MINISTRY OF SCIENCE AND HIGHER EDUCATION OF RUSSIAN FEDERATION
Federal State Autonomous Educational Institution of Higher Education
Far Eastern Federal University
(FEFU)
SCHOOL OF BIOMEDICINE

AGREED
Head of OP
_____
(Signed) (Full name)

CLAIM
Director of the Department of Medical Biology and Biotechnology
_____
(Signed) (Acting Name)
December 30, 2021

WORK PROGRAM OF THE DISCIPLINE
Medical and pharmaceutical biotechnology
Direction of training 06.04.01 Biology
Master's Programme in Molecular and Cell Biology
Form of training: full-time

Course 1 semester 2
lectures 18 h.
practical classes 00 hour.
lab work 6 hours
total hours of classroom load 36 hours.
independent work 72 hours.
including 27 hour exam preparation
credit 0 semester
exam 2 semester

The work program is drawn up in accordance with the requirements of the Federal State Educational Standard in the direction of training 06.04.01 **Biology**, approved by the order of the Ministry of Education and Science of Russia dated 11.08.2020 No. 934.

The work program was discussed at the meeting of the Department of Medical Biology and Biotechnology Protocol dated December 30, 2021 No. 5

Director of the Department of Medical Biology and Biotechnology , Ph.D.V.V. Kumeiko

Compiled by: Cand. Biol. Ph.D., Associate Professor M.T. Handy

Vladivostok
2021

1. The work program was revised at the meeting of the Department of Medical Biology and Biotechnology, protocol from "__" __ № _____

2. The work program was revised at the meeting of the Department of Medical Biology and Biotechnology, the protocol of "____" ___ № _____

3. The work program was revised at the meeting of the Department of Medical Biology and Biotechnology, protocol from "__" __ № _____

4. Work program revised at the meeting of the Department of Medical Biology and Biotechnology, minutes dated "_ ___ № _____

5. The work program was revised at the meeting of the Department of Medical Biology and Biotechnology, protocol dated "__" __ № _____

I. GOALS AND OBJECTIVES OF MASTERING THE DISCIPLINE

The purpose of the course: the formation and development of general professional and professional competencies necessary for professional activities in the field of biotechnology for the production of substances of drugs, as well as preventive and diagnostic means by biotechnological methods of synthesis and transformation, as well as a combination of biological and chemical methods.

Objectives of the course: 1) study of technological modes of growing microorganisms-producers, cultures of tissues and cells of plants and animals to obtain biomass, its components, metabolic products, directed biosynthesis of biologically active compounds and other products, study of their composition and methods of analysis, technical and economic evaluation criteria, creation of effective compositions of biological preparations and development of ways of their application.

2) study of processes and devices of microbiological synthesis, including physicochemical kinetics, hydrodynamics, mass and heat exchanges in fermentation apparatuses, thickening of biomass, separation of cell suspensions, drying, granulation, extraction, isolation, fractionation, purification, control and storage of final target products.

3) mastering the methods and means of developing new technological processes based on microbiological synthesis, biotransformation, biocatalysis, immunosorption, biodestruction, bioacidation and the creation of biocomposting systems for various wastes, purification of man-made waste (wastewater, gas emissions, etc.), the creation of closed technological schemes of microbiological production, the latter taking into account environmental protection issues.

4) mastering the methods and means of developing scientific and methodological foundations for the application of standard biosystems at the molecular, cellular, tissue and organismal levels in scientific research, quality control and safety assessment of the use of pharmaceutical, medical, veterinary and perfumery-cosmetic biological products.

5) teaching students the ability to correctly assess the compliance of biotechnological production with the rules of Good Manufacturing Practice (GMP), environmental safety requirements in relation to biological facilities used in production and target products.

Professional competencies of graduates and indicators of their achievement:

Task type	Code and name of professional competence (the result of mastery)	Code and name of the competency achievement indicator
research	PK-2. It is able to apply the methodological foundations of design,	PC -2.1. Develops rules and algorithms for designing, performing laboratory biological and environmental studies.

	perform laboratory biological, environmental research, use modern equipment and computing complexes in molecular and cell biology.	PC -2.2. Performs laboratory biological, environmental research using the scientific methodological foundations of fundamental research.
		PC -2.3. Applies the methodological foundations of design, laboratory biological, environmental research, uses modern
research	PC -3. It is able to conduct research on biopolymers, their components and complexes, the structure and function of genes and genomes.	SC -3.1. Studies the structure and functions of biopolymers, their components and complexes, mechanisms for storing, transmitting and implementing genetic information at the molecular level.
		PC -3.2. It characterizes in detail the main processes occurring in a living cell: the processes of replication, transcription, translation, recombination, repair, processing of RNA and proteins, protein folding and docking.
		SC -3.3. He investigates the main methods of intermolecular interactions and mutual regulation of the processes of functioning of a living cell as part of a multicellular organism.
		PC-3.4. Analyzes the structure and functions of genes and genomes, conducts structural and functional analysis of individual proteins and the proteome as a whole.
research	PK-7. Able to develop new drugs, conduct biomedical research using living organisms and biological systems of various levels of organization.	PP-7.1. Conducts substantiation of biomedical research in order to develop drugs using living organisms and biological systems of various levels of organization.
		PP-7.2. Defines the goals and objectives of biomedical research and development of medicines. Plans biomedical research, carries out the selection of the design of scientific research in accordance with the goals and objectives.
		PC-7.3. Conducts biomedical research using living organisms and biological systems of various levels of organization, analyzes the results obtained.
		PC-7.4. Interprets the obtained results of biomedical research and development in order to elucidate the molecular mechanisms of biochemical processes.

Code and name of the competency achievement indicator	Name of the assessment indicator (the result of training in the discipline)

PC -2.1. Develops rules and algorithms for designing, performing laboratory biological and environmental studies.	Knows: -basic concepts, formulas and laws of natural science disciplines in professional activities, methods of mathematical analysis and modeling, theoretical and experimental research; -biotechnological aspects used in biotechnology; objects of biotechnology and their biotechnological functions, principles of cell culture; -the essence of molecular genetics methods; -stages of selection of target products
PC -2.2. Performs laboratory biological, environmental research using the scientific methodological foundations of fundamental research.	Can: -conduct experimental studies and tests according to a given methodology, use mathematical processing of experimental data; -use the language of molecular biotechnology; select biological objects
PC -2.3. Applies the methodological foundations of design, laboratory biological, environmental research, uses modern	Owns: -the basic laws of natural science disciplines in industrial microbiology and biotechnology, methods of mathematical analysis and modeling, theoretical and experimental research methods and principles for improving industrial microbiology and biotechnology;
SC -3.1. Studies the structure and functions of biopolymers, their components and complexes, mechanisms for storing, transmitting and implementing genetic information at the molecular level.	Knows: -resources of natural biocenoses as sources of biologically active substances (BAV); -methods, methods and principles of implementation and management of biotechnological processes Can: - carry out biotechnological processes of production and production of biologically active substances; - carry out biotechnological processes of production and manufacture of medicines; - carry out stage-by-stage control and standardization of the resulting drugs Owns: -ability to implement and manage biotechnological processes
PC -3.2. It characterizes in detail the main processes occurring in a living cell: the processes of replication, transcription, translation, recombination, repair, processing of RNA and proteins, protein folding and docking.	Knows: -modern achievements of biological sciences and biomedical technologies; -basic principles of regulation of metabolism and growth rate of microorganisms, methods of cultivation of microorganisms, quantitative characteristics of culture growth, equipment for the cultivation of microorganisms, storage of microorganisms; -the main producers and methods of obtaining biotechnological medicinal substances, their physical, chemical and pharmacological properties. -biotechnological processes in the production and manufacture of medicines; -the main stages of the biotechnological process;

