for obtaining biomedical products. Technological possibilities for obtaining various biomedical products useful for humans using microorganisms (enzymes, vitamins, organic acids, antibiotics, amino acids), the main schemes and conditions of microbial synthesis production and the main areas of their use.

##### Why is this interesting/needs to be studied?

The discipline is interesting to study, as understanding various technological processes, standardization parameters, and product requirements is a necessary basis for creating technology for various types of biomedical products.

##### Why can you learn?

##### Knowledge:

- classification biomedical products;
- methods of manufacturing biomedical products;

- main and auxiliary stages of the technological process;
- kinetics of microbiological processes;
- basic compounds obtained by microbial synthesis;
- technology and conditions for industrial production of products using microorganisms;
- questions regarding the features of the structure and development of microorganisms used to obtain various compounds by microbial synthesis;
- industrial technologies for cultivating cell cultures and viruses

**Skill:**

- use regulatory, reference and scientific literature to solve professional tasks;
- conduct a search to solve professional problems;
- work on equipment and apparatus for producing finished and intermediate products;
- taking into account the properties of substances and auxiliary materials, find the optimal option in the methods of obtaining biomedical products;
- carry out technological calculations;
- work at all levels of the biotechnological process: from developing an idea and its experimental verification in the laboratory to scaling the process to the production level;
- perform work related to the acquisition, research and application of microorganisms, enzymes, biologically active substances, products of biosynthesis and biotransformation ;
- work with instruments and equipment to study the properties of microorganisms used, cell cultures, and substances obtained with their help in laboratory and industrial conditions;
- work on installations and equipment for carrying out biotechnological processes.

**How can you use the acquired knowledge and skills?**

The acquired knowledge and skills can be used to determine the belonging of biotechnological products to a certain class. To select the main and auxiliary stages of the technological process of obtaining and controlling a certain type of biomedical product. To perform work related to the obtaining, research and use of microorganisms. To work with instruments and equipment to study the properties of the microorganisms used.

**Program competencies that must be formed after studying the discipline and that correspond to the educational program "Medical Engineering":****General competencies**

ZK 01 - Ability to apply knowledge in practical situations.

ZK 02 - Knowledge and understanding of the subject area and understanding of professional activity.

ZK 06 - Ability to search, process and analyze information from various sources.

GC 07 - Ability to generate new ideas (creativity).

GC 08 - Ability to make informed decisions.

GC 11 - Ability to evaluate and ensure the quality of work performed.

**Professional competencies**

FC 03 - Ability to learn and apply new methods and tools for analysis, modeling, design, and optimization of medical devices and systems.

FC 04 – Ability to provide technical and functional characteristics of systems and devices used in medicine and biology (in prevention, diagnostics, treatment and rehabilitation);

FC 05 – Ability to apply physical, chemical, biological and mathematical methods in the analysis and modeling of the functioning of living organisms and biotechnical systems;

FC 6 – Ability to effectively use tools and methods for analysis, design , calculation, and testing in the development of biomedical products and services;

FC 8 – Ability to conduct research and observations on the interaction of biological, natural and artificial systems (prostheses, artificial organs, etc.)

FC 9 – Ability to identify, formulate, and solve engineering problems related to the interaction between living and non-living systems;

FC 11 – Ability to develop, plan and conduct experiments according to given technical and biomedical methods, applying mathematical methods in analysis, modeling the functioning of living organisms, systems and processes in biology and medicine, computer processing, analysis and synthesis of the results obtained.

FC 12 – Ability to ensure and monitor compliance with safety and biomedical ethics when working with medical equipment.

