National Technical University of Ukraine
"Igor Sikorsky Kyiv Politechnic Institute

Department of Translational
Medical Bioengineering

SPECIALIZED EQUIPMENT
IN REGENERATIVE AND BIOPHARMACEUTICAL ENGINEERING

Syllabus of the Course

Course Information

Level of higher education	***The first (bachelor)***
Knowledge branch	*16- Chemical engineering and bioengineering*
Speciality	*163 Biomedical Engineering*
Educational programme	*Regenerative and Biopharmaceutical Engineering, Medical engineering*
Course Status	*Elective*
Forms of Education	*full-time*
Year / Semester	*3rd year, Spring semester*
Course Volume / Credits	*4 ECTS (Lectures: 26 hours, Practical classes: 28 hours, Self-study: 66 hours)*
Final control measure form	*Exam*
Розклад занять	*https://schedule.kpi.ua*
Language of instruction	*Ukrainian*
Course	Lectures: Assistant of the Department, Bertosh Nataliya Volodymyrivna (@Bertosh_Natali) Practical classes: Assistant of the Department, Bertosh Nataliya Volodymyrivna (@Bertosh_Natali)
Course platform	Google classroom

Course Syllabus

1. Description of the Course, Its Purpose, Subject of Study, and Learning Outcomes

What will be studied?

During the study of this educational component, students acquire in-depth knowledge and skills related to the equipment support of regenerative and biopharmaceutical engineering.

The discipline focuses on specialized equipment used to implement processes for the production of biomaterials, medical devices, and pharmaceutical products at various stages of the technological cycle. This includes methods for selecting equipment according to its technological purpose, approaches to equipment design and calculation, as well as the features of different equipment designs within the same technological group.

Why is this course important and worth studying?

One of the key tasks of an engineer in the fields of biomedical engineering and biopharmacy is the ability to design technologies for the production of biomaterials, medical devices, and pharmaceutical products. An integral part of this task is the selection of appropriate equipment for the implementation of technological processes, which is impossible without sufficient knowledge of the equipment used in the industry.

What can students learn?

Knowledge:

- *processes and equipment in biopharmaceutical engineering;*

- *equipment for the implementation of technological processes in pharmaceutical production;*
- *equipment for the manufacture of medical devices;*
- *equipment for auxiliary operations and preparatory processes;*
- *equipment for separation and purification;*
- *equipment for obtaining various dosage forms;*
- *equipment for packaging and filling of finished products.*

Skills:

- *to distinguish technological processes depending on the target product obtained;*
- *to select technological equipment for the implementation of processes based on their specific characteristics;*
- *to calculate technological equipment according to specified process parameters;*
- *to integrate equipment into technological production lines.*

How can the acquired knowledge and skills be applied?

The acquired knowledge and skills can be applied to the study and use of various analytical methods and tools, as well as to the integrated application of engineering approaches for the development, design, and implementation of equipment required for biopharmaceutical processes.

Program Competencies *(in accordance with the Educational Program "Regenerative and Biopharmaceutical Engineering")*

General Competencies:

GC 05 – Ability to conduct research at an appropriate scientific level.

Professional (Specialized) Competencies*:*

PC 03 – Ability to study and apply new methods and tools of analysis, modeling, design, and optimization of medical devices and systems.

PC 06 – Ability to effectively use tools and methods for analysis, design, calculation, and testing in the development of biomedical products and services.

PC 11 – Ability to analyze biological objects of different levels of organization (acaryotes, prokaryotes, eukaryotes: human and animal cells and tissues) and their individual components (proteins, nucleic acids, etc.) using biological, chemical, physical, and mathematical methods.

PC 12 – Ability to design and organize production processes involving biological objects of different levels of organization (biological agents) for obtaining biosynthesis or biotransformation products of health-promoting, preventive, or therapeutic (biopharmaceutical) purpose, or for the development of biomedical technologies.

PC 13 – Ability to integrate engineering and biological methods for the development, design, and implementation of regenerative and biopharmaceutical technologies, as well as the engineering foundations of translational medicine.

Program Learning Outcomes*:*

PLO 01 – Knowledge of the organization and principles of functioning of biological objects and their individual components under in vivo and in vitro conditions, as well as methods for their study and evaluation (biological, chemical, physical, and mathematical).