	-resources of natural biocenoses as sources of biologically active substances (BAV); -methods, methods and principles of implementation and management of biotechnological processes Can: - carry out biotechnological processes of production and production of biologically active substances and individual components of microbial cells; - carry out biotechnological processes of production and manufacture of medicines; - carry out stage-by-stage control and standardization of the drugs obtained (determination of the antimicrobial activity of antibiotics, the activity of enzyme preparations, the viability of microorganisms); - isolate and purify BAS from biomass and culture fluid; - regulate and improve the biotechnological process in order to obtain a high-quality final product; ensure compliance with the rules of industrial hygiene, environmental protection, labor protection and safety Owns: -methods of controlled cultivation of microorganisms; -methods of immobilization of microbial cells -technology for obtaining biologically active substances and individual components of microbial cells; ability to implement and manage biotechnological processes
SC -3.3. He investigates the main methods of intermolecular interactions and mutual regulation of the processes of functioning of a living cell as part of a multicellular organism.	Knows: -theoretical foundations of the most important technological and microbiological processes and their practical application for obtaining valuable waste products of microorganisms in an industrial way; -
PC-3.4. Analyzes the structure and functions of genes and genomes, conducts structural and functional analysis of individual proteins and the proteome as a whole.	Knows: -methods, hardware design and technologies for the production of specialized biological products using microbiological synthesis, biocatalysis, genetic engineering; fundamentals of microbial biotechnology, selection and genetic design of microorganisms; -basic requirements for microorganisms - producers Can: -apply modern ideas about the basics of biotechnological production, genetic engineering in the selection and study of producer microorganisms; use knowledge about the basics of microbial biotechnology, breeding work to solve problems in the national economy Owns: -modern ideas about the methods of genetic engineering, nanobiotechnology, molecular modeling for the purposes of biotechnology; -methods of independent search and analysis of information in the field of industrial microbiology and biotechnology;

	-methods of search, selection and research of microorganisms; knowledge of modern apparatus and equipment for research work
PP-7.1. Conducts substantiation of biomedical research in order to develop drugs using living organisms and biological systems of various levels of organization.	Knows: -innovative ways to create medicines based on the use of genomics, proteomics and bioinformatics data; -new methods and techniques in the development, production and circulation of medicines; -methods for determining the benignity of producer microorganisms, determining the concentration of viable cells and their enzymatic activity. Can: -conduct research to improve the biotechnological process; to use new methods and techniques in the field of design of medicines and diagnostic drugs. Owns: -new methods and techniques in the field of design of medicines and diagnostic drugs; -physicochemical, microbiological and biochemical methods of analysis to confirm the purity of the producer, the authenticity of medicines, the detection of impurities and quantitative assessment; -the ability to participate in scientific research; skills in introducing new methods and techniques in the field of design of medicines and diagnostic drugs.
PP-7.2. Defines the goals and objectives of biomedical research and development of medicines. Plans biomedical research, carries out the selection of the design of scientific research in accordance with the goals and objectives.	Knows: -the physical nature of phenomena and processes in the body; -the structure of the human body in conjunction with the functions of systems and organs; -methods of constructing models of physiological systems at the subcellular, cellular, tissue and systemic levels of the human body; -methods for solving the problems of parameter identification and selection of informative signs on real clinical and experimental data; -methods of studying biochemical and physiological processes and phenomena occurring at the cellular, organ and systemic levels in the human body
PC-7.3. Conducts biomedical research using living organisms and biological systems of various levels of organization, analyzes the results obtained.	Can: apply known models of body systems to analyze physiological processes and states. -identify model parameters from experimental data or from the results of a clinical trial; -to carry out applied and practical projects for the study of biochemical, biophysical and physiological processes and phenomena occurring at the cellular, organ and system levels in the human body Owns: -methods of studying biochemical and physiological processes and phenomena occurring at the cellular, organ and systemic levels in the human body;

	-methods of applied and practical projects for the study of biochemical, biophysical and physiological processes and phenomena occurring at the cellular, organ and system levels in the human body
PC-7.4. Interprets the obtained results of biomedical research and development in order to elucidate the molecular mechanisms of biochemical processes.	Knows: -theoretical foundations of obtaining various biotechnological products; -patterns of kinetics of the growth of microorganisms and the formation of metabolic products; -methods of cultivation of microorganisms classification of enzymes, units of activity of enzymes; -methods of obtaining enzyme preparations; areas of application of enzymes in medicine. Can: -conduct the process of cultivation of microorganisms, cell cultures of plants and animals; -select optimal conditions that stimulate the maximum accumulation of the target product; -isolate, identify and culture microorganisms producing biomass and various metabolic products; -work with pure cultures of microorganisms, plants and animals; -isolate enzymes from various objects, investigate the properties and determine the kinetic parameters of enzymes; -evaluate the quantitative characteristics of the growth of microorganisms -Owns: -methods of working with microorganisms, plant and animal cell cultures; rules of safe work in the laboratory; -methods of calculating the basic parameters of biotechnological processes; -methods of biotransformation; -principles of production, research and application of enzymes, viruses, microorganisms, cell cultures of animals and plants, products of their biosynthesis and biotransformation

II. LABORIOUSNESS OF DISCIPLINE AND TYPES OF TRAINING SESSIONS IN THE DISCIPLINE

The total labor intensity of the discipline is 3 credit units (108 academic hours), (1 credit unit corresponds to 36 academic hours).

Types of training sessions and work of the student in the discipline are:

Designation	Types of training sessions and work of the student

Lek	Lecture
Ave	Practical exercises
WED:	Independent work of the student during the period of theoretical training
including control	Independent work of the student and contact work of the student with the teacher during the period of intermediate certification
including OK	Online Course
	And other types of work

Structure of the discipline:

The form of training is full-time.

№	Name of the section Discipline	Semester	Number of hours by types of training sessions and work of the student						Intermediate attestation forms
			Lek	Lab	Ave	OK	WED	Control	
1	Chemistry and technology of phytopreparations	2	10	18	0	0	45		
2	Medical Biotechnology	2	8		0				
	Total:	2	18	18	0	0	45	27	Exam

THE STRUCTURE AND CONTENT OF THE THEORETICAL PART OF THE COURSE
(LECTURES (18 HOURS))

SECTION 1. CHEMICALS AND TECHNOLOGY OF PHYTOPREPARATIONS

Topic 1. Introduction to the subject "Pharmaceutical and medical biotechnology". Section phytopreparations. Vegetable raw materials. Characteristics of biologically active substances (**2 hours**).

Topic 2. Creation of bioobjects of the methodof cellular and genetic engineering (technologyof obtaining recombinant DNA). Recombinant proteins as drugs (**2 hours**).

Topic 3. Genomics and proteomics. Their implications for modern biotechnology and for the search for new drugs. The concept of the "materiality" (vital necessity) of a gene (**2 hours**).

Topic 4. The main stages of the biotechnological process. General characteristics. The basic structure of biotechnological production of drugs. The process of biosynthesis. Classification by technological parameters (**2 hours**).

Topic 5. A unified system of GLP, GCP and GMP in the introduction into practice and production of medicinal preparationsBiotechnology in solving

environmental problems and eliminating anthropogenic impacts on the environment. Prospects for the development of biotechnology in the XXI century (**2 hours**).

SECTION 2. Medical Biotechnology

Topic 6. Problems of search, creation and use of antibiotics in medical practice (2 hours).

– Antibiotics and homeostasis correctors as secondary microbial metabolites in higher eukaryotes.

– Mechanisms of biosynthesis of antibiotics.

– Biotechnology of antibiotics.

– Molecular mechanisms of antibiotic resistance. Search for new natural betalactams and targeted transformation of the betalactam molecule.

Topic 7. Drugs obtained in the pharmaceutical industry by biotechnological methods (**2 hours**).

– Biotechnology of steroid hormones.

– Vitamins. Microbiological synthesis.

– Methods for obtaining amino acids (acid, alkaline, enzymatic hydrolysis, chemical, chemical-enzymatic, microbiological).

– Obtaining probiotics.

– Isolation of enzymes from biological objects.

– Production of recombinant insulin by biotechnological methods

Topic 8. Biotechnology of medicinal products based on plant cell and tissue cultures (general characteristics, transgenic plants) (**2 hours**).

Topic 9. Immunobiotechnology as one of the sections of biotechnology (**2 hours**).

IV. STRUCTURE AND CONTENT OF THE PRACTICAL PART OF THE COURSE AND INDEPENDENT WORK

Laboratory work (18 hours)

Session 1 Antibiotics

Laboratory work 1. Search and characterization of microorganisms producing antibiotics.

Laboratory work 2. Comparison of morphological characteristics of the main producers of antibiotics in surface and deep cultivation.

Laboratory work 3. Determination of the concentration of the antibiotic by diffusion in agar.

Laboratory work 4. Qualitative determination of antibiotics omomycinar and galtamycinar in extracts of culture liquid using thin-layer chromatography (TLC) on silifol plates.

Laboratory work 5. Qualitative and quantitative determination of fusidic acid.

Laboratory work 6. The study of micro-morphological features of BAV producers (on the example of the producer of homomycinar Streptomyces chromopurpureos) at different stages of cultivation (trophophase, idiophase) with the choice of optimal conditions for the process of antibiotic biosynthesis (laboratory work ends with the execution of a drawing and a description of microscopy of the object under study).