**Program learning outcomes that must be achieved after studying the discipline and that correspond to the educational program "Medical Engineering":**

PRN 1 – Apply knowledge of the basics of mathematics, physics and biophysics, bioengineering, chemistry, engineering graphics, mechanics, resistance and strength of materials, properties of gases and liquids, electronics, computer science, acquisition and analysis of signals and images, automatic control, systems analysis and decision-making methods at the level necessary to solve biomedical engineering problems;

PRN 2 - Formulate logical conclusions and substantiated recommendations regarding the evaluation, operation and implementation of biotechnical , medical and bioengineering tools and methods;

PRN 3 – Manage complex activities or projects , be responsible for making engineering decisions in unpredictable conditions, conduct feasibility and safety assessments of projects ;

PRN 4 – Apply the provisions of regulatory and technical documents that regulate the procedure for product certification and production certification;

PRN 5 – Be able to use databases, mathematical and software for data processing and computer modeling of biotechnical systems ;

PRN 11 – To control the quality and operating conditions of medical equipment and medical materials, artificial organs and prostheses ;

PRN 19 – Mastery of engineering methods for calculating elements of medical devices and systems, modern methods for testing the experimental integrity and operability of biotechnical systems and determining their characteristics, methods for selecting classical and modern structural materials, as well as means of designing devices, devices and systems for medical and biological purposes;

PRN 20 – Knowledge and use of methods for researching biomedical engineering objects, methods and means of systematizing and processing experimental information, methods of statistical processing for modeling and simulation of processes and systems of physical and biological nature, modern programming technologies and tools that support their use, methods for designing digital and microprocessor systems for medical purposes;

PRN 21 – Understanding and using scientific and technical principles, methods and research methods, tools for the development, planning and design of experimental and cutting-edge research in the field of biomedical engineering objects using medical, biological, biomedical devices and biotechnical systems, biomaterials for medical purposes, as well as for quantitative assessment of the functioning of physiological systems.

## **2. Prerequisites and postrequisites of the discipline (place in the structural and logical scheme of study according to the relevant educational program)**

Knowledge of the basics of mathematics, physics, analytical chemistry and instrumental methods of analysis, microbiology, as well as biotechnology and bioengineering. The academic discipline belongs to the cycle of elective academic disciplines, therefore its normative (mandatory) connection with other disciplines is not provided for in the structural and logical scheme of training.

## **3. Content of the academic discipline**

### ***Lecture topics:***

- Fundamentals of microbial synthesis of biomedical products.
- Microbial synthesis technologies for obtaining vitamins.
- Obtaining amino acids through microbial synthesis.
- Technology for producing recombinant proteins.
- Microbial synthesis technologies for enzyme production.
- Microbial synthesis of antibiotics.
- Technological aspects of obtaining probiotic preparations.
- Technological foundations of bacteriophage production.
- Microbial synthesis technologies for hormone production.
- Packaging and storage of biomedical products. Primary and secondary packaging, stability, logistics.
- Standardization and quality control of biomedical products
- Main areas of use of biomedical products obtained through microbial synthesis.
- Regulatory and legal regulation of biomedical products.

### ***Topics of practical classes.***

- Main types of products of microbial synthesis. General patterns of synthesis of primary and secondary metabolites by microorganisms.
- Classification of biomedical products. Analysis of real examples of products and products.
- Biotechnological production of vitamins and their control .
- General principles of amino acid synthesis by microorganisms. One- and two-stage production of amino acids.
- Methods of protein isolation and purification in pharmaceutical biotechnology.
- Features of the synthesis of organic acids by microorganisms under aerobic and anaerobic conditions
- Comprehensive assessment of microorganisms producing a wide range of enzymes.
- Principles of control of antibiotics obtained by microbial synthesis.
- Biotechnological methods for obtaining probiotic preparations .
- Features of standardization of probiotic preparations.
- Technological foundations of bacteriophage production.
- Principles of control of hormones obtained by microbial synthesis.
- Quality control of biomedical products. Selection of parameters and testing methods.
- Packaging and labeling of biomedical products. Development of a sample label and secondary packaging.