PLO 04 – Ability to apply knowledge of mathematics, physics and biophysics, bioengineering, chemistry, engineering graphics, mechanics, strength of materials, gas and liquid properties, electronics,

informatics, signal and image acquisition and analysis, automatic control, systems analysis, and decision-making methods at a level necessary to solve biomedical engineering problems.

PLO 19 – Ability to apply knowledge of chemistry and bioengineering to create, synthesize, and use artificial biotechnical and biological objects.

PLO 20 – Ability to organize bioengineering processes depending on the characteristics of the biological object used and/or the final product.

***Programme Competencies** (in accordance with the Educational Program "Medical Engineering")*

General Competencies:

GC 05 Ability to conduct research at an appropriate level.

Professional Competencies:

PC 03 Ability to study and apply new methods and tools of analysis, modeling, design, and optimization of medical devices and systems.

PC 04 Ability to ensure the technical and functional characteristics of systems and devices used in medicine and biology (for prevention, diagnosis, treatment, and rehabilitation).

PC 06 Ability to effectively use tools and methods for analysis, design, calculation, and testing in the development of biomedical products and services.

PC 09 Ability to identify, formulate, and solve engineering problems related to interactions between living and non-living systems.

Programme Learning Outcomes

PLO 02 Formulate logical conclusions and well-grounded recommendations regarding the evaluation, operation, and implementation of biotechnical, medical-technical, and bioengineering devices and methods.

PLO 04 Apply provisions of regulatory and technical documentation governing product certification and production attestation procedures.

PLO 08 Understand theoretical and practical approaches to the development and management of medical equipment and medical technology.

2. Prerequisites and Postrequisites of the Course (Place in the structural and logical scheme of the educational program)

The course belongs to the elective educational components of the professional training cycle.

There are no mandatory prerequisites for starting this course; however, prior completion of the compulsory educational component "Biotechnology and Bioengineering" and/or the elective course "Technologies of Biomedical Products" is recommended.

3. Course Content

Lecture Topics

№	Тема	Заняття	Тиждень вивчення
1	***Topic 1. Specialized Equipment Used in Regenerative and Biopharmaceutical Engineering.*** *Features of technological processes in regenerative and biopharmaceutical engineering. Classification of processes in*	*Lecture 1, Practical class 1*	*1*

	regenerative and biopharmaceutical engineering. Classification of equipment for the implementation of technological processes		
Section 1. Equipment for Auxiliary Technological Processes.			
2	***Topic 2. Air Preparation.*** *Methods of air preparation depending on its industrial application. Ventilation systems. Air preparation equipment: fans, air heaters, coarse and fine filters. Air preparation in laboratories: laminar flow cabinets, biological safety cabinets, fume hoods.*	*Lecture 2, Practical class 1*	*2*
3	***Topic 3. Water Preparation.*** *Methods of water preparation for various technological equipment. Industrial-scale water preparation equipment: filters (mechanical, ion-exchange, membrane, etc.). Water preparation in laboratory conditions: distillers. Water transportation systems. Pumps..*	*Lecture 3, Practical class 1*	*3*
4	***Topic 4. Mechanical Processes.*** *Equipment for size reduction processes. Sieving of bulk materials. Mixing of solid materials. Mechanisms for solid material handling. Feeding devices in bioengineering. Granulation of bulk products.*	*Lecture 4, Practical class 2*	*4*
Section 2. Equipment for Main Technological Processes			
5	***Topic 5. 3D Printing Technologies.*** *Application of 3D printing and 3D bioprinting for regenerative medicine. 3D printing methods. Bioinks. Equipment for 3D printing processes.*	*Lecture 5, Practical class 2*	*5*
6	***Topic 6. Cultivation Equipment.*** *Equipment for cultivation of plant and animal cell cultures at industrial and laboratory scales. Equipment for hybridoma technologies and immobilized cultures. Laboratory equipment for microorganism cultivation.*	*Lecture 6, Practical class 2*	*6*
7	***Topic 7. Laboratory Determination of Biological Substances.*** *Methods for determining immunological parameters of the human body. Equipment for ELISA diagnostics. Methods for DNA and RNA analysis and genome decoding. Equipment for PCR diagnostics and DNA sequencing.*	*Lecture 7, Practical class 3*	*7*
8	***Topic 8. Microprocessor Control in Manufacturing.*** *Bacteriological and microbiological analyzers. Screening equipment. Systems for automation and identification of microorganisms. Systems for microscopy and microorganism counting.*	*Lectures 8–9, Practical class 3*	*8*
Section 3. Equipment for Target Product Separation and Purification			
9	***Topic 9. Artificial Cooling.*** *Cooling to low temperatures: moderate and deep cooling. Sublimation. Equipment for low-temperature cooling: low-temperature refrigerators, freezers, Dewar vessels, freeze dryers, etc.*	*Lecture 10, Practical class 4*	*10*
10	***Topic 10. Chromatography.*** *Application of chromatography for target product separation and purification. Types of chromatography. Sorbents for chromatographic separation. Equipment for chromatographic processes at industrial and laboratory scales.*	*Lecture 11, Practical class 4*	*11*
11	***Topic 11. Membrane Separation Methods.*** *Membrane separation methods for liquids: microfiltration, ultrafiltration, reverse osmosis, membrane dialysis. Semipermeable*	*Lecture 12, Practical class 4*	*12*

