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

INSTITUTE OF LIFE SCIENCES AND BIOMEDICINE (SCHOOL)

AGREED
Head of Educational Program
_____ V.V. Kumeiko
(Signed) (Surname)

CLAIM
Director of the Production Company Structural subdivision
_____ V.V. Kumeiko
(Signed) (Surname)
April 12, 2023

DISCIPLINE WORK PROGRAM (RAP)
"Drug Development"
Area of study 06.03.01 Biology
Form of training: full-time

The work program is drawn up in accordance with the requirements of the Federal State Educational Standard in the field of training 06.03.01 Biology, approved by the order of the Ministry of Education and Science of the Russian Federation dated 07.08.2020 No. 9 20

The work program was discussed at the meeting of the Department of Medical Biology and Biotechnology, Minutes No. 3 dated April 12, 2023.

Director of the Department of Medical Biology and Biotechnology V.V. Kumeiko
Authors: Candidate of Biological Sciences, Associate Professor Kumeiko V.V.

Vladivostok
2022

Back of the title page of the RPD

1. The work program was revised at the meeting of the Department/Department/Division (implementing the discipline) and approved at the meeting of the Department/Department/Division (graduating structural unit), minutes of "

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2. The work program was revised at the meeting of the Department/Department/Division (implementing the discipline) and approved at the meeting of the Department/Department/Division (graduating structural unit), minutes of "

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Abstract of the discipline

Drug Development

The total labor intensity of the discipline is 3 credit units / 108 academic hours. It is a discipline of the compulsory part of the EP, studied in the 3rd year and ends *with a test.* The curriculum provides for 18 hours of lectures, 36 hours of practical work, *18* hours of laboratory work, and *36 hours* of hours for independent work of the student.

Language: Russian.

Objective: Todeepen theoretical knowledge and practical skills in the field of drug development.

Tasks:

- in-depth study of the theoretical foundations of drug development;
- Improving practical skills in drug development.

For successful study of the discipline, students should have the following preliminary competencies:

-comprehends the principles of structural and functional organization of biological systems;

- anduses physiological, cytological, histological, biochemical, biophysical methods of analysis to assess the state of living objects and monitor their habitat;

- anduses the basic laws of physics, chemistry, earth sciences and biology in his professional activities.

Competencies are obtained as a result of studying the disciplines of *biochemistry, general biology, molecular and cellular biology*, the student should be ready to study such disciplines as immunology, practicalmedicine, forming competencies:

- aanalyzes the pharmacokinetics and pharmacodynamics of the studied objects based on knowledge of morphofunctional features, physiological states and pathological processes in the body;

•To establish methods for the synthesis and analysis of specific nanostructured drugs;

• todevelop the technology of production nanostructured medicines;

- Conductcomplex tests of experimental formulations of nanostructured drugs.

Students' Competencies, Indicators of Their Achievement and Learning Outcomes in the Discipline

Code and name of professional competence (result of mastering)	Code and name of the competency indicator
PC-3 Capable of conducting experimental studies of biologically active substances and developing medicines and medical devices	PC-3.1 Uses knowledge and methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances
	PC-3.2 Able to apply molecular modeling methods for the development of drugs and medical devices
	PC-3.3 Capable of developing medicines and medical devices using pharmacological research methods and pharmaceutical technologies
	PC-3.4 Capable of developing nanosystems for the creation of medicines and medical devices
	PC-3.5 Capable of conducting preclinical trials of drugs and medical devices

Code and name of the competency indicator	Name of the assessment indicator (the result of learning in the discipline)
PC-3.1 Uses knowledge and methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances	Knows Methods of Physiology, Biochemistry, Molecular and Cellular Biology. Can use the methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances. Owns skills of knowledge and methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances.
PC-3.2 Able to apply molecular modeling methods for the development of drugs and medical devices	Knows Molecular Modeling Methods. Can Apply molecular modeling methods. Owns molecular modeling methods for the development of medicines and medical devices.
PC-3.3 Capable of developing medicines and medical devices using pharmacological research methods and pharmaceutical technologies	Knows methods of pharmacological research and pharmaceutical technologies. Can Apply pharmacological research methods and pharmaceutical technologies. Owns ability to develop medicines and medical devices.
PC-3.4 Capable of developing nanosystems for the creation of medicines and medical devices	Knows methods of pharmacological research and pharmaceutical technologies. Can apply development methods to the creation of medicines and medical devices. Owns