Laboratory work 7. Determination of the optimal parameters for the biosynthesis of the antitumor antibiotic rubomycin* (when choosing the optimal biosynthesis process according to the proposed parameters, it is required to reflect the dynamics of changes in fermentation indicators on one graph with different scales in accordance with the proposed example).

Session 2 Amino Acids

Laboratory work 8. Cultivation of the plasmid strain *Escherichia coli* - the producer of threonine.

Session 3. Vitamins and coenzymes

Laboratory work 9. Biotechnological use of microorganisms in the preparation of vitamin C*

Laboratory work 10. Biotechnological use of microorganisms in the preparation of vitamins and coenzymes (on the example of extraction of ubiquinone-10 from the biomass of Gluconobacter oxydans)

Session 4. Steroid hormones

Laboratory work 11. The use of biotechnological methods in the production of steroid hormones.

Laboratory work 12. Microbiological transformation of steroid hormones using immobilized Arthrobacter globiformis cells (reaction 1, 2-dehydration)

Session 5. Probiotics

Laboratory work 13. Preparations based on live cultures of lactic acid bacteria.

Session 6. Biological preparations of plant origin

Laboratory work 14. Preparations based on plant biomass obtained *by in vitro method.*

Session 7. Immobilized bioobjects (cell cultures and individual enzymes).

Laboratory work 15. Immobilization of *E. coli* cells – the producer of penicillinacylase – and the production of 6-aminopenicillanoic acid by hydrolysis of benzylpenicillin by immobilized cells.

Laboratory work 16. Influence of immobilization conditions on the productivity of microbial cells.

Session 8. Recombinant proteins.

Laboratory work 17. *Analysis of E. coli* cell culture for the presence of an insulin-producing vector.

Session 9. Vaccine

Laboratory work 18. Control of specific measles vaccine activity

Session 10. Nucleic acids

Laboratory work 19. Isolation of the total fraction of nucleic acids from animal tissues

Laboratory work 20. Isolation and purification of DNA. Marmoor's method. Method of A.S. Orlov and E.I. Orlova. Schmidt-Tanghauser method. Isolation and hydrolysis of ribonucleins from yeast cells. Isolation of DNA from whole blood.

Schedule for the implementation of independent work in the discipline:

№ p/n	Due Date/Deadlines	Type of independent work	Approximate norms of execution time	Form of control
5 semester				
1	1-10 weeks	Work with the notes, study of the literature on the discipline, preparation for a practical lesson, preparation for control testing, writing reports, solving tests	20	Abstract or presentation, control testing
2	11-18 weeks	Work with the notes, study of the literature on the discipline, preparation for a practical lesson, preparation for control testing, preparation of reports, solving tests	25	Abstract, control testing
3	session	Exam Preparation	27	Exam

Independent work of students consists of preparation for practical classes, work on recommended literature, writing reports on the topic of the seminar session, preparing presentations.

The teacher offers each student individual and differentiated tasks. Some of them can be carried out in a group (for example, the preparation of a report and presentation on one topic can be done by several students with the division of their duties - one prepares the scientific and theoretical part, and the second conducts an analysis of practice).

Independent work can be carried out individually or by groups of students, depending on the purpose, volume, specific subject of independent work, the level of complexity and the level of skills of students.

Control of the results of independent work of students should be carried out within the time allotted for mandatory training sessions and extracurricular independent work of students in the discipline, can take place in written, oral or mixed form.

Self-service tasks

1. Writing an essay on the topic proposed by the teacher or independently chosen by the student and agreed with the teacher.

2. Preparation of presentations using multimedia equipment.

V. EDUCATIONAL AND METHODOLOGICAL SUPPORT OF INDEPENDENT WORK OF STUDENTS

Methodical instructions for the abstract

Goals and objectives of the abstract

The abstract (from the Latin *refero* - report, report) is a brief statement of the problem of a practical or theoretical nature with the formulation of certain conclusions on the topic under consideration. The problem chosen by the student is studied and analyzed on the basis of one or more sources. Unlike the course work, which is a comprehensive study of the problem, the abstract is aimed at analyzing one or more scientific papers.

The objectives of writing an essay are:

– development of students' skills to search for topical problems of modern legislation;

– development of skills of summary of the material with the allocation of only the most essential points necessary to reveal the essence of the problem;

– development of skills in analyzing the studied material and formulating their own conclusions on the chosen issue in writing, scientific, competent language.

The tasks of writing an essay are*:*

– to teach the student to convey the opinions of the authors, on the basis of whose works the student writes his essay, as correctly as possible;

– teach the student to correctly state his position on the problem analyzed in the essay;

– prepare the student for further participation in scientific and practical conferences, seminars and competitions;

– help the student to determine the topic of interest to him, the further

disclosure of which can be carried out when writing a term paper or diploma;

– understand for yourself and state the reasons for your agreement (disagreement) with the opinion of this or that author on this issue.

Basic requirements for the content of the abstract

The student should use only those materials (scientific articles, monographs, manuals) that are directly related to his chosen topic. Detached reasoning that is not related to the problem being analyzed is not allowed. The content of the abstract should be specific, only one problem should be investigated (several are allowed only if they are interrelated). The student must strictly adhere to the logic of presentation (start with the definition and analysis of concepts, proceed to the formulation of the problem, analyze the ways of its solution and draw the appropriate conclusions). The abstract should end with the derivation of conclusions on the topic.

In its *structure* , the abstract consists of:

1.Title page*;*

2.Introduction, where the student formulates the problem to be analyzed and investigated;

3.The main text, in which the selected topic is consistently revealed. Unlike the term paper, the main text of the essay involves the division into 2-3 paragraphs without allocating chapters. If necessary, the text of the abstract can be supplemented with illustrations, tables, graphs, but they should not "overload" the text;

4.Conclusions, where the student formulates the conclusions drawn on the basis of the main text.

5.List of references. This list names both those sources that the student refers to in the preparation of the essay, and others that were studied by him during the preparation of the essay.

The volume of the abstract is 10-15 pages of typewritten text, but in any case should not exceed 15 pages. Spacing – 1.5, font size – 14, margins: left – 3cm, right – 1.5 cm, top and bottom – 1.5cm. Pages should be numbered. The paragraph indent from the beginning of the line is 1.25 cm.

The procedure for submitting the abstract and its evaluation

Essays are written by students during the semester within the terms set by the teacher in a particular discipline, reported by the student and submitted for discussion. The printed version is handed over to the teacher leading the discipline.

Based on the results of the test, the student is assigned a certain number of points, which is included in the total number of points the student scored during the semester. When evaluating the abstract, the correspondence of the content to the chosen topic, the clarity of the structure of the work, the ability to work with scientific literature, the ability to pose a problem and analyze it, the ability to think

logically, the possession of professional terminology, and the literacy of design are taken into account.

Abstracts and presentation topics

1. Biological objects-producers of therapeutic, prophylactic and diagnostic means. Bioobjects are enzymes used as industrial biocatalysts.
2. Biological facilities as a means of production of medicinal, prophylactic and diagnostic agents.
3. Screening of BAV producers from soil microorganisms.
4. LZ "Search and characterization of microorganisms-producers of antibiotics".
5. Engineering enzymology. Immobilized biological objects in the conditions of biotechnological production.
6. Methods of immobilization of enzymes and whole cells.
7. LZ "Immobilization of E. coli cells – the producer of penicillinacylase – and the production of 6-APK by hydrolysis of benzylpenicillin by immobilized cells".
8. Components of the biotechnological process.
9. The basic structure of biotechnological production of medicines.
10. Molecular mechanisms of intracellular regulation of metabolism.
11. Mechanisms of regulation of biosynthesis of primary metabolites used as drugs.
12. Mechanisms of regulation of biosynthesis of secondary metabolites Secondary microbial metabolites are inhibitors of signal transduction.
13. Regulation of BAS biosynthesis under production conditions.
14. LZ "Determination of optimal parameters for the biosynthesis of the antitumor antibiotic rubomycin".
15. Recombinant proteins and polypeptides.
16. Production of bioregulators with species specificity for humans by microbiological synthesis.
17. Cultures of plant cells and tissues as a source of medicines.
18. Production of medicinal substances based on plant tissue cultures.
19. LZ "Obtaining callus cell culture and assessing its quality".
20. Secondary microbial metabolites – inhibitors of signal transduction
21. Pharmaceutical preparations based on live cultures of symbiont microorganisms (normoflors, eubiotics, probiotics, microbiotics).
22. Normoflors. Growing. Control.