	membranes. Equipment for membrane processes.		
12	***Тема 12. Topic 12. Production of Finished Products.*** *Dosage forms of target products: solid, liquid, and semi-solid. Equipment for obtaining various dosage forms of finished products. Production of sterile preparations. Equipment for packaging and labeling.*	*Lecture 13, Practical class 5*	*13*

Practical Classes Topics

№	***Practical Work***
1	*Selection of Equipment for Conducting a Technological Process*
2	*Calculation of Equipment for Conducting a Technological Process*
3	*Modular Test Work. Part 1*
4	*Development of a Schematic Diagram of Equipment*
5	*Calculation and Selection of Equipment for Product Purification*
6	*Preparation of the Final Product*
7	*Modular Test Work. Part 2*
8	*Final Assessment / Credit*

4. Learning Materials and Resources

Core Recommended Literature:

1. Стасевич М.В., Милянич., А.О., Стрельников Л.С., Крутських Т.В, Бучкевич І.Р., Зайцев О.І Гузьова., І.О., Стрілець О.П., Гладух Є.В., Новіков В.П. Технологічне обладнання біотехнологічної і фармацевтичної промисловості: підручник [для вищ, навч. закл.] - Львів : Видавництво "Новий світ-2000", 2019. - 409 с.

2. Сухенко Ю.Г., Жеплінська М.М., Муштрук М.М. Процеси і апарати харчових виробництв. Лабораторний практикум: [Навчальний посібник] / За ред. проф. Ю.Г. Сухенка. – К. ЦП «КОМПРИНТ», 2018. – 234 с.

3. Данилов І.П., Самойленко С.І. Апарати мікробіологічної промисловості — Харків: НТУ «ХПІ», 2008.

4. О. І. Черевко, А. М. Поперечний Ч-46 Процеси і апарати харчових виробництв: підручник / О. І. Черевко, А. М. Поперечний. — 2-е видання, доп. та випр. — Х.: Світ Книг, 2014. — 495 с.

Additional Literature:

5. Новіков В.П., Сидоров Ю.І., Чуєшов В.І. Процеси і апарати хіміко-фармацевтичної промисловості.Навч посібник для фарм і хім спец. ВНЗ: [Навчальний посібник] / В 3 томах - Вінниця; "Нова книга", 2009. - 816 с.

6. Стасевич М.В., Милянич., І.О., Гузьова., І.О., Бучкевич І.Р., Мусянович Р.Я., Гладух Є.В., Зайцев О.І Крутських Т.В, Стрілець О.П., Стрельников Л.С., Новіков В.П. Обладнання технологічних процесів фармацевтичних та біотехнологічної виробництв: навчальний посібник для студ. напрямку «Фармація і Біотехнолог» - Вінниця: «Нова книга», 2012. - 408 с.

7. Технологія ліків промислового виробництва: підручник для студ. вищ. навч. закл. : в 2-х ч. / В. І. Чуєшов, Є.В. Гладух, І. В. Сайко та ін. - 2-е вид., перероб. і доп. - Х. : НФаУ : Оригінал, 2012.

8. Сидоров Ю.І., Влязло Р.Й., Новиков В.П. Процеси і апарати мікробіологічної промисловості. Технічні розрахунки. Приклади і задачі. Основи проектування виробництв. Навч. посібник у 3 ч. – 4.І. Ферментація – Львів, Видавництво Національного університету «Львівська політехніка», 2004 – 240 с.