Code and name of the competency indicator	Name of the assessment indicator (the result of learning in the discipline)
	the ability to develop nanosystems for the creation of medicines and medical devices.
PC-3.5 Capable of conducting preclinical trials of drugs and medical devices	Knows methods of preclinical testing of medicines and medical devices. Can conduct preclinical trials of medicines and medical devices. Owns skills in conducting preclinical trials of medicines and medical devices.

To form the above competencies within the framework of the discipline "Drug Development", the following educational technologies and methods of active/interactive learning are used: a business game, work in small groups, a round table.

I. Goals and objectives of mastering the discipline

Objective: Todeepen theoretical knowledge and practical skills in the field of drug development.

Tasks:

- in-depth study of the theoretical foundations of drug development;
- Improving practical skills in drug development.

Students' Competencies, Indicators of Their Achievement and Learning Outcomes in the Discipline

Code and name of professional competence (result of mastering)	Code and name of the competency indicator
PC-3 Capable of conducting experimental studies of biologically active substances and developing medicines and medical devices	PC-3.1 Uses knowledge and methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances
	PC-3.2 Able to apply molecular modeling methods for the development of drugs and medical devices
	PC-3.3 Capable of developing medicines and medical devices using pharmacological research methods and pharmaceutical technologies
	PC-3.4 Capable of developing nanosystems for the creation of medicines and medical devices
	PC-3.5 Capable of conducting preclinical trials of drugs and medical devices

Code and name of the competency indicator	Name of the assessment indicator (the result of learning in the discipline)
PC-3.1 Uses knowledge and methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances	Knows Methods of Physiology, Biochemistry, Molecular and Cellular Biology. Can use the methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances. Owns skills of knowledge and methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances.
PC-3.2 Able to apply molecular modeling methods for the development of drugs and medical devices	Knows Molecular Modeling Methods. Can Apply molecular modeling methods. Owns molecular modeling methods for the development of medicines and medical devices.
PC-3.3 Capable of developing medicines and	Knows

Code and name of the competency indicator	Name of the assessment indicator (the result of learning in the discipline)
medical devices using pharmacological research methods and pharmaceutical technologies	methods of pharmacological research and pharmaceutical technologies. Can Apply pharmacological research methods and pharmaceutical technologies. Owns ability to develop medicines and medical devices.
PC-3.4 Capable of developing nanosystems for the creation of medicines and medical devices	Knows methods of pharmacological research and pharmaceutical technologies. Can apply development methods to the creation of medicines and medical devices. Owns the ability to develop nanosystems for the creation of medicines and medical devices.
PC-3.5 Capable of conducting preclinical trials of drugs and medical devices	Knows methods of preclinical testing of medicines and medical devices. Can conduct preclinical trials of medicines and medical devices. Owns skills in conducting preclinical trials of medicines and medical devices.

II. Labor intensity of the discipline and types of training in the discipline

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

The types of training and work of the student in the discipline are:

Designation	Types of Study Sessions and Student Work
Mild	Lecture
Lex electric.	
Ave	Practical exercises
Pp electric.	
Lab	Labs
WED:	Student's independent work during the period of theoretical training
	And other types of work

III. Structure of the discipline

The form of study is full-time.

№	Section Name Discipline	S e	Number of hours by type of training and work of the student	

		m e s t e r	Mild	Lab	Ave	OK	WE D	Contr ol	Forms of intermediate attestation
1	Section 1. General Principles of Drug Substance Development.	5	9	9	18	-	18	-	Questions for the test
2	Section 2. Preclinical studies	5	9	9	18	-	18	-	Questions for the test
	Total:	5	18	18	36	-	36	-	Credit

IV. CONTENT OF THE THEORETICAL PART OF THE COURSE

Lectures

Section 1. General Principles of Drug Substance Development.