#### 4. Educational materials and resources

##### Basic recommended literature:

1. Biotechnology and bioengineering. Part 1. Fundamentals of biotechnology. Recommendations for performing laboratory work: A textbook for bachelor's degree applicants studying in the educational and professional program "Regenerative and biopharmaceutical engineering" specialty 163 Biomedical engineering // Electronic network ed./ Compiled by: V. V. Motronenko , T. M. Lutsenko, L. M. Dronko : Kyiv: Igor Sikorsky Kyiv Polytechnic Institute. – Kyiv: Igor Sikorsky Kyiv Polytechnic Institute, 2022. – 82 p.
2. Biotechnology and bioengineering. Part 1. Fundamentals of biotechnology. Recommendations for practical work: A textbook for bachelor's degree applicants studying in the educational and professional program "Regenerative and biopharmaceutical engineering" specialty 163 Biomedical engineering // Electronic network ed. / Compiled by: V. V. Motronenko , T. M. Lutsenko, L. M. Dronko : Kyiv: Igor Sikorsky Kyiv Polytechnic Institute. – Kyiv: Igor Sikorsky Kyiv Polytechnic Institute, 2022. – 96 p.
3. Bondar I. V. Industrial microbiology. Food and agrobiotechnology . / I. V. Bondar, V. M. Gulyaev. – Dneprodzerzhinsk: DSTU, 2004. – 280 p.
4. Butsenko L. M. Technologies of microbial synthesis of medicinal products: a textbook . / L. M. Butsenko , Yu. M. Penchuk , T. P. Pirog . – Kyiv: NUHT, 2010. – 323 p.
5. Galkin O. Yu. Biotechnological foundations of the creation of serological diagnostics of infectious and non-infectious diseases: monograph. / O. Yu. Galkin, V. P. Shirobokov, A. A. Grigorenko, O. M. Dugan , T. M. Lutsenko, A. G. Komar. – Kyiv: NTUU “KPI”, 2015. – 204 p.
6. Gerasimenko V. G. Biotechnology: textbook. / V. G. Gerasimenko, M. O. Gerasimenko, M. I. Tsvilikhovsky , I. Ya. Kotsyumbas , M. O. Zakharenko , A. F. Obrazhey , A. M. Holovko. – Kyiv: INCOS, 2006. – 647 p.
7. Golovei O. P. Asepsis of biotechnological production: lecture notes. / Compiled by: O. P. Golovei , V. M. Gulyaev. – Kamyanske : DSTU, 2017. – 140 p.
8. Gregirchak N. M. Immobilized enzymes and cells in biotechnology: lecture notes / N. M. Gregirchak , M. M. Antonyuk. – Kyiv: NUHT, 2011. – 59 p.
9. Digtyar S. V. Branches of modern biotechnology: textbook. / S. V. Digtyar, M. O. Yelizarov, O. V. Maznytska , O. O. Nykyforova, O. V. Novokhatko , A. V. Pasenko , O. A. Sakun . – Kremenichuk: PP Shcherbatykh O. V., 2021 – 126 p.
10. Ignatyuk O. A. Basic ecological principles and concepts: a textbook. / O. A. Ignatyuk . – Kyiv: Polytechnic, 2006. – 268 p.
11. Kaprelyants L. V. Theoretical foundations of biotechnology: textbook. / L. V. Kaprelyants . – Kharkiv: Gymnasium, 2020. – 291 p.
12. Kaprelyants L. V. Technical microbiology: textbook / L. V. Kaprelyants , L. M. Pylypenko, A. V. Yegorova – Kherson: Oldi -Plus, 2020. – 430 p.
13. Karlash Yu. V. Fundamentals of design of biotechnological productions: lecture notes / Yu. V. Karlash . – Kyiv: NUHT, 2013. – 143 p.
14. Klyachenko O. L. Bioengineering: textbook. / O. L. Klyachenko , M. D. Melnychuk, Yu. V. Kolomiets. – Vinnytsia: LLC “ Nilan -LTD”, 2015. – 458 p.
15. Klyachenko O. L. Ecological biotechnology: theory and practice: textbook. / O. L. Klyachenko , M. D. Melnychuk, T. V. Ivanova. – Vinnytsia: Nilan -LTD, 2015. – 254 p.
16. Kovalenko V. O. Technical microbiology: textbook / V. O. Kovalenko, I. V. Tsykhanovskaya , T. A. Lazareva, A. A. Koval, M. G. Ilyukha , O. V. Aleksandrov. – Kharkiv: Svit knig, 2013. – 679 p.