9. Сидоров Ю.І., Влязло Р.Й., Новиков В.П. Процеси і апарати мікробіологічної промисловості. Технічні розрахунки. Приклади і задачі. Основи проектування виробництв. Навч. посібник у 3 ч. –

4.II. Оброблення культуральних рідин – Львів, Видавництво Національного університету «Львівська політехніка», 2004 – 296 с.

10. 5. Кулявець В.Р, Беспалова О.Я. Види біопринтерів для друку органів. УДК 004.386.6 URL https://ela.kpi.ua/server/api/core/bitstreams/5ca9eb58-f171-40e1-97be-916e50fcecf0/content

11. Інтернет джерело: URL https://nauka.ua/card/shcho-take-biodruk-vin-shozhij-na-zvichajnij-druk-na-paperi-yaki-chornila-vin-vikoristovuye-ta-dlya-chogo

12. Моделювання процесів мембранного розділення: навчальний посібник [Електронний ресурс]: навч.посіб. Для студ. спеціальності 133 «Галузеве машинобудування», спеціалізації «Інжиніринг, комп'ютерне моделювання та проектування обладнання хімічних і нафтопереробних виробництв» / КПІ ім. Ігоря Сікорського ; уклад.: С.В. Гулієнко. – Електронні текстові данні (1 файл: 3,17 Мбайт). – Київ :

КПІ ім. Ігоря Сікорського, 2017. – 166 с.

13.Моделювання і оптимальне керування процесів мембранної дистиляції [Електронний ресурс] :монографія /Л.Р. Ладієва, О.А. Жулинський, Р.М.Дубік. – Київ: КПІ ім. Ігоря Сікорського. 2022, - 171 с.m3.Конспект лекцій з курсу „Процеси та апарати хімічної технології" , розділ «Мембранні процеси» для студентів II-V курсів усіх спеціальностей / Укл.: О.О. Тертишний, О.В. Тертишна. – Дніпропетровськ: ДВНЗ УДХТУ, 2011.– 79

14.Коваленко І.В. К – Пакувальне обладнання. Конспект лекцій: Навч. посіб. з курсу для студ. спец. 7.090223 – «Машини і технології паковання»/І.В. Коваленко. – К.: 2014. – с.: іл. бібліогр.: с. 211.

Learning Content

5. Methodology for Mastering the Course (Educational Component)

Organization of Lectures

Lectures are conducted using pre-prepared lecture materials, which are studied by students and presented in the form of reports on the lecture topics, using visual aids. During and after the lectures, students and the instructor have the opportunity to ask questions and discuss the presented material. Specific topics within the lecture course may include discussions to emphasize key, fundamental, and problematic aspects of the subject. Students are encouraged to take notes during lectures. Presentations and/or lecture notes (or their fragments) are made available for download on the distance learning platform "Sikorsky".

Organization of Practical Classes

Practical classes are aimed at deepening theoretical knowledge and developing practical skills related to the topics covered in the lecture course and studied independently by students.

Conducting a practical class involves the instructor presenting the basic (strategic) principles of the corresponding topic and reviewing typical examples. Students complete practical tasks using applied approaches to implement technological processes relevant to the session's theme.

Within each practical session, students are assigned individual tasks to be completed independently, with the possibility of consulting the instructor on fundamental and applied aspects of the task. These tasks involve analyzing problem situations related to the lecture material. If necessary, practical classes include familiarization with regulatory documents, methodological guidelines, and solving situational problems.

Materials for preparing for practical classes are available for download on the "Sikorsky" distance learning platform. Students present the results of individual practical tasks in the form of a report, justifying the decisions made.

During weeks 7 and 13, students complete a Modular Test Work (MTW), divided into two parts, each lasting 45 minutes. The MTW consists of open-ended questions and includes both theoretical and practical tasks.

Lectures and practical classes are conducted according to the class schedule: https://schedule.kpi.ua . The typical sequence is lectures first, followed by practical classes. Detailed information is communicated to students through relevant channels, including the "Sikorsky" platform, the electronic "Campus", and the Telegram chat.