Topic 1. Historical Aspects of Methods of Obtaining Medicines.

Topic 2. Sources of pharmacologically active substances.

Topic 3. Methods of obtaining medicinal substances: empirical, directed synthesis, targeted synthesis.

Topic 4. Drug development cycle, stages and stages.

Topic 5. Modern Approaches to the Discovery of Medicinal Substances.

Section 2. Preclinical studies.

Topic 6. Steps of the pharmacokinetic process.

Topic 7. Experimental pharmacokinetic studies.

Topic 8. Assessment of toxicity of drug substances.

V. THE CONTENT OF THE PRACTICAL PART OF THE COURSE AND INDEPENDENT WORK

Practical exercises

Class 1. Strategy for the development of new medicines. Methods of obtaining medicinal substances: empirical, directed synthesis, targeted synthesis. Drug development cycle, stages and stages. Fundamentals of Organic and Medicinal Chemistry in the Synthesis of Medicinal Substances.

Class 2. Production of medicines of natural origin. Production of medicines from natural LRS and animal products. Preparation of drugs from cell and tissue culture. Identification of new medicinal plants and new types of medicinal plant raw materials.

Class 3. Rational design in the discovery of new drug substances. Moore's Law in Pharmacology. Metagenomics. Problems in the discovery of new drug substances. Opportunities of new omics technologies for pharmacology. Multilevel modeling of the action of drug substances. Molecular Modeling in Drug Discovery. Molecular dokinng.

Lesson 4-5. Preclinical Studies: Prototypes, Hits, Leads, Lead Optimization, Drug Candidates.

Probability of success in drug development. A new paradigm for drug development. Criteria in the study of the active compound. Lead generation strategy. The role of biological targets in the development of new drugs. Correct dosing of drugs in the experiment. Studies on volunteers.

Lesson 6-7. Preclinical studies. ADME.

Steps of the pharmacokinetic process. Experimental pharmacokinetic studies. In vitro pharmacokinetic studies. Probability of establishing an in vivo/in vitro correlation. Study design for a new active ingredient in one animal species. Scope of study of the pharmacokinetics of a multicomponent drug.

Class 8-9. Preclinical studies. Toxicity assessment.

Grounds for registration of a medicinal product. Requirements for reducing the scope of research. General principles of research. Assessment of acute and chronic toxicity. Methods for the study of specific types of toxicity.

Class 10. Clinical studies.

Phases of clinical trials. Comparison of study types. Group distribution design, types of randomization. Blocks and stratification in randomization.

Class 11. Clinical Studies

Bioequivalence test. Inferiority assessment design. Adaptive research design. Principles of camouflage.

Class 12. Principles of development of new dosage forms.

Current trends in the creation of new dosage forms. Systems for targeted delivery of drug substances. Controlled-release drug systems. Onthe particles. Biopolymer dosage forms. Biodegradable dosage forms. Evaluation of the efficacy of the dosage form.

Labs

Lab 1. Methods of obtaining medicinal substances: empirical, directed synthesis, targeted synthesis.

Lab 2. Drug development cycle, stages and stages.

Lab 3. Modern Approaches to the Discovery of Medicinal Substances.

Lab 4. Steps of the pharmacokinetic process.

Lab 5. Experimental pharmacokinetic studies.

Lab 6. Assessment of toxicity of drug substances.

Self-paced work

Students' independent work is aimed at improving the skills and abilities acquired during classroom classes, as well as developing self-organization and self-discipline skills.

The support of independent work consists in the continuous development of the student's rational methods of cognitive activity, the transition from the activity performed under the guidance of the teacher to the activity organized independently, to the complete replacement of control on the part of the teacher with self-control.