17. Fundamentals of biotechnology: teaching manual / O. O. Kravchenko, O. M. Savchuk, L. I. Ostapchenko ; Kyiv. National Taras Shevchenko University. - Kyiv: Kyiv University, 2019. - 269 p. : fig., table. - Bibliography : p. 267-269.
18. Medicinal products. Good manufacturing practice: guideline ST-N MOZU 42-4.0:2020. – Kyiv: Ministry of Health of Ukraine, 2020. – 356 p.
19. Melnychuk M. D. Plant biotechnology. / M. D. Melnychuk, T. V. Novak, V. O. Kunakh. – Kyiv: Polygraph Consulting , 2003. – 512 p.
20. Melnychuk M. D. General (industrial) biotechnology: a textbook / M. D. Melnychuk, O. L. Klyachenko , V. V. Boroday, Yu. V. Kolomiets. – Kyiv: FOP Korzun D.Yu., 2014. – 252 p.
21. Patyka T. I. Biotechnology of microbial synthesis: a textbook. / T. I. Patyka, M. V. Patyka. – Vinnytsia: LLC “ Nilan -LTD”, 2018. – 272 p.
22. Pirog T. P. General microbiology: textbook / T. P. Pirog . – Kyiv: NUHT, 2004. – 471 p.
23. Yulevych O. I. Biotechnology: a textbook. / O. I. Yulevych , S. I. Kovtun, M. I. Gil . – Mykolaiv: MDAU, 2012. – 476 p.
24. Yulevych O. I. General biotechnology: course of lectures. / O. I. Yulevych , O. I. Karateeva . – Mykolaiv: MNAU, 2022. – 107 p.
25. Biotechnology of microbial synthesis: a textbook. NUBiP of Ukraine. Patyka T.I., Patyka M.V. Vinnytsia: LLC " Nilan -LTD", 2018: 272.
26. Pirog T.P., Penchuk Y.M. Biochemical foundations of microbial synthesis. – K.: Lira-K, 2019. – 304 p.
27. Okafor N. Modern Industrial Microbiology and Biotechnology , 2017
28. McNeil V., Harvey LM Practical Fermentation Technology , 2008 .
29. Sidorov Y.I. Processes and apparatuses of the microbiological and pharmaceutical industry: a textbook. / Y.I.Sidorov , R.Y. Vlyazlo . V.P.Novikov . – Lviv: Intellect-West, 2008. – 736 p.
30. of medicines: a textbook for students of higher education : in 2 parts / V.I. Chuyeshov , E.V. Gladukh , I.V. Saiko and others - 2nd ed., revised and supplemented - Kh.: NFAU. - 2 parts - 638 p .
31. Pharmaceutical development of biotechnological and biological products. ST-N MOZU 42-8.1:2013. – Kyiv, 2013. – 20 p.

#### **Additional literature:**

32. Regulation (EC) No. 1394/2007 of the European parliament and of the council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC Regulation (EC) No. 726/2004. Available at : [http://ec.europa.eu/health/sites/health/files/files/eudralex/vol1/reg\\_2007\\_1394/reg\\_2007\\_1394\\_en.pdf](http://ec.europa.eu/health/sites/health/files/files/eudralex/vol1/reg_2007_1394/reg_2007_1394_en.pdf)
33. Pharmaceutical Encyclopedia / Chairman of the Editorial Board and author of the foreword V.P. Chernykh . – 3rd ed. – K.: “MORION”, 2016. – 1952 p.
34. Pharmaceutical and medical-biological aspects of drugs. Textbook / Edited by I.M. Pertsev . - Second edition. - Vinnytsia: NOVA KNYGA, 2007. - 728 p.
35. Janicki S., Sznitowska M., Zielinski W. Dostepnosc pharmaceutical and accessibility biology Lekow . - Warsaw , 2001.-242 p.
36. Biopharmaceuticals : Biochemistry and Biotechnology , 2nd Edition . - 2013. - 544
37. Encyclopedia of pharmaceutical technology . Third Edition . / Edited by J. Swarbrick . – New York , London : Informa healthcare , 2007 - 1171
38. Guideline on immunogenicity assessment of biotechnology-derived therapeutic proteins , EMEA/CHMP/BMWP/14327/2006. Available at : [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline).