6. Independent Work of the Student

- *Preparation for lectures and computer-based practical classes; participation in discussions of relevant topics; self-assessment of acquired knowledge; study of recommended sources and literature; preparation for module control assessment and individual assignments; final credit assessment, etc.*

№ з/п	*Titles of Topics and Issues Assigned for Independent Study and References*	*Hours*
1	***Topic 1. Specialized Equipment in Regenerative and Biopharmaceutical Engineering*** ***Issues for independent study:*** *Features of technological processes, critical stages, and comparative characteristics of modern specialized equipment for auxiliary technological processes.* *[1,C.9-13].*	***2***
2	***Topic 2. Air Preparation and Ventilation Systems*** ***Issues for independent study: Technological requirements for air in laboratory and industrial processes; comparative characteristics of modern ventilation systems and equipment ensuring sterility.*** *[1,C.20-13.].*	***3***
3	***Topic 3. Water Preparation and Pumps***	***3***

	Issues for independent study: *Methods of water preparation for laboratory and industrial processes; comparative characteristics of pumping equipment; development of water supply and purification schemes with justification of equipment selection and evaluation of energy efficiency and reliability.* *[3,C.28-30;4,C.71-83.].*	
4	***Topic 4. Mechanical Processes: Grinding, Sieving, Mixing, Granulation*** ***Issues for independent study:*** Comparative characteristics of modern equipment for mechanical processes; development of mixing and granulation schemes for a specific product; evaluation of the influence of equipment parameters on product quality and homogeneity. *[1,C 98-114; 2,C.14-20]*	***3***
5	***Тема 5. Topic 5. 3D Printing and 3D Bioprinting Technologies.*** ***Issues for independent study: Modern 3D printing technologies in regenerative medicine; comparative evaluation of their effectiveness for tissue constructs; critical equipment parameters ensuring biomaterial quality.*** *[10; 11.].*	***4***
6	***Topic 6. Cultivation Equipment*** ***Issues for independent study: Cultivation schemes; justification of equipment selection; influence of technological parameters on growth and productivity of cultures.*** *[3, C.66-71.].*	***4***
7	***Topic 7. Laboratory Determination of Biological Substances*** ***Issues for independent study: Methods for determination of immunological indicators, nucleic acids, and genome sequencing; comparative analysis of modern laboratory equipment for ELISA and PCR; key parameters ensuring accuracy and reliability of measurements; review of innovative solutions in patents for laboratory systems.*** *[5,C.25-35;11,C.40-47].*	***4***

8	***Topic 8. Microprocessor Control and Automation Systems*** ***Issues for independent study: Automation and identification systems for microorganisms in production; comparative analysis of modern bacteriological and microbiological analyzers; application of microprocessor control to improve technological process efficiency..*** *[1,C.359-391.]*	***4***
9	***Topic 9. Artificial Cooling and Sublimation*** ***Issues for independent study: Operating principles and comparative analysis of equipment for moderate and deep cooling and sublimation; development of cooling and storage schemes with justification of equipment selection; evaluation of energy efficiency and reliability of modern refrigerators, freezers, and freeze dryers.*** *[1, C.334-350;4,C.297-316.]*	***3***
10	***Topic 10. Chromatography and Sorbents*** ***Issues for independent study: Types of chromatography and their application for target product isolation; characteristics of modern sorbents; development of chromatographic process schemes for laboratory and industrial scales; comparative efficiency analysis of chromatographic equipment.*** *[3,C.143-150.]*	***4***
11	***Topic 11. Membrane Separation Methods*** ***Issues for independent study: Microfiltration, ultrafiltration, reverse osmosis, and membrane dialysis methods; characteristics of modern membrane equipment; membrane separation schemes for practical processes; comparative analysis of patents and innovative technological solutions in membrane processes.*** *[12,C.24-54;13, C.15-17.]*	***4***

12	***Topic 12. Production of Finished Products and Packaging*** ***Issues for independent study: Technologies for producing solid, liquid, and semi-solid products; equipment for manufacturing sterile preparations; development of packaging and labeling schemes with justification of equipment selection; review of patents and innovative packaging solutions.*** *[14,C.24-30;C.98-117.]*	***2***
13	***Individual Assignment*** ***Issues for independent study: Selection and calculation of equipment for a technological process; development of a process flow diagram and justification of parameters; analysis and optimization of technological processes; preparation of finished products under laboratory conditions.*** *[1-14.]*	***15***
14	***Підготовка до модульної контрольної роботи (МКР)*** ***Перелік питань що виноситься на самостійне опрацювання.*** *Систематизація знань з попередніх тем; аналіз прикладів розрахунків та схем обладнання; розробка власних варіантів завдань для самоперевірки.* *[1-14.]*	***5***
15	***Preparation for Module Control Assessment (MCA)*** ***Issues for independent study: Systematization of knowledge from previous topics; analysis of calculation examples and equipment flow diagrams; development of individual self-assessment tasks.*** *[1-14.]*	***6***
Total		*66*

Individual Assignment

The curriculum requires the completion of a report. The report is prepared as a presentation on a lecture topic and is presented during a classroom session.