Questions and assignments for self-study

1. The Concept of Good Practices in Pharmacy (GXP).
2. Harmonization of requirements and standards in the pharmaceutical sector.
3. Main regulatory procedures in the field of circulation of medicines.
4. International system of cooperation of pharmaceutical inspections.
5. International requirements for pharmaceutical development.
6. Structure of ICH (International Conference on Harmonization) documents.
7. Elements of pharmaceutical development.
8. Development strategies and innovations in the pharmaceutical industry.
9. Concept and principles of Good Laboratory Practice (GLP).
10. Types and stages of preclinical studies. Ethical aspects.
11. Regulatory documents for conducting preclinical studies.
12. Basic block programs of preclinical research.
13. Concept and principles of Good Clinical Practice (GCP).
14. Types and Phases of Clinical Trials. Legal and ethical aspects.
15. Clinical Trial Planning, Safety Reporting.
16. Conducting clinical trials to assess bioequivalence.
17. Basic Provisions of the System of State Registration of Medicines.
18. Procedure for Formation of the Registration Dossier for a Medicinal Product.
19. Procedure for Expert Examination in Registration of Medicinal Products.

VI. MONITORING THE ACHIEVEMENT OF THE COURSE OBJECTIVES

Item No.	Supervised sections/topics of the discipline	Code and name of the indicator of achievement	Learning Outcomes	Evaluation Tools	
				Current control	Intermediate Certification
1	Section 1. General Principles of Drug Substance Development.	PC-3.1 Uses knowledge and methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances	Knows Methods of Physiology, Biochemistry, Molecular and Cellular Biology. Can use the methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances. Owns skills of knowledge and methods of physiology, biochemistry, molecular and cellular biology to study the properties of biologically active substances.	Test	Questions for the test
		PC-3.2 Able to apply molecular modeling methods for the development of drugs and medical devices	Knows Molecular Modeling Methods. Can Apply molecular modeling methods. Owns molecular modeling methods for the development of medicines and medical devices.	At thePoll	Questions for the test

2	Section 1. General Principles of Drug Substance Development.	PC-3.3 Capable of developing medicines and medical devices using pharmacological research methods and pharmaceutical technologies	Knows methods of pharmacological research and pharmaceutical technologies. Can Apply pharmacological research methods and pharmaceutical technologies. Owns ability to develop medicines and medical devices.	Test	Questions for the test
		PC-3.4 Capable of developing nanosystems for the creation of medicines and medical devices	Knows methods of pharmacological research and pharmaceutical technologies. Can apply development methods to the creation of medicines and medical devices. Owns the ability to develop nanosystems for the creation of medicines and medical devices.	Oral Questioning	Questions for the test
		PC-3.5 Capable of conducting preclinical trials of drugs and medical devices	Knows methods of preclinical testing of medicines and medical devices. Can conduct preclinical trials of medicines and medical devices. Owns skills in conducting preclinical trials of medicines and medical devices.	Test	Questions for the test

VII. EDUCATIONAL AND METHODOLOGICAL SUPPORT OF STUDENTS' INDEPENDENT WORK

Guidelines for writing and formatting an abstract

Abstracting of educational and scientific literature involves an in-depth study of individual scientific works, which should ensure the development of the necessary skills for working on the book. All this will contribute to the expansion of scientific horizons, the improvement of their theoretical training, and the formation of scientific competence.

Textbooks, individual monographic studies and articles on issues provided for by the program of the academic discipline are offered for abstracting. When selecting literature on the chosen issue, it is necessary to cover the most important areas of development of this science at the present stage. Particular attention should be paid to those literary sources that (directly or indirectly) can help the specialist in his practical activities. However, this section also includes works and individual studies on issues that go beyond the discipline being studied. It is recommended to use this literature if you want to expand your knowledge in any branch of science.