39. Capes-Davis A. Freshney's Culture of Animal Cells : A Manual of Basic Technique and Specialized Applications / Amanda Capes-Davis , R. Ian Freshney . – 8th Edition . - [S. l.], 2021. – 832 p.
40. Tomorrow AL The natural functions of secondary metabolites / AL Demain , A. Fang // Advances in Biochemical Engineering / Biotechnology . - 2000. - Vol . 69. - P. 1-39.
41. Glick BR Molecular biotechnology . Principles and applications of recombinant DNA / BR Glick , JJ Pasternak . - 2nd ed . - Washington : ASM Press , 2002. - 760 p.
42. ICH Topic Q5A (R1) Quality of biotechnology products : viral safety evaluation of biotechnology products derived from cell lines of human or animal origin (CPMP/ICH/295/95). – London : European Medicines Agency , 1997. – 29 p.
43. Industrial biotechnology takes off in Europe / M. Lex // Science Progress . - 2008. - Vol . 91, No. 1. - P. 39-64.
44. Junter GA Immobilized Viable Cell Biocatalysts / GA Junter , T. Jouenne // Comprehensive Biotechnology . - 2011. - Vol . 2. - P. 491-505.
45. Marchev AS Large-Scale Production of Specialized Metabolites In Vitro Cultures / AS Marchev , ID Stoykova , MI Georgiev // Methods in Molecular Biology . - 2024. - Vol . 2827. – P. 303-322.

## Educational content

### 5. Methodology for mastering the academic discipline (educational component)

Lectures are held according to the classic scheme: in a visual form, the lecturer presents the relevant topic. During the lecture and after it, applicants have the opportunity to ask questions. A discussion between the lecturer and applicants can be held on individual issues of the lecture course - or to focus on important, fundamental and problematic points. Applicants can take notes during the lectures, and the presentation and/or lecture notes or its fragments are presented with the possibility of downloading on the Sikorsky distance learning platform.

Practical classes are aimed at acquiring deeper knowledge and skills on topics covered in the lecture course and independently mastered by applicants. The algorithm for conducting a practical class provides for the following: the teacher presents basic (strategic) theses within the framework of the relevant topic, applicants present mini-reports with pre-formed problem questions within the framework of the relevant topic, a discussion takes place between the speaker, other applicants and the teacher, which aims to clarify all the fundamental and applied issues of obtaining biomedical products using microbial synthesis. Applicants' reports involve the preparation of a corresponding analytical note in the form of a small review of literature in Ukrainian, as well as a visual presentation, which allows you to deepen your skills in written and oral scientific Ukrainian. If necessary, during practical classes, regulatory documents, methodological recommendations, etc., are studied (familiarized), as well as solving situational problems. At the last practical session, candidates complete a modular test (MCR) in the form of a test. Material that is useful for preparing for practical sessions is provided with the possibility of downloading on the Sikorsky distance learning platform.

Lectures and practical classes are held according to the schedule of classes <http://rozklad.kpi.ua/> according to the following scheme: on each topic, lectures are held first, and after their completion - practical classes. Detailed information is provided to applicants through appropriate communication channels, in particular through the platforms "Sikorsky" and "Campus ".

| No. of the company | Topic                                  | Program learning outcomes | Main tasks       |                     |
|--------------------|--|---------------------------|------------------|---------------------|
|                    |  |                           | Control West     | Term implementation |
| 1.                 | Fundamentals of microbial synthesis of | PRN -01, PRN-             | Practical work 1 | 1st week            |