Reports are prepared by groups of 2–3 students, with group composition determined by the instructor during the first class.

The report consists of:

- *A multimedia presentation;*
- *A textual commentary to be voiced during the report;*
- *Answers to questions related to the topic of the report.*

The content of the report must correspond to the lecture topic and cover its main points.

Requirements for the Multimedia Presentation

The presentation should include the following sections:

Title slide, which must include:

- *Course title;*
- *Lecture topic;*
- *Names of the presenters (with the percentage of each student's contribution and the list of tasks performed indicated in parentheses).*
- *Lecture plan (main points to be covered in the report).*
- *Introduction (justification of the topic's relevance).*
- *Main part — slides summarizing the main material according to the lecture plan, using illustrative materials.*
- *Conclusions.*
- *List of references.*

Deadlines

- *The assignment is issued to students in week 2 of the course.*
- *Students are given 4 weeks to complete the individual assignment.*
- *The report is submitted in week 6, after which it is presented during the lecture session according to the educational schedule.*

Assessment of the Individual Assignment

The grade for the report is formed based on the following components:

- *Visual quality of the multimedia presentation and its correspondence to the report content — 30%;*
- *Completeness of topic coverage and alignment with the lecture plan — 60%;*
- *Answers to questions — 10%.*

After the report, the instructor provides feedback on its strengths, weaknesses, and the overall quality of the individual assignment. The contribution of each student to the group result is considered in the assessment. The percentage of personal contribution is determined by the group members and indicated on the title slide of the presentation.

Course Policy

7. Course Policy and Assessment Control

Course Policy

Assessment of learning outcomes is conducted according to the principles of transparency, objectivity, and academic integrity, as defined by higher education standards and regulatory documents of Igor Sikorsky KPI.

Incentive and Penalty Points

Students may be awarded incentive or penalty points, with a total not exceeding 10 points.

Incentive points may be awarded for:

- *Participation in international or national scientific conferences related to the course topic, provided that abstracts are published — 5 points;*
- *Preparation of a manuscript for a scientific article (review or experimental) or participation in professional competitions — up to 10 points;*
- *Active and consistent participation in practical classes — up to 10 points.*

Penalty points may be applied for:

- *Missing deadlines for practical assignments — -1 point per week of delay;*
- *Completing the modular test work outside the scheduled practical session without a valid reason — -1 point.*

Attendance

No penalty points are applied for missing lectures or practical classes.

However, attendance is recommended, as it ensures the assimilation of theoretical material and the development of practical competencies required by the educational program.

Assessment Events and Missed Sessions

Assessment activities are conducted according to the schedule announced at the beginning of the semester.

In case of absence from the modular test work without a valid reason, the result is 0 points.

Completing assessment tasks at another time is allowed only in the presence of documented valid or force majeure reasons and with the instructor's consent.

Retaking modular test works or repeating individual assignments is not provided.

Ensuring Objectivity in Assessment

Objectivity in assessing learning outcomes is ensured through:

- *Use of individual assignments formulated according to the educational program;*
- *Application of clear assessment criteria and rating systems;*
- *Use of official communication channels with a preserved history of interactions;*
- *Possibility of having written works checked by another instructor as decided by the department.*

In case of disputes, assessment is conducted in accordance with the "Regulations on Appeals at Igor Sikorsky KPI": http://osvita.kpi.ua/node/182.

Appeal Procedure

Students have the right to receive reasoned explanations regarding the grade received.

If the student disagrees with the assessment results, they may appeal to the faculty dean's office following the established procedure: http://osvita.kpi.ua/node/182.

Academic Integrity

Students are required to adhere to the principles of academic integrity in all types of academic work and must provide proper references for all sources used.