23. LZ "Determination of the concentration of viable cells of lactobacilli, bifidobacteria and enterococci, as well as the active and titrated acidity of the culture fluid".

24. Amino acids. The basics of their biotechnological production.

25. Production of amino acids by biotechnological methods.

26. LZ "Fermentation of threonine; identification and determination of the content of this amino acid in the culture fluid."

Criteria for evaluating the abstract

The above understanding of the abstract as an integral author's text determines the criteria for its evaluation: the novelty of the text; the validity of the choice of source; the degree of disclosure of the essence of the issue; compliance with the requirements for registration.

Novelty of the text: a) relevance of the research topic; b) novelty and independence in the formulation of the problem, formulation of a new aspect of the known problem in the establishment of new connections (interdisciplinary, intra-subject, integration); c) the ability to work with research, critical literature, systematize and structure the material; d) the appearance of the author's position, the independence of assessments and judgments; e) stylistic unity of the text, unity of genre features.

The degree of disclosure of the essence of the issue: a) the correspondence of the plan to the topic of the abstract; b) compliance of the content with the topic and plan of the abstract; c) completeness and depth of knowledge on the topic; d) the validity of the methods and methods of working with the material; f) the ability to generalize, draw conclusions, compare different points of view on one issue (problem).

Validity of the choice of sources: a) evaluation of the literature used: whether the most well-known works on the research topic are involved (including journal publications of recent years, recent statistical data, summaries, references, etc.).

Compliance with the requirements for design: a) how correctly the references to the literature used, the list of references are drawn up; b) assessment of literacy and culture of presentation (including spelling, punctuation, stylistic culture), knowledge of terminology; c) compliance with the requirements for the volume of the abstract.

The reviewer should clearly formulate the remark and questions, preferably with references to the work (it is possible to specific pages of the work), to research and factual data that the author did not take into account.

The reviewer can also indicate: whether the students have addressed the topic earlier (abstracts, written works, creative works, Olympiad works, etc.) and whether there are any preliminary results; how the graduate conducted the work (plan,

intermediate stages, consultation, revision and revision of what was written or the absence of a clear plan, rejection of the recommendations of the manager).

The student submits an abstract for review no later than a week before the defense. The reviewer is the supervisor. Experience shows that it is advisable to familiarize students with a review a few days before the defense. Opponents are appointed by a teacher from among the students. For the oral presentation of the student, 10-20 minutes are enough (approximately the same time as the answers on the tickets for the exam).

Grade 5 is set if all the requirements for writing and defending the abstract are met: the problem is identified and its relevance is substantiated, a brief analysis of various points of view on the problem under consideration is made and its own position is logically stated, conclusions are formulated, the topic is fully disclosed, the volume is maintained, the requirements for external design are met, the correct answers to additional questions are given.

Score 4 - the basic requirements for the abstract and its defense are met, but there are shortcomings. In particular, there are inaccuracies in the presentation of the material; there is no logical sequence in the judgments; the volume of the abstract is not maintained; there are omissions in the design; incomplete answers are given to additional questions during the defense.

Score 3 – there are significant deviations from the requirements for abstracting. In particular: the topic is covered only partially; factual errors are made in the content of the abstract or when answering additional questions; there is no conclusion during the defense.

Score 2 - the topic of the essay is not disclosed, there is a significant misunderstanding of the problem.

Grade 1 – the abstract is not presented to the students.

VI. MONITORING THE ACHIEVEMENT OF COURSE OBJECTIVES

No p/n	Supervised sections / topics of the discipline	Achievement indicator code and name	Learning outcomes	Assessment tools	
				current control	Intermediate-accurate certification
1	Chemistry and technology of phytopre	PC -2.1. Develops rules and algorithms for designing, performing laboratory	Knows: −basic concepts, formulas and laws of natural science disciplines in professional activities, methods of mathematical analysis and	UO-2 Colloquium questions PR-1 test	Question Exam 14, 15, 19, 21, 22, 24, 25, 26, 27 UO-1

	parations	biological and environmental studies.	modeling, theoretical and experimental research; −biotechnological aspects used in biotechnology; objects of biotechnology and their biotechnological functions, principles of cell culture; −the essence of molecular genetics methods; −stages of selection of target products		interview
		PC -2.2. Performs laboratory biological, environmental research using the scientific methodologica l foundations of fundamental research.	Can: −conduct experimental studies and tests according to a given methodology, use mathematical processing of experimental data; −use the language of molecular biotechnology; select biological objects	PR-7 Reference notes PR-4 abstract UO-3 report	Question Exam 14, 15, 19, 21, 22, 24, 25, 26, 27
		PC -2.3. Applies the methodologica l foundations of design, laboratory biological, environmental research, uses modern	Owns: −the basic laws of natural science disciplines in industrial microbiology and biotechnology, methods of mathematical analysis and modeling, theoretical and experimental research methods and principles for improving industrial microbiology and biotechnology;	PR-6 practical tasks	Question Exam 14, 15, 19, 21, 22, 24, 25, 26, 27
		SC -3.1. Studies the structure and functions of biopolymers, their components and complexes, mechanisms for storing, transmitting and implementing genetic information at	Knows: −resources of natural biocenoses as sources of biologically active substances (BAV); −methods, methods and principles of implementation and management of biotechnological processes Can: – carry out biotechnological processes of production and production of biologically active substances;	UO-2 Colloquium questions PR-1 test	Question Exam 4, 5, 9, 11, 16, 17, 18, 20, 23, 28-50, 66-75 UO-1

		the molecular level.	– carry out biotechnological processes of production and manufacture of medicines; – carry out stage-by-stage control and standardization of the resulting drugs Owns: −ability to implement and manage biotechnological processes		
		PC -3.2. It characterizes in detail the main processes occurring in a living cell: the processes of replication, transcription, translation, recombination, repair, processing of RNA and proteins, protein folding and docking.	Knows: −modern achievements of biological sciences and biomedical technologies; −basic principles of regulation of metabolism and growth rate of microorganisms, methods of cultivation of microorganisms, quantitative characteristics of culture growth, equipment for the cultivation of microorganisms, storage of microorganisms; −the main producers and methods of obtaining biotechnological medicinal substances, their physical, chemical and pharmacological properties. −biotechnological processes in the production and manufacture of medicines; −the main stages of the biotechnological process; −resources of natural biocenoses as sources of biologically active substances (BAV); −methods, methods and principles of implementation and management of biotechnological processes Can: – carry out biotechnological processes of production and production of biologically active substances and individual components of microbial cells; – carry out biotechnological processes of production and manufacture of medicines;		interview

			– carry out stage-by-stage control and standardization of the drugs obtained (determination of the antimicrobial activity of antibiotics, the activity of enzyme preparations, the viability of microorganisms); – isolate and purify BAS from biomass and culture fluid; – regulate and improve the biotechnological process in order to obtain a high-quality final product; ensure compliance with the rules of industrial hygiene, environmental protection, labor protection and safety Owns: −methods of controlled cultivation of microorganisms; −methods of immobilization of microbial cells −technology for obtaining biologically active substances and individual components of microbial cells; ability to implement and manage biotechnological processes		
		SC -3.3. He investigates the main methods of intermolecular interactions and mutual regulation of the processes of functioning of a living cell as part of a multicellular organism.	Knows: −theoretical foundations of the most important technological and microbiological processes and their practical application for obtaining valuable waste products of microorganisms in an industrial way; −	PR-7 Reference notes PR-4 abstract UO-3 report	Question Exam 4, 5, 9, 11, 16, 17, 18, 20, 23, 28-50, 66-75
		PC-3.4. Analyzes the structure and functions of genes and genomes, conducts structural and	Knows: −methods, hardware design and technologies for the production of specialized biological products using microbiological synthesis, biocatalysis, genetic engineering; fundamentals of	PR-6 practical tasks	Question Exam 4, 5, 9, 11, 16, 17, 18, 20, 23, 28-50, 66-75

		functional analysis of individual proteins and the proteome as a whole.	microbial biotechnology, selection and genetic design of microorganisms; −basic requirements for microorganisms - producers Can: −apply modern ideas about the basics of biotechnological production, genetic engineering in the selection and study of producer microorganisms; use knowledge about the basics of microbial biotechnology, breeding work to solve problems in the national economy Owns: −modern ideas about the methods of genetic engineering, nanobiotechnology, molecular modeling for the purposes of biotechnology; −methods of independent search and analysis of information in the field of industrial microbiology and biotechnology; −methods of search, selection and research of microorganisms; knowledge of modern apparatus and equipment for research work		
2	Medical Biotechnology	PP-7.1. Conducts substantiation of biomedical research in order to develop drugs using living organisms and biological systems of various levels of organization.	Knows: −innovative ways to create medicines based on the use of genomics, proteomics and bioinformatics data; −new methods and techniques in the development, production and circulation of medicines; −methods for determining the benignity of producer microorganisms, determining the concentration of viable cells and their enzymatic activity. Can: −conduct research to improve the biotechnological process; to use new methods and techniques in the field of		