| No. of the company | Topic   | Program learning outcomes  | Main tasks                        |                     |
|--------------------|---|----------------------------|-----------------------------------|---------------------|
|                    |   |                            | Control West                      | Term implementation |
|                    | <i>biomedical products.</i>   | 21                         |                                   |                     |
| 2.                 | <i>Microbial synthesis technologies for obtaining vitamins.</i>   | PRN -01, PRN-19            | Practical work 2                  | 2nd week            |
| 3.                 | <i>Obtaining amino acids through microbial synthesis.</i>   | PRN -01, PRN-02            | Practical work 3                  | 3rd week            |
| 4.                 | <i>Technology for producing recombinant proteins.</i>   | PRN -01, PRN-02, PRN-20    | Practical work 4                  | 4th week            |
| 5.                 | <i>Microbial synthesis technologies for enzyme production.</i>  | PRN -01, PRN-03            | Practical work 5                  | Week 5              |
| 6.                 | <i>Microbial synthesis of antibiotics.</i>  | PRN -02, PRN-05            | Practical work 6                  | Week 6              |
| 7.                 | <i>Technological aspects of obtaining probiotic preparations.</i>   | PRN -05, PRN-20            | Practical work 7                  | Week 7              |
| 8.                 | <i>Technological foundations of bacteriophage production.</i>   | PRN -01, PRN-02            | Practical work 8                  | Week 8              |
| 9.                 | <i>Microbial synthesis technologies for hormone production.</i>   | PRN -02, PRN-11            | Practical work 9                  | Week 9              |
| 10.                | <i>Packaging and storage of biomedical products. Primary and secondary packaging, stability, logistics.</i> | PRN -02, PRN-11            | Practical work 10                 | Week 10             |
| 11.                | <i>Standardization and quality control of biomedical products</i>   | PRN-11, PRN-20             | Practical work 11                 | Week 11             |
| 12.                | <i>Main areas of use of biomedical products obtained through microbial synthesis.</i>                       | PRN-04, PRN-11, PRN-20     | Practical work 12                 | 12th week           |
| 13.                | <i>Regulatory and legal regulation of biomedical products.</i>  | PRN-01, PRN-02, PRN-20     | Practical work 13                 | Week 13             |
| 14.                | <i>Modular test work</i>  |                            | Practical work 14                 |                     |
| 15.                | <i>Abstract</i>   | PRN-02<br>PRN-05<br>PRN-18 | <i>Designing and sending work</i> | Week 14             |

### 6. Independent work of the applicant

The total amount of independent work within the discipline is 66 hours, including:

- Studying lecture material – 7 hours;
- preparation for practical classes – 13 hours;
- preparation for the modular test (MCR) – 4 hours;
- writing an essay – 10 hours;
- preparation for the test – 6 hours;
- independent study of topics – 26 hours.

|            |   |                     |
|------------|---|---------------------|
| No. salary | the topics and issues that is taken out on its own processing and reference to the educational literature | Number hours of SRS |
|------------|---|---------------------|



| No. salary   | the topics and issues that is taken out on its own processing and reference to the educational literature   | Number hours of SRS |
|--------------|---|---------------------|
| 1            | <b>Topic 1. Metabolic engineering of microorganisms as a tool for increasing the yield of biomedical products.</b><br><u>List of questions for independent study:</u> Principles of control of metabolic pathways of microorganisms. Genetic and physiological approaches to optimizing the synthesis of target compounds . Impact metabolic regulation on productivity process .<br>[6, 26, 42]. | 6                   |
| 2            | <b>Topic 2. Bioreactors and cultivation modes in the production of biomedical products.</b><br><u>List of questions submitted for independent study:</u> Types of bioreactors ( batch , fed-batch , continuous ). Design features. Influence of cultivation mode on the growth of microorganisms and product accumulation.<br>[17, 30].   | 6                   |
| 3            | <b>Topic 3. Raw materials and nutrients media for microbial synthesis of biomedical products .</b><br><u>List of questions What is taken out on its own processing :</u> Sources carbon , nitrogen, micro and macro elements . Natural and synthetic Nutrient media . Quality requirements raw materials .<br>[20, 21, 23].   | 4                   |
| 4            | <b>Topic 4. Isolation and purification of microbial synthesis products.</b><br><u>List of questions to be submitted for independent study:</u> Methods of cell destruction, separation, extraction, concentration and purification of biomedical products. The impact of these stages on product quality.<br>[11, 16].  | 4                   |
| 5            | <b>Topic 5. Growth kinetics of microorganisms and mathematical modeling of biotechnological processes processes .</b><br><u>List of questions What is submitted for independent processing:</u> Cell growth models . Dependence growth rate from substrate concentrations . Balance equations bioprocesses .<br>[29].   | 4                   |
| 6            | <b>Topic 6. Biosafety in the production of biomedical products of microbial origin.</b><br><u>List of issues to be considered independently:</u> Biological safety levels. Contamination control. Protection of personnel and the environment.<br>[12, 25 ].  | 2                   |
| <b>Total</b> |   | 26                  |

## Policy and control

### 7. Academic discipline policy (educational component)

#### Violation of task deadlines and incentive points

Applicants may be awarded incentive points. The total amount of incentive points cannot exceed 10 points.