The academic integrity policy is regulated by the Code of Honor of Igor Sikorsky KPI: https://kpi.ua/code. Work may be checked for textual plagiarism if necessary.

Ethical Standards

Participants in the educational process must adhere to ethical standards according to the Code of Honor of Igor Sikorsky KPI: https://kpi.ua/code.

Distance Learning

Online courses are provided in cases of force majeure (e.g., quarantine measures) and for inclusive education of students with special needs.

Inclusive Education

This course is designed for students with special educational needs; however, it requires significant visual engagement. Depending on individual needs, distance learning may be used

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8. Types of Assessment and Rating System of Learning Outcomes (RSLO)

Current assessment evaluates students' activity and performance during lectures and practical classes, completion of the Individual Student Assignment (ISA), as well as performance in the Modular Test Work (MTW). A detailed distribution of points for different types of academic activities is presented in the table below.

№	Assessment Activity	%	Weighted Points	Quantity	Total
1	Completion of practical tasks	40	8	5	40
2	Completion of ISA	30	30	1	30
3	Modular Test Work (MTW)	30	30	1	30
Total					100

1. Completion of Practical Tasks

The maximum score for practical tasks is 40 points. Students complete 5 practical tasks independently and present them orally during the session. Each task is graded out of 8 points as follows:

- *Complete and thorough answer — 8 points*
- *Minor error — 7 points*
- *Minor error and incomplete answer — 6.5 points*
- *Significant error — 3.75 points*
- *No answer — 0 points*

2. Completion of Individual Student Assignment (ISA)

The maximum score for the ISA is 30 points. Students prepare 1 report, evaluated based on the multimedia presentation, oral presentation, and answers to questions.

Multimedia presentation — maximum 10 points:

- *Complete and thorough — 10*
- *Minor error — 7.5*
- *Minor error and incomplete — 5*
- *Significant error — 2.5*
- *No answer — 0*

Oral presentation — maximum 15 points:

- *Complete and thorough — 15*
- *Minor error — 13.5*
- *Minor error and incomplete — 10*
- *Significant error — 5*

- *No answer — 0*

Answering questions — maximum 5 points:

- *Complete and thorough — 5*
- *Minor error — 3.75*
- *Minor error and incomplete — 2.5*
- *Significant error — 1.25*
- *No answer — 0*

3. Modular Test Work (MTW)

The maximum score for the MTW is 30 points. The MTW consists of two parts, each graded 15 points, including 3 open theoretical questions. Each question is graded out of 5 points:

- *Complete and thorough answer — 5*
- *Minor error — 4.75*
- *Minor error and incomplete — 3.5*
- *Significant error — 1.25*
- *No answer — 0*

Assessment criteria for each activity are announced to students before the tasks are assigned.

Calendar Assessment

Calendar assessment is conducted twice per semester (weeks 7–8 and weeks 14–15) as a monitoring tool for compliance with syllabus requirements and the rating system..

Calendar Assessment Period		*First Calendar Control*	*Second Calendar Control*
		Weeks 7-8	*Weeks 14-15*
Conditions for certification	*Current assessment ≥ 50% of maximum current rating*		
	Completion of practical tasks	*16*	*40*
	Completion of ISA	*0*	*30*
	Modular Test Work	*15*	*30*
Maximum current rating			*100*

Semester Assessment

Semester assessment is conducted in the form of a final credit. Conditions for admission to the final assessment are listed below:.

Mandatory conditions for admission		
1	*Current rating*	*RD ≥ 36*
2	*Completion of current assessment*	*Modular Test Work*
3	*Practical classes*	*Completion of practical tasks*
4	*Individual Student Assignment*	*Completion of ISA*

Automatic passing is possible. The overall rating for the semester consists of the points accumulated by the student throughout the semester (100% of the total rating).

The final credit is conducted during the last scheduled class, where students are informed of their current rating and final grade.

If a student disagrees with the final grade or has a rating below 60 points, a final oral test is required. In this case, the points accumulated during the semester are annulled, and the credit is awarded solely based on the final oral test results.