Along with literature on general issues, students are supposed to read literature taking into account the profile of their professional activity, obtained independently. Not all the proposed literature is equal in content and volume, so different approaches to its study are possible. In one case, it can be a general abstract of several literary sources of different authors devoted to the consideration of the same issue, in the other case, it can be a detailed study and abstract of one of the recommended works or even its separate sections, depending on the degree of complexity of the issue (problematic). In order to decide what to do in each case, you should consult with the teacher.

The choice of a specific work for the abstract should be preceded by a detailed acquaintance with the list of all literature given in the curriculum of the discipline. It is recommended to first familiarize yourself with the selected work by looking at the subheadings, highlighted texts, diagrams, tables, and general conclusions. Then it is necessary to read it carefully and thoughtfully (delving into the ideas and methods of the author), making notes on a separate sheet of paper about the main provisions and key issues. After reading, you should think over the content of the article or a separate chapter, paragraph (if we are talking about a monograph) and briefly write it down. Only strict definitions and formulations of laws should be written out verbatim. Sometimes it's helpful to include one or two examples to illustrate. In the event that there are unclear passages, it is recommended to read the following exposition, as it can help to understand the previous material, and then return to the comprehension of the previous exposition.

The result of the work on literary sources is an abstract.

When preparing an abstract, it is necessary to highlight the most important theoretical provisions and substantiate them independently, paying attention not only to the result, but also to the methodology used in the study of the problem. Reading scientific literature should be critical. Therefore, it is necessary to strive not only to assimilate the main content, but also the method of proof, to reveal the features of different points of view on the same issue, to assess the practical and theoretical significance of the results of the reviewed work. A very desirable element of the abstract is the expression by the listener of his own attitude to the ideas and conclusions of the author, supported by certain arguments (personal experience, statements of other researchers, etc.).

As mentioned above, abstracts of monographs and journal articles of a research nature must contain a definition of the problem and specific objectives of the research, a description of the methods used by the author, as well as the conclusions that he came to as a result of the research. The proposed literature for abstracting is constantly updated.

Instructions for writing essays:

General requirements for the abstract:

The abstract should be written according to the standard scheme, including:

- Title page
-contents
-introduction
- Main part
- Conclusionof the E
- List of references.

It is desirable to include tables and (or) figures in the text of the abstract: diagrams, graphs.The volume of the abstract: 10-20 pages of A4 format computer layout in the Times New Roman editor, with 1.5 intervals, in 14 fonts. The title of the topic of the essay should fully correspond to the chosen option.

The structure of the abstract should meet the standard requirements for writing essays: introduction, justification for the choice of topic, presentation of the topic, conclusion. More detailed requirements for the written design of the abstract are presented in the Procedure "Requirements for the design of written works performed by FEFU students and listeners" http://law.wl.dvgu.ru/docs/treb_2012.pdf

Approximate list of abstract topics:

1. Mechanisms of energy production in mitochondria.
2. The liver is its role in the human body.
3. Alcoholism and drug addiction are metabolic disorders.
4. Influence of trace elements on enzyme activity.

5. Metabolic connections of the Krebs cycle.
6. Types of jaundice.
7. Biotransformation of xenobiotics in the body.
8. Cholesterol fund in the human body and ways of its consumption.
9. Biological role of iron, molybdenum and zinc.

Criteria and Indicators Used in the Evaluation of the Educational Essay

Criteria	Indicators
1. Novelty of the abstracted text Max. – 5 points	- relevance of the problem and topic;- novelty and independence in the formulation of the problem, in the formulation of a new aspect of the problem selected for analysis;- the presence of the author's position, independence of judgments.
2. Degree of disclosure of the essence of the problemMax. – 5 points	- correspondence of the plan to the topic of the abstract;- correspondence of the content to the topic and plan of the abstract;- completeness and depth of disclosure of the main concepts of the problem;- validity of ways and methods of working with the material;- ability to work with literature, systematize and structure the material;- ability to generalize, compare different points of view on the issue under consideration, argue the main provisions and conclusions.
3. Reasonableness of the choice of sourcesMax. – 5 points	- the range and completeness of the use of literary sources on the problem;- attraction of the latest works on the problem (journal publications, materials of collections of scientific papers, etc.).
4. Compliance with Registration Requirements Max. – 5 points	- correct formatting of references to the literature used;- literacy and culture of presentation;- knowledge of terminology and conceptual apparatus of the problem;- compliance with the requirements for the volume of the abstract;- culture of design: highlighting paragraphs.
5. Literacy Max. - 5 points	- absence of spelling and syntax errors, stylistic errors;- absence of typos, abbreviations of words, except for generally accepted ones;- literary style.