Incentive points are awarded for the following activities:

- creating infographics or other means of graphical interpretation of information for one of the course topics (5 points);
- participation in international or all-Ukrainian scientific conferences, congresses, etc. (on the subject of the academic discipline) (subject to publication of abstracts of reports) (5 points);
- preparation of a manuscript of a review or experimental article or participation in competitions (subject to winning a prize) on the topic of the academic discipline (10 points).

***Attending classes***

No penalty points are awarded for absence from classes. However, applicants are encouraged to attend classes, as they teach theoretical material and develop practical skills necessary for the thorough formation of relevant competencies .

The assessment system is focused on receiving points for student activity, as well as completing tasks that can develop practical skills and abilities.

***Missed assessment controls***

Assessment tests scheduled to be administered during class are conducted on a pre-determined day, which is announced to students during the first week of the educational process. Conducting such assessment tests on another day is permitted in cases of serious and/or force majeure circumstances.

In the event of the applicant's absence from a practical session where he is expected to give a presentation, such a presentation is either postponed to another practical session or replaced by the preparation of an analytical note on the relevant topic of 5-10 pages (in the case of special force majeure circumstances).

The result of the module test for an applicant who did not appear for the test is zero. In this case, the applicant has the opportunity to complete the module test at another time in agreement with the teacher. Postponement of the test date is possible only for good reasons (force majeure circumstances). Re-testing is not provided within the framework of the modular test.

***Ensuring objectivity in assessing applicants***

The objectivity of the assessment of applicants at all stages of mastering the discipline is ensured through the following mechanisms. First, the use of test forms for assessing knowledge. Second, detailed recommendations on the rating system for assessing learning outcomes (Section 8 of the Syllabus ). Third, the use by applicants and teachers of all possible communication tools that ensure the preservation of the history of communications (e-mail, social networks, messengers, etc.). Fourth, in case of disagreement with the assessment results, another teacher who has the appropriate professional competence and is appointed by the department for the current academic year may be involved in checking the written works of applicants. In the absence of a coordinated opinion of the teachers on the assessment of the applicant's work, the issue is brought to a meeting of the department, and the issue is resolved in accordance with the "Regulations on Appeals at Igor Sikorsky Kyiv Polytechnic Institute" <http://osvita.kpi.ua/node/182> .

***Procedure for appealing the results of assessment control measures***

On the day of the announcement of the results of the control measure, the applicant has the right to individually ask all the questions that interest him regarding the results of the control measure. If the applicant does not agree with the assessment, he has the right to file an appeal to the dean's office of the faculty, which is regulated by the "Regulations on Appeals at Igor Sikorsky Kyiv Polytechnic Institute" <https://osvita.kpi.ua/node/182>. In order to ensure the objectivity of the assessment of written works, they are checked by two teachers of the department (lecturer; teacher conducting practical classes, or other teacher who is competent in this discipline and determined by the department).

**Academic integrity**

When using copyrighted content, analytical research results, and/or other information, applicants must cite the source.

The policy and principles of academic integrity are defined in Section 3 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute" ( <https://kpi.ua/code> ). In the event of a need to check academic texts prepared for applicants for the presence of text borrowings, the applicant may contact the teacher or the responsible person of the department for checking academic texts.

**Norms of ethical behavior**

The norms of ethical behavior of applicants and employees are defined in Section 2 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute" ( <https://kpi.ua/code> ).

**Distance learning**

Online courses are provided in case of force majeure circumstances (in particular, quarantine measures) and for inclusive education of applicants with special needs.

**Inclusive learning**

The academic discipline is designed for students with special educational needs, but it should be taken into account that it places a heavy load on the visual apparatus. Depending on the special needs of students, distance learning may be used.