Final Credit Test

Conducted orally during the last class of the semester.
The credit test consists of 5 theoretical questions, each graded out of 20 points:
Complete and thorough answer — 20 points
Minor error — 15 points
Minor error and incomplete answer — 10 points
Significant error — 5 points
No answer — 0 points

Таблиця відповідності рейтингових балів оцінкам за університетською шкалою:

Кількість балів	*Оцінка*
100-95	Відмінно
94-85	Дуже добре
84-75	Добре
74-65	Задовільно
64-60	Достатньо
Менше 60	Незадовільно
Не виконані умови допуску	Не допущено

9. Additional Information on the Course (Educational Component)

Topic 1. Specialized Equipment in Regenerative and Biopharmaceutical Engineering

What does regenerative and biopharmaceutical engineering study?
Features of technological processes in regenerative and biopharmaceutical engineering.
Classification of technological processes in biopharmaceutical production.
Main groups of equipment used in technological processes.
Differences between auxiliary and main technological equipment.
Examples of specialized equipment for biomedical production.

Topic 2. Air Preparation and Ventilation

The role of air preparation in biopharmaceutical production.
Main stages of air preparation.
Classification of ventilation systems.
Purpose and operating principles of fans.
Types of air heaters and their applications.
Coarse, fine, and HEPA filters.
Operating principles of laminar flow cabinets.
Differences between laminar flow cabinets and biosafety cabinets.
Air quality requirements in laboratory rooms.

Topic 3. Water Preparation

Requirements for water in different technological processes.
Main methods of water preparation.
Principles of mechanical filtration.
Ion-exchange water purification methods.
Membrane methods of water preparation.
Water distillation: principles and applications.
Types of pumps for water transport.
Main parameters of pumping equipment.
Piping systems for water transportation.

Topic 4. Mechanical Processes

Classification of mechanical processes in industry.
Equipment for material grinding.
Operating principles of sieving equipment.
Equipment for mixing solid materials.
Mechanisms for bulk material transport.
Purpose of feeding devices in bioengineering.
Granulation processes and related equipment.

Topic 5. 3D Printing and 3D Bioprinting Technologies

Principles of 3D printing.
Main 3D printing methods.
Features of 3D bioprinting.
Requirements for bioinks.
Main components of a 3D printer.
Applications of 3D bioprinting in regenerative medicine.
Advantages and limitations of 3D bioprinting.

Topic 6. Cultivation Equipment

Purpose of cultivation processes.
Equipment for cell culture growth.
Bioreactors: classification and operating principles.
Equipment for microorganism cultivation.
Features of hybrid technologies.
Immobilized cultures: advantages and disadvantages.
Laboratory equipment for cultivation.

Topic 7. Laboratory Determination of Biological Substances

Main methods of immunological diagnostics.
Principles of ELISA diagnostics.
Main components of an ELISA analyzer.
Methods for DNA and RNA determination.
Principles of PCR diagnostics.
Equipment for DNA sequencing.
Comparison of ELISA and PCR methods.

Topic 8. Microprocessor Control and Automation

Role of microprocessor control in bioproduction.
Purpose of bacteriological analyzers.
Systems for automatic microorganism identification.
Screening equipment.
Automated microscopy systems.
Methods for microorganism counting.
Advantages of automated control systems.

Topic 9. Artificial Cooling and Sublimation

Purpose of artificial cooling.
Types of cooling according to temperature regimes.
Operating principles of low-temperature refrigerators.
Dewar vessels: structure and applications.

Principles of sublimation drying.
Equipment for lyophilization.
Applications of low temperatures in biopharmacy.

Topic 10. Chromatography

Purpose of chromatographic methods.
Classification of chromatography types.
Principles of chromatographic separation.
Types of sorbents and their properties.
Equipment for laboratory chromatography.
Industrial chromatographic systems.
Advantages and limitations of chromatographic methods.

Topic 11. Membrane Separation Methods

Principles of membrane separation.
Microfiltration and its applications.
Ultrafiltration.
Reverse osmosis.
Membrane dialysis.
Types of semi-permeable membranes.
Equipment for membrane processes.

Topic 12. Finished Product Manufacturing

Concept of the final product form.
Types of finished products (solid, liquid, paste-like).
Equipment for producing different product forms.
Features of sterile product preparation.
Product sterilization methods.
Packaging equipment.
Labeling and quality control of finished products.

Syllabus of the Course

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Approved by the Department of Translational Medical Bioengineering (Protocol № 3 dated 29.09.2025)

Agreed by the Faculty Methodological Commission (Protocol № 2 dated 29.09.2025)

***In case of any differences in interpretation of the information in the educational programme, the Ukrainian text shall prevail.**