Guidelines for Maintenance, Submission Requirements and Criteria for Evaluating the Outline

A synopsis (from the Latin conspectus – review) is a written text in which the content of the main source of information is briefly and consistently stated. To take notes is to bring to some order the information gleaned from the original. The process is based on the systematization of what has been read or heard. Notes can be made both in the form of precise excerpts, quotations, and in the form of a free presentation of meaning. The manner of writing the synopsis, as a rule, is close to the style of the original source. If the synopsis is written correctly, it should reflect the logic and semantic connection of the information being recorded.

In well-made notes, it is easy to find specialized terminology that is clearly explained and clearly highlighted for memorizing the meanings of various words.

Using the outline information, it is easier to create meaningful creative or scientific works, various essays and articles.

Note-taking rules

1. Read the text carefully. Along the way, mark incomprehensible places, new words, names, dates.

2. Make inquiries about the persons and events mentioned in the text. When recording, do not forget to put reference data in the fields.

3. When reading the text for the first time, make a simple outline. When re-reading, try to summarize the main points of the text, noting the author's arguments.

4. The final stage of note-taking consists of re-reading the previously marked passages and writing them down consecutively.

5. When taking notes, you should try to express the author's thought in your own words.

6. Strive to ensure that one paragraph of the author's text is conveyed in one, maximum two sentences.

When taking notes of lectures, it is recommended to adhere to the following basic rules.

1. Do not start writing down the material from the first words of the teacher, first listen to his thought to the end and try to understand it.

2. Start writing at the moment when the teacher, having finished the presentation of one idea, begins to comment on it.

3. In the synopsis, it is necessary to highlight individual parts. It is necessary to distinguish between headings, subheadings, conclusions, to separate one topic from another. Selection can be done with an underline or a different color (just don't turn the text into colorful pictures). It is recommended to indent paragraphs and points of the plan, white lines to separate one thought from another, and numbering. If definitions, formulas, rules, and laws can be made more visible in the text, they are framed. Over time, you'll have your own selection system.

4.Create your entries using accepted conventions. When taking notes, be sure to use a variety of signs (they are called signal signs). These can be pointers and directional arrows, exclamation and question marks, combinations PS (afterword) and NB (pay attention). For example, you can denote the word "therefore" with a mathematical arrow =>. Once you've developed your own character set, it's easier and faster to create an outline and then study it.

5. Don't forget about abbreviations (abbreviated words), equal and inequality signs, more and less.

6. Abbreviations are very useful for creating a correct outline. Be careful, though. Connoisseurs believe that abbreviations such as "d-t" (to think) and similar

ones should not be used, since later a large amount of time is spent on deciphering, and after all, the reading of the synopsis should not be interrupted by extraneous actions and reflections. The best thing to do is to develop your own system of abbreviations and use them to denote the same words (and nothing else) in all entries. For example, the abbreviation "g-t" will always and everywhere be the word "to speak," and the capital "P" will be the word "work."

7. Undoubtedly, foreign words will help to organize a good synopsis. The most common among them are English. For example, the abbreviated "ok" successfully denotes the words "excellent", "wonderful", "good".

8. Complex and lengthy reasoning should be avoided.

9. When taking notes, it is better to use declarative sentences, avoid independent questions. Questions are appropriate in the margins of the outline.

10. Do not try to record the material verbatim, in this case the main idea is often lost, and it is difficult to keep such a record. Discard secondary words, without which the main idea is not lost.

11. If there are terms in the lecture that you do not understand, leave a place, clarify their meaning with the teacher after the lesson.