			design of medicines and diagnostic drugs. Owns: −new methods and techniques in the field of design of medicines and diagnostic drugs; −physicochemical, microbiological and biochemical methods of analysis to confirm the purity of the producer, the authenticity of medicines, the detection of impurities and quantitative assessment; −the ability to participate in scientific research; skills in introducing new methods and techniques in the field of design of medicines and diagnostic drugs.		
		PP-7.2. Defines the goals and objectives of biomedical research and development of medicines. Plans biomedical research, carries out the selection of the design of scientific research in accordance with the goals and objectives.	Knows: −the physical nature of phenomena and processes in the body; −the structure of the human body in conjunction with the functions of systems and organs; −methods of constructing models of physiological systems at the subcellular, cellular, tissue and systemic levels of the human body; −methods for solving the problems of parameter identification and selection of informative signs on real clinical and experimental data; −methods of studying biochemical and physiological processes and phenomena occurring at the cellular, organ and systemic levels in the human body	UO-2 Colloquium questions PR-1 test	question exam. 1-8, 10, 11 ,12, 39, 47, 48, 51-65 UO-1 interview
		PC-7.3. Conducts biomedical research using living organisms and biological	Can: apply known models of body systems to analyze physiological processes and states.	PR-7 Reference notes PR-4 abstract UO-3 report	Question Exam 1-8, 10, 11 ,12, 39, 47, 48, 51-65

		systems of various levels of organization, analyzes the results obtained.	–identify model parameters from experimental data or from the results of a clinical trial; –to carry out applied and practical projects for the study of biochemical, biophysical and physiological processes and phenomena occurring at the cellular, organ and system levels in the human body Owns: –methods of studying biochemical and physiological processes and phenomena occurring at the cellular, organ and systemic levels in the human body; –methods of applied and practical projects for the study of biochemical, biophysical and physiological processes and phenomena occurring at the cellular, organ and system levels in the human body		

VII. LIST OF REFERENCES AND INFORMATION AND METHODOLOGICAL SUPPORT OF THE DISCIPLINE

Main literature

(electronic and printed publications)

1. Aleshina, E.S. Culturing of microorganisms as a basis for biotechnological process [Electronic resource]: uchebnoe posobie / E.S. Aleshina, E.A. Drozdova, N.A. Romanenko – Electron. text data. – Orenburg: Orenburg State University, EBS ASV, 2017. – 192 p. – Access mode: http://www.iprbookshop.ru/71282.html. – EBS «IPRbooks»

2. Gorlenko, V.A. Scientific foundations of biotechnology. Part 1. Nanotechnologii v biologii [Elektronnyi resurs]: uchebnoe posobie / V.A. Gorlenko, N.M. Kutuzova, S.K. Pyatunina. –Electron. text data. – M.: Prometheus, 2013. – 262 p. – Access mode: http://www.iprbookshop.ru/24003.html. – EBS «IPRbooks»

1. Lukanin, A.V. Engineering biotechnology: fundamentals of technology of microbiological production: Textbook / A.V. Lukanin – M.:NRC INFRA-M, 2016. – 304 p. – Access mode: http://znanium.com/catalog/product/527386

2. Lukanin, A.V. Engineering biotechnology: fundamentals of technology of microbiological production: ucheb. posobie / A.V. Lukanin. – M.: INFRA-M, 2017. – 304 p. – Access mode: http://znanium.com/catalog/product/768026

3. Lukanin, A.V. Engineering biotechnology: processes and devices of microbiological production: ucheb. posobie / A.V. Lukanin. – M.: INFRA-M, 2018. – 451 p. – Access mode: http://znanium.com/catalog/product/961375

3. Makhmutkin, V.A. Obshchaya i pharmaceutical'naya biotechnologiya [Elektronnyi resurs]: uchebnoe posobie / sost.: V. A. Makhmutkin, N.I. Tanayeva. –Electron. text data.— Samara: REAVIZ, 2009. – 118 p. – Access mode: http://www.iprbookshop.ru/10164.html. – EBS «IPRbooks»

4. Orekhov, S.N. Pharmaceutical Biotechnology A Guide to Practical Exercises: A Textbook. [Electronic resource] / S.N. Orekhov, ed. by V.A. Bykov, A.V. Katlinskogo – M.: GEOTAR-Media, 2013. – 384 p. – access mode http://www.studentlibrary.ru/book/ISBN9785970424995.html

5. Sazykin, Yu.O. Biotechnology: a textbook for students of higher educational institutions / Yu.O. Sazykin, S.N. Orekhov, I.I. Chakaleva; ed. by A.V. Katlinsky – M.: Akademiya, 2014. – 282 p. http://lib.dvfu.ru:8080/lib/item?id=chamo:785446&theme=FEFU

6. Sirotkin, A.S. Teoreticheskie osnovy biotechnologii [Elektronnyi resurs]: uchebno-metodicheskoe posobie / A.S. Sirotkin, V.B. Zhukova. –Electron. text data. – Kazan: Kazan National Research Technological University, 2010. – 87 p. – Access mode: http://www.iprbookshop.ru/63475.html. – EBS «IPRbooks»

Further reading

(print and electronic publications)

1. Biotechnology: [textbook for universities]: in 8 kn. Kn. 6 . Microbiological production of biologically active substances and preparations / V.A. Bykov, I.A. Krylov, M.N. Manakov [et al.]; ed. by N.S. Egorov, V.D. Samuilov. – Moscow: Vysshaya shkola, 1987. – 143 c. http://lib.dvfu.ru:8080/lib/item?id=chamo:53941&theme=FEFU

2. Biryukov, V.V. Fundamentals of Industrial Biotechnology: A Textbook / V.V. Biryukov, [red. L. I. Galitskaya]. – M.: KolosS, 2004. – 296 p. http://lib.dvfu.ru:8080/lib/item?id=chamo:231970&theme=FEFU

3. Krieger, O.V. Organization of biotechnological production [Electronic resource]: uchebnoe posobie / O.V. Krieger, S.A. Ivanova. –Electron. dan. – Kemerovo: KemGU, 2018. – 99 p. – Access mode: https://e.lanbook.com/book/107701.

4. Orekhov, S.N. Pharmaceutical biotechnology. Guide to practical classes: uchebnoe posobie [Elektronnyi resurs] / Pod red. V.A. Bykova, A.V. Katlinskogo. – M.: GEOTAR, 2013. – 384 p.: http://www.studmedlib.ru/book/ISBN9785970413036.html

5. Osnovy promyshlennoi biotechnologii [Elektronnyi resurs]: uchebnoe

posobie / K.B. Biyashev [i dr.]. –Electron. text data. – Almaty: Nur-Print, 2015. – 164 c .– Access mode: http://www.iprbookshop.ru/67117.html. – EBS «IPRbooks».

6. Ryabkova G.V. Biotechnology (Biotechnology) [Elektronnyi resurs]: uchebno-metodicheskoe posobie / Ryabkova G.V. – Electron. text data. – Kazan: Kazan National Research Technological University, 2012. – 152 p. – Access mode: http://www.iprbookshop.ru/61942.html. – EBS «IPRbooks»

7. Schmid, R. Visual Biotechnology and Genetic Engineering / R. Schmid; trans. with German. A.A. Vinogradova, A.A. Sinyushina. – Moscow: BINOM. Laboratory of Knowledge, 2014. – 324 p. http://lib.dvfu.ru:8080/lib/item?id=chamo:797469&theme=FEFU

Regulatory materials

1. O osnovakh http://www.garant.ru/ zaschrany iznaniya grazhdanskikh v Rossiiskoi Federatsii [Elektronnyi resurs]: Federal'nyi zakon No 323-FZ ot 21 novya 2011 g.: otsl. izm. 03 iyulya 2016 g. // GARANT: informatsional'nogo pravoevaya sistema. – Mode of access: http://www.garant.ru/.

2. On the approval of the terms and stages of accreditation of specialists, as well as categories of persons with medical, pharmaceutical or other education and subject to accreditation of specialists [Electronic resource]: Order of the Ministry of Health of the Russian Federation of February 25, 2016 No 127n GARANT: information and legal system. – Access mode: http://www.garant.ru/.