**8. Types of control and rating system for assessing learning outcomes (RSO)**

**Current control** . Current control includes work in lectures, practical and laboratory classes, completion of an individual assignment (abstract), as well as writing a modular test. The detailed distribution of points between types of classes is given in the table below.

| No           | Control measure           | %  | Weighted score | Number | Total      |
|--------------|---------------------------|----|----------------|--------|------------|
| 1            | Performing practical work | 60 | 6              | 10     | 60         |
| 2            | Abstract                  | 30 | 30             | 1      | 30         |
| 3            | Modular test work (MKR)   | 10 | 10             | 1      | 10         |
| <b>Total</b> |                           |    |                |        | <b>100</b> |

**Work in practical classes** . Work in practical classes involves short messages from the applicant on a predetermined question (10 messages for each applicant). Each message is evaluated at 6 points: full disclosure of the question - 6 points, the presence of minor omissions - 4.0-6.0 points, the presence of minor errors - 2.0-3.9 points, the presence of significant errors - 0.5-1.9 points.

**Modular test work (MCW)** is conducted in the form of a test, which is evaluated out of 10 points.

**The essay (individual independent task)** is evaluated at 30 points (20 points for the work itself and 10 for the defense): full disclosure of the issue – 20 points, the presence of minor omissions – 12.0-19.9 points, the presence of minor errors – 6.0-11.9 points, the presence of significant errors – 0.5-6.9 points.

The evaluation criteria for each test are necessarily announced to students. before publishing and completing tasks.

**Calendar control .**

Calendar control is carried out twice a semester (weeks 7-8 and 14-15) as a monitoring of the current status of implementation of the requirements of the syllabus and the rating assessment system.

|   |                           | First calendar control                | Second calendar control |
|---|---------------------------|---------------------------------------|-------------------------|
| Calendar control period                   |                           | 7-8 weeks                             | 14-15 weeks             |
| Conditions for obtaining a calendar check | Current control           | $\geq 50\%$ of maximum current rating |                         |
|   | Performing practical work | 15                                    | 30                      |
|   | Abstract                  | -                                     | 10                      |
|   | MKR                       | -                                     | -                       |
| Maximum current rating                    |                           | 15                                    | 40                      |

**The maximum semester rating** of the applicant: 60 points (10 reports in practical classes) + 10 points (MKR) + 30 (essay) = 100 points.

**Semester control:** The admission conditions for semester control are given in the table.

| Mandatory condition for admission to the test |                         |                                       |
|---|-------------------------|---------------------------------------|
| 1   | Current rating          | $RD \geq 40$                          |
| 2   | Current control measure | Modular test work                     |
| 3   | Practical classes       | Performing practical tasks            |
| 4   | Abstract                | Execution and defense of the abstract |

At the last scheduled class, students are informed of their current rating, indicating whether they are allowed/not allowed to take the test. If the semester rating is 60 points or higher, the applicant can receive the test automatically. In case of disagreement or a rating of less than 60 points, the test is taken in the form of a test.

Table of correspondence of rating points to grades on the university scale :

| Number of points             | Rating           |
|------------------------------|------------------|
| 100-95                       | Perfectly        |
| 94-85                        | Very good        |
| 84-75                        | Good             |
| 74-65                        | Satisfactorily   |
| 64-60                        | Enough           |
| <60                          | Unsatisfactorily |
| Admission conditions not met | Not allowed      |

### 9. Additional information on the discipline (educational component)

The questions submitted for semester control correspond to the topics of lectures and practical classes.

Recognition of learning outcomes acquired in non-formal/ informal education is carried out in accordance with the "Temporary Regulation on the Procedure for Recognition of Learning Outcomes Acquired by Students of Igor Sikorsky Kyiv Polytechnic Institute in Non-formal/ Informal Education" (<https://osvita.kpi.ua/node/119>).

**The working program of the academic discipline ( syllabus ):****Compiled by:** Ph.D. , Assoc. Lutsenko T.M.**Approved** by the TMBI Department (Minutes No. 1 dated 08/28/2023)**Approved** by the methodological committee of the faculty/NII (minutes No. 1 dated 09/1/2023)