3. O biomeditsinskikh cellular products [Elektronnyi resurs]: Federal'nyi zakon No 180-FZ ot 15 iyunya 2016 g.: accepted gosudarstvennoy Soumoy 08 nya 2016 g // GARANT: informatsional'nogo pravoravovaya sistema. – Mode of access: http://www.garant.ru/.

4. On approval of the procedure for the destruction of falsified biomedical cell products, poor-quality biomedical cell products and counterfeit biomedical cell products [Electronic resource]: Conclusion of the Ministry of Economic Development of the Russian Federation on the assessment of the regulatory impact on the draft Resolution of the Government of the Russian Federation dated November 28, 2016 N 36281-SS / D26i // GARANT: information and legal system. - Access mode: Access mode: http://www.garant.ru/.

5. Comprehensive program for the development of biotechnologies in the Russian Federation for the period up to 2020 (Approved April 24, 2012 No. 1853p-P8) // GARANT: information and legal system. – Access mode: http://www.garant.ru/.

Normative documents

1. GOST R 57095-2016. Biotechnology. Terms and definitions. - Introduced. 01.05.2017, date of departure. ism. 13.07.2017. – M.: Standartinform, 2016. – 16 p.
2. GOST R 57079-2016 Biotechnology. Classification of biotechnological products. - Introduced. 01.05.2017, date of departure. ism. 13.07.2017. – M.: Standartinform, 2016. – 19 p.

List of resources of the information and telecommunication network "Internet"

1. Ministry of Health of the Russian Federation – official website: https://www.rosminzdrav.ru/
2. Central Research Institute of Organization and Informatization of Healthcare – official website: http://mednet.ru/
3. Research Institute of Biomedical Chemistry named after V.N. Orekhovich – official site: http://www.ibmc.msk.ru/
4. State Pharmacopoeia XIII edition in three volumes, 2015 http://femb.ru/feml
5. Federal Electronic Medical Library http://feml.scsml.rssi.ru/feml/
6. FEFU Scientific Library http://www.dvfu.ru/web/library/nb1

VIII.METHODICAL INSTRUCTIONS FOR MASTERING THE DISCIPLINE

Recommendations for planning and organizing the time allotted for the study of the discipline "Medical and Pharmaceutical Biotechnology":

– study of the lecture notes on the same day after the lecture – 10-15 minutes;

– repetition of the lecture the day before the next lecture – 10-15 minutes;

– study of theoretical material on the recommended literature and notes – 1 hour per week;

– preparation for the practical lesson – 1.5 hours.

The total time spent on the development of the course "Medical and Pharmaceutical Biotechnology" by students will be about 6 hours per week.

The educational process of a student in the discipline "Medical and Pharmaceutical Biotechnology" is reduced to a consistent study of the topics of classroom classes: lecture and practical. On the basis of lectures, the student proceeds to the implementation of practical ones. In addition, for an in-depth study of a certain topic, students independently perform a task in accordance with the methodological guidelines for the CPC.

Mastering the discipline "Medical and Pharmaceutical Biotechnology" includes several components of educational activities.

1. Careful reading of the work program of the discipline (helps to holistically see the structure of the studied issues).

2. Study of methodological recommendations for independent work of students.

3. The most important component of the development of the discipline is attending lectures (mandatory) and their note-taking. In-depth development of lecture material is facilitated by preliminary preparation, including reading the previous lecture, working with economic dictionaries, textbooks and scientific materials.

4. Regular preparation for seminars and active work in the classroom, including:

- repetition of the material of the lecture on the topic of the seminar;
- familiarity with the lesson plan and the list of basic and additional literature, with the teacher's recommendations for preparing for the lesson;
- study of scientific information on this topic in various textbooks and scientific materials;
- reading primary sources and proposed additional literature;
- writing out the main terms on the topic, finding their explanation in economic dictionaries and encyclopedias and maintaining a glossary;

– preparation of notes, the text of the report, if necessary, a plan for answering the main questions of the practical lesson, drawing up schemes, tables;

– visiting the teacher's consultations in order to clarify the complex issues that have arisen in preparation for the lesson, re-passing the control tasks.

5. Preparation for oral interviews, independent and control works.

6. Independent study of topics not presented at lectures. Writing notes on teacher-recommended sources.

7. Preparation for the exam (during the semester), repetition of the material of the entire course of the discipline "Pharmaceutical Biotechnology".

If the student does not attend certain classes, for a good reason, the student works out the material in the classroom, while the points for this lesson are not reduced. If the validity of the missed lesson by the student is not documented, in such cases the academic scores are reduced, according to the policy of the discipline. In order to clarify the material on a particular topic, the student can attend the hours of the teacher's consultation, according to the approved schedule. At the end of the course, the student undergoes an intermediate control of knowledge in this discipline in the form of an exam.

Thus, when studying the course "Medical and Pharmaceutical Biotechnology", you should carefully listen to and take notes on the material presented in the classroom classes. For its understanding and qualitative assimilation, the following sequence of actions is recommended:

1. After the end of the training sessions, to consolidate the material, review and think over the text of the lecture listened to, analyze the examples considered (10-15 minutes).

2. When preparing for the lecture, repeat the text of the previous lecture, think about the next topic (10-15 minutes).

3. During the week, choose the time to work with the recommended literature and to solve problems (1 hour each).

4. When preparing for practical exercises, repeat the basic concepts on the topic of the lesson, study examples. When solving the problem, it is necessary to preliminarily understand what theoretical material should be used. Outline a solution plan, try to solve 1 - 2 practical problems on its basis.

The theoretical part of the discipline "Medical and Pharmaceutical Biotechnology" is revealed in lecture classes, the lecture is the main form of training, where the teacher is given the basic concepts of the discipline.

The sequence of presentation of the material in lecture classes is aimed at forming an indicative basis for students for the subsequent assimilation of the material during independent work.

In practical classes during discussions at seminars, when discussing abstracts and in classes using active learning methods, students learn to analyze and predict the development of pharmaceutical biotechnology, reveal its scientific and social problems.

Practical classes of the course are held in all sections of the curriculum. Practical work is aimed at the formation of students' skills of independent theoretical, research work. In the course of practical classes, the student performs a set of tasks that allow to consolidate the lecture material on the topic under study, to gain basic skills in the field of obtaining and controlling medicines, the industrial production of which is based on the use of:

- plant cell cultures (adaptagens, antiarrhythmic, cardiotropic diseases);
- bacteria (vitamins, enzymes, prebiotics, eubiotics, antibiotics);
- fungi (hormones, antibiotics);
- chimeric cells of genetically engineered producers (amino acids, insulin, interferons, monoclonal antibodies).

The active consolidation of theoretical knowledge is facilitated by the discussion of the problematic aspects of the discipline in the form of practical exercises using active learning methods. At the same time, there is a development of skills of independent research activities in the process of working with scientific literature, periodicals.

IX. MATERIAL AND TECHNICAL SUPPORT OF DISCIPLINE

Mastering the discipline "Medical and Pharmaceutical Biotechnology" involves the use of the following material and technical support: A multimedia classroom equipped with broadband Internet access. Computer class. All computers are connected to the FEFU corporate computer network and are in a single domain.

To perform independent work, students in fefu residential buildings are provided with Wi-Fi.

Name of equipped premises and premises for independent work	List of main equipment
Laboratory auditorium equipped with a multimedia complex Vladivostok, Russky Island, Ajax village, 10, aud. M104P, M424, M811P	FluoView FV1200MPE Deep Optical Biomaterial Imaging System, SM 1950 Microtome Freezing System, Leica, Microtome RM2265, Leica, CompacT SelecT Robotic System for Automated Cell Culture, Laboratory Cryostorage 24K, Taylor Wharton, High-Speed MoFlo Astrios EQ Cell Sorter, Beckman Coulter, Galaxy 130R CO2 Incubator, Eppendorf, Ion Chef™ Instrument, Thermo Fisher Scientific, System DNA Sequence Analysis Ion S5™ XL System, Thermo Fisher Scientific, Genetic Analyzer Applied Biosystems 3500, Thermo

	Fisher Scientific, Automated System Biacore X100 System for Analysis of Intermolecular Interactions, Rheological Properties Analysis System HAAKE MARS III, Thermo Fisher Scientific, Atomic Force Microscope (Probe) BioScope Resolve, Bruker
Reading rooms of the FEFU Scientific Library with open access to the fund (building A – level 10)	HP All-in-One 400 All-in-One 19,5 (1600x900), Core i3-4150T, 4GB DDR3-1600 (1x4GB), 1TB HDD 7200 SATA, DVD+/-RW,GigEth,Wi-Fi,WT,usb kbd/mse,Win7Pro (64-bit)+Win8.1Pro(64-bit),1-1-1 Wty Internet access speed 500 Mbps. Workplaces for people with disabilities are equipped with Braille displays and printers; equipped with: portable devices for reading flat-printed texts, scanning and reading machines video magnifier with the ability to regulate color spectra; magnifying electronic magnifiers and ultrasonic markers

X. VALUATION FUNDS

Code and name of the competency achievement indicator	Name of the assessment indicator (the result of training in the discipline)
PC -2.1. Develops rules and algorithms for designing, performing laboratory biological and environmental studies.	Knows: -basic concepts, formulas and laws of natural science disciplines in professional activities, methods of mathematical analysis and modeling, theoretical and experimental research; -biotechnological aspects used in biotechnology; objects of biotechnology and their biotechnological functions, principles of cell culture; -the essence of molecular genetics methods; -stages of selection of target products
PC -2.2. Performs laboratory biological, environmental research using the scientific methodological foundations of fundamental research.	Can: -conduct experimental studies and tests according to a given methodology, use mathematical processing of experimental data; -use the language of molecular biotechnology; select biological objects
PC -2.3. Applies the methodological foundations of design, laboratory biological, environmental research, uses modern	Owns: -the basic laws of natural science disciplines in industrial microbiology and biotechnology, methods of mathematical analysis and modeling, theoretical and experimental research methods and principles for improving industrial microbiology and biotechnology;
SC -3.1. Studies the structure and functions of biopolymers, their components and complexes, mechanisms for storing, transmitting and implementing genetic information at the molecular level.	Knows: -resources of natural biocenoses as sources of biologically active substances (BAV); -methods, methods and principles of implementation and management of biotechnological processes Can: - carry out biotechnological processes of production and production of biologically active substances;

	- carry out biotechnological processes of production and manufacture of medicines; - carry out stage-by-stage control and standardization of the resulting drugs Owns: -ability to implement and manage biotechnological processes
PC -3.2. It characterizes in detail the main processes occurring in a living cell: the processes of replication, transcription, translation, recombination, repair, processing of RNA and proteins, protein folding and docking.	Knows: -modern achievements of biological sciences and biomedical technologies; -basic principles of regulation of metabolism and growth rate of microorganisms, methods of cultivation of microorganisms, quantitative characteristics of culture growth, equipment for the cultivation of microorganisms, storage of microorganisms; -the main producers and methods of obtaining biotechnological medicinal substances, their physical, chemical and pharmacological properties. -biotechnological processes in the production and manufacture of medicines; -the main stages of the biotechnological process; -resources of natural biocenoses as sources of biologically active substances (BAV); -methods, methods and principles of implementation and management of biotechnological processes Can: - carry out biotechnological processes of production and production of biologically active substances and individual components of microbial cells; - carry out biotechnological processes of production and manufacture of medicines; - carry out stage-by-stage control and standardization of the drugs obtained (determination of the antimicrobial activity of antibiotics, the activity of enzyme preparations, the viability of microorganisms); - isolate and purify BAS from biomass and culture fluid; - regulate and improve the biotechnological process in order to obtain a high-quality final product; ensure compliance with the rules of industrial hygiene, environmental protection, labor protection and safety Owns: -methods of controlled cultivation of microorganisms; -methods of immobilization of microbial cells -technology for obtaining biologically active substances and individual components of microbial cells; ability to implement and manage biotechnological processes
SC -3.3. He investigates the main methods of intermolecular interactions and mutual regulation of the processes of functioning of a living cell as part of a multicellular	Knows: -theoretical foundations of the most important technological and microbiological processes and their practical application for obtaining valuable waste products of microorganisms in an industrial way;

organism.	-
PC-3.4. Analyzes the structure and functions of genes and genomes, conducts structural and functional analysis of individual proteins and the proteome as a whole.	Knows: - methods, hardware design and technologies for the production of specialized biological products using microbiological synthesis, biocatalysis, genetic engineering; fundamentals of microbial biotechnology, selection and genetic design of microorganisms; - basic requirements for microorganisms - producers Can: - apply modern ideas about the basics of biotechnological production, genetic engineering in the selection and study of producer microorganisms; use knowledge about the basics of microbial biotechnology, breeding work to solve problems in the national economy Owns: - modern ideas about the methods of genetic engineering, nanobiotechnology, molecular modeling for the purposes of biotechnology; - methods of independent search and analysis of information in the field of industrial microbiology and biotechnology; - methods of search, selection and research of microorganisms; knowledge of modern apparatus and equipment for research work
PP-7.1. Conducts substantiation of biomedical research in order to develop drugs using living organisms and biological systems of various levels of organization.	Knows: - innovative ways to create medicines based on the use of genomics, proteomics and bioinformatics data; - new methods and techniques in the development, production and circulation of medicines; - methods for determining the benignity of producer microorganisms, determining the concentration of viable cells and their enzymatic activity. Can: - conduct research to improve the biotechnological process; to use new methods and techniques in the field of design of medicines and diagnostic drugs. Owns: - new methods and techniques in the field of design of medicines and diagnostic drugs; - physicochemical, microbiological and biochemical methods of analysis to confirm the purity of the producer, the authenticity of medicines, the detection of impurities and quantitative assessment; - the ability to participate in scientific research; skills in introducing new methods and techniques in the field of design of medicines and diagnostic drugs.
PP-7.2. Defines the goals and objectives of biomedical research and development of medicines. Plans biomedical research, carries out the selection of the design of scientific research in accordance with the goals and objectives.	Knows: - the physical nature of phenomena and processes in the body; - the structure of the human body in conjunction with the functions of systems and organs;

	-methods of constructing models of physiological systems at the subcellular, cellular, tissue and systemic levels of the human body; -methods for solving the problems of parameter identification and selection of informative signs on real clinical and experimental data; -methods of studying biochemical and physiological processes and phenomena occurring at the cellular, organ and systemic levels in the human body
PC-7.3. Conducts biomedical research using living organisms and biological systems of various levels of organization, analyzes the results obtained.	Can: apply known models of body systems to analyze physiological processes and states. -identify model parameters from experimental data or from the results of a clinical trial; -to carry out applied and practical projects for the study of biochemical, biophysical and physiological processes and phenomena occurring at the cellular, organ and system levels in the human body Owns: -methods of studying biochemical and physiological processes and phenomena occurring at the cellular, organ and systemic levels in the human body; -methods of applied and practical projects for the study of biochemical, biophysical and physiological processes and phenomena occurring at the cellular, organ and system levels in the human body
PC-7.4. Interprets the obtained results of biomedical research and development in order to elucidate the molecular mechanisms of biochemical processes.	Knows: -theoretical foundations of obtaining various biotechnological products; -patterns of kinetics of the growth of microorganisms and the formation of metabolic products; -methods of cultivation of microorganisms classification of enzymes, units of activity of enzymes; -methods of obtaining enzyme preparations; areas of application of enzymes in medicine. Can: -conduct the process of cultivation of microorganisms, cell cultures of plants and animals; -select optimal conditions that stimulate the maximum accumulation of the target product; -isolate, identify and culture microorganisms producing biomass and various metabolic products; -work with pure cultures of microorganisms, plants and animals; -isolate enzymes from various objects, investigate the properties and determine the kinetic parameters of enzymes; -evaluate the quantitative characteristics of the growth of microorganisms -Owns:

	- methods of working with microorganisms, plant and animal cell cultures; rules of safe work in the laboratory; - methods of calculating the basic parameters of biotechnological processes; - methods of biotransformation; - principles of production, research and application of enzymes, viruses, microorganisms, cell cultures of animals and plants, products of their biosynthesis and biotransformation

Exam materials,
containing a set of approved according to the established form of questions, exam tickets for the exam

1. Modern biotechnology. The concept of a biological object. General information about biological objects.

2. General classification of biotechnological products. Classification of biotechnological pharmaceutical products.

3. Existing definitions of biotechnology as a science and sphere of production. Biotechnology is one of the foundations of modern pharmacy.

4. Biotechnology as a basic stage and as one of the intermediate stages in the production of a medicinal substance. Biotechnological process that fully ensures the receipt of the target product

5. Biosynthesis and organic synthesis are complementary ways of creating drugs (on the example of antibiotics and hormones).

6. Using the properties of a biological object to improve it in order to create an effective and safe production of medicines.

7. Improvement of biological facilities used in the production of medicinal and diagnostic drugs. Methods of selection.

8. Improvement of biological facilities used in the production of medicinal and diagnostic drugs. Methods of introducing foreign genes: transformation, transduction, conjugation.

9. Methods of engineering enzymology in the production of medicines. Advantages of using immobilized bioobjects in the isolation and purification of drugs.

10. Immobilization of enzymes and whole cells of bioobjects in biotechnological production. Environmental and economic benefits.

11. Methods of immobilization of enzymes and whole cells. Examples of the use of immobilized bioobjects in the medical industry.

12. Immobilization of enzymes and cells-producers of medicinal substances.

13. Conditions necessary for higher organisms and microorganisms in biotechnological systems in the production of drugs. Life support systems.

14. Components of biotechnological production. Preparatory and main stages of production.

15. Methods of sterilization of process air, equipment and nutrient media in biotechnological production.

16. Thermal sterilization of nutrient media. The Deindorfer-Humphrey criterion. Preservation of the biological usefulness of the environments during their sterilization.

17. Classification of industrial biosynthesis of medicinal substances by the organization of material flows, by methods of cultivation of producers, by the role of the target product in the metabolism of the producer.

18. Influence of physical, chemical, and biological factors on fermentation processes.

19. Distinctive differences between deep and surface fermentation.

20. Criteria characterizing the process of biosynthesis.

21. Fermentation apparatus (fermenters). Process control systems.

22. General information about the device of bioreactors of different types. What types of bioreactors are used to work with industrial biocatalysts.

23. Features of the isolation of target products from the culture liquid, distinguishing the process from the isolation of target products during organic synthesis.

24. Centrifugation and separation in biotechnological production. Types of centrifuges. Types of separators. Specifics of application when working with biological objects and products of biosynthesis.

25. Filtration methods in biotechnological production. Specifics related to biological facilities and parameters of culture fluids. Pre-treatment of culture liquids. Filter presses. Sheet filters.

26. Membrane separation methods in biotechnological production. Microfiltration. Electrodialysis. Reverse osmosis. Ultrafiltration.

27. Drying methods for bioobjects and biosynthesis products. Spray "dryers". Sublimation "dryers". Physical phenomena in the cell during freezing.

28. Plant cells. Application in the biotechnological process for the transformation of medicinal substances.

29. Methods of cultivation of plant cells. Callus and suspension cultures. Immobilization of plant cells.

30. Biotechnological production of drugs based on plant cell cultures. Totipotency. Advantages of using cell cultures.

31. Suspension cultivation of plant cells: parameters of the biological object

to be taken into account; devices for cultivation.

32. GMP rules and their importance for the production of medicines. Features of GMP in the case of biotechnological production.

33. GMP rules in the production of biotechnological medicines. Reasons for the existence of international, regional and national GMP rules.

34. GMP Rules and Pharmacopoeia Monographs. Their complementarity.

35. A list of the main sections in the GMP rulebook. The meaning of the individual sections.

36. Rules of GLP and GCP in the testing of new drugs (on the example of antibiotics).

37. Biotechnology of amino acids. Chemical-enzymotic method of production. Microbiological synthesis.

38. Intracellular regulation of amino acid biosynthesis and ways of intensification of this process in production.

39. Construction of amino acid producer strains and process intensification pathways by optimizing fermentation conditions.

40. Production of vitamins and coenzymes by biotechnology methods. Production of vitamin B_{12}. Producers. Genetically engineered strain.

41. Production of vitamin B_2. Producers. Genetically engineered strain.

42. Production of ascorbic acid. Combination of the stages of chemical synthesis and bioconversion. Microorganisms that carry out bioconversion in various schemes for the production of ascorbic acid. The stage of conversion of D-sorbitol to L-sorbose.

43. Obtaining vitamin PP. NAD producers. Ways to increase the yield of the target product.

44. Producers of ergosterol, β-carotene, ubiquinones. Biotechnological schemes of obtaining.

45. Microbiological transformation of steroids in the creation of medicinal steroid drugs.

46. The main sources of raw materials for the production of steroid drugs.

47. Physiological feasibility of biotransformations of steroid compounds.

48. Bioconversion of steroids. Biological objects used for 11-hydroxylation, 1, 2-dehydrogenation, side chain cleavage processes.

49. Microbiological synthesis of hydrocortisone and production of prednisone from it by bioconversion.

50. Producers of antibiotics. Habitat. Selection methods.

51. Biological role of antibiotics. Causes of their late accumulation in the fermentation medium compared to the accumulation of biomass producer

52. General data on the biosynthesis of antibiotics. Precursors of β-lactam

antibiotics, aminoglycosides, erythromycin, tetracycline.

53. Multi-enzyme complexes in the cells of antibiotic producers.

54. Regulation of antibiotic biosynthesis. Carbon and nitrogen catabolite regulation. Inhibition by the type of feedback (retro-inhibition).

55. Mold fungi are producers of antibiotics. The main features of the structure of the cell and the cycle of development during fermentation. Antibiotics formed by fungi.

56. Antibiotics and other BAVs formed by fungi. General data on their chemical structure and application. Properties of producers.

57. Actinomycetes are producers of antibiotics. Features of the structure and cycle of development during fermentation. Antibiotics formed by actinomycetes.

58. Bacteria (eubacteria) are producers of antibiotics. The structure of the cell. Antibiotics formed by bacteria.

59. Semi-synthetic antibiotics. Biosynthesis and organic synthesis in the creation of semi-synthetic antibiotics (examples).

60. Mechanisms of resistance to β-lactam antibiotics. New β-lactam antibiotics effective against resistant forms of bacteria. Purposeful transformation.

61. Mechanisms of development of resistance to aminoglycoside antibiotics. New effective aminoglycosides. Purposeful transformation.

62. Liposomal dosage forms of antibiotics. Advantages over traditional forms. Methods of obtaining.

63. Natural sources of antibiotic resistance genes. Organizational measures as one of the ways to combat antibiotic resistance.

64. Preparations of normoflors: colibacterin, bifidumbacterin, lactobacterin, bificol. Properties. Purpose of application. Microorganisms that serve as the basis of drugs.

65. Lactic acid bacteria. Mechanisms of suppressive action on pathogenic and putrefactive bacteria. Other functions favorable to the human body. Preparations based on lactic acid bacteria.

66. Preparations based on live cultures of symbiont microorganisms. Value in dysbiosis.

67. Recombinant proteins. Construction and features of cultivation of microorganisms-producers of proteins foreign to them.

68. Purification of recombinant proteins obtained by microbiological synthesis. Specific impurities in the final product: control and removal.

69. Insulin. Sources of raw materials. Recombinant human insulin. Causes of obtaining by microbiological synthesis. Diagram of the production process.

70. Construction of strains-producers of human insulin. Advantages of E. coli as a producer.

71. Immunobiotechnology of drugs.

72. Monoclonal antibodies. Production and application.

73. The ELISA principle. Homogeneous and heterogeneous ELISA. Applications. Advantages.

74. Vaccine. Classification. Characteristics of each individual type of vaccine: live, inactivated, subunit, DNA vaccines.

75. Features of the technology of obtaining vaccines. Control of specific activity. Storage.

Criteria for assessing students on the exam by discipline

"Medical and Pharmaceutical Biotechnology"

Points (rating)	**Score of the test/exam** (standard)	**Requirements for the formed competencies**
100-85 points	*"Excellent"*	The "excellent" grade is given to the student if he has deeply and firmly mastered the program material, exhaustively, consistently, clearly and logically coherently presents it, is able to closely link the theory with practice, freely copes with tasks, questions and other types of application of knowledge, and does not find it difficult to answer when modifying tasks, uses the material of monographic literature in the answer, correctly justifies the decision made, has versatile skills and techniques performing practical tasks.
85-76 points	*"Good"*	The grade "good" is given to the student if he firmly knows the material, correctly and substantively presents it, without allowing significant inaccuracies in the answer to the question, correctly applies theoretical provisions when solving practical questions and problems, possesses the necessary skills and techniques for their implementation.
75-61 points	*"satisfactory"*	The grade "satisfactory" is given to the student if he has knowledge only of the basic material, but has not mastered its details, admits inaccuracies, insufficiently correct wording, violations of the logical sequence in the presentation of the program material, has difficulties in performing practical work.
60-50 points	*"unsatisfactory"*	The grade "unsatisfactory" is given to a student who does not know a significant part of the program material, makes significant mistakes, uncertainly, with great difficulties performs practical work. As a rule, the grade "unsatisfactory" is given to students who cannot continue their studies without additional classes in the relevant discipline.