Evaluation criteria:

86-100 points are given to the student if the abstract is presented in the most understandable form, has a plan, schemes and drawings in the structure, reveals all the basic concepts and questions given above;

76-85 points are given to the student if the abstract is presented in a sufficiently understandable form, has schemes and/or drawings in the structure, reveals more than half of the main concepts and questions;

75-61 points are given to the student if the abstract is presented in a relatively understandable form and reveals half of the main concepts and questions;

60-50 points are given to the student if the outline is presented in an incomprehensible form and reveals less than half of the main concepts and questions.

VIII. LIST OF REFERENCES AND INFORMATIONAL AND METHODOLOGICAL SUPPORT OF THE DISCIPLINE

Reference citations

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pharmacotherapy: Textbook]. Moscow: Vuzovskiy uchebnik: NITs Infra-M, 2012. – 237 p. + CD-ROM. (binding, cd rom)ISBN 978-5-9558-0258-9. – Text : electronic. – URL: https://znanium.com/catalog/product/261014

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4. K. K. Kevra, A. V. Khapalyuk, L. N. Gavrilenko [i dr.] [i dr.] [Clinical pharmacology: textbook] / M. K. Kevra, A. V. Khapalyuk, L. N. Gavrilenko [i dr.] ; edited by M. K. Kevre. - Minsk: Vysheishaya shkola, 2015. — 575 c. — ISBN 978-985-06-2454-3. — Text : electronic // Digital educational resource IPR SMART : [site]. — URL: https://www.iprbookshop.ru/48005.html

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Further reading

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2. Shimanovsky N.L., Epinetov M.A., Melnikov M.Ya. Moscow , Fizmatlit Publ., 2010. – 623 p. (in Russian). http://lib.dvfu.ru:8080/lib/item?id=chamo:299676&theme=FEFU

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5. Natural compounds. Synthesis, Chemical Structure and Biological Activity: Selected Works / G. B. Elyakov; [guest editor V. A. Stonik] ;. Vl-k: Dalnauka, 2007. 351 p. (in Russian). http://lib.dvfu.ru:8080/lib/item?id=chamo:265439&theme=FEFU

6. Human Biochemistry: Textbook in 2 vols. / R. Murray, D. Grenner, P. Mayes (et al.); transl. by V. V. Borisov, E. V. Dainichenko. Moscow : Mir BINOM. Lab. Znanie Publ., 2009. – 381 p. (in Russian). http://lib.dvfu.ru:8080/lib/item?id=chamo:277691&theme=FEFU

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

1. http://elibrary.ru/ - Scientific Electronic Library
2. http://science.km.ru/ - electronic resource on different sections of biology
3. http://elementy.ru/ is an informational and educational resource dedicated to natural sciences.
4. http://www.iprbookshop.ru/ is the IPRbooks electronic library system.
5. http://znanium.com/ - EBS "Znanium".
6. https://nplus1.ru/ - N+1, a popular science online publication about science, engineering and technology
7. http://antropogenez.ru/ is a popular science information resource about human evolution
8. http://web.a.ebscohost.com/ehost/search/basic?sid=851485f8-6200-4b3e-aaab-df4ba7be3576@sessionmgr4008&vid=1&tid=2003EB is a collection of books on various sections from the EBSCOhost database.

9. http://rosalind.info/problems/locations/- resource for self-study of bioinformatics Rosalind.

10. http://www.ncbi.nlm.nih.gov/ website of the- National Center for Biotechnology Information (NCBI).

11. http://www.mendeley.com/- *Mendeley*: Free reference manager and PDF organizer; Librarian Program.

12. http:// www.ebi.ac.uk – website of the European Bioinformatics Institute

13. http:// www.scopus.com – Scopus bibliographic database and citation index

14. http://thomsonreuters.com/thomson-reuters-web-of-science/ Web of Science bibliographic database and citation index

List of information technologies and software

1. Microsoft Office Professional Plus 2013 is an office suite that includes software for working with various types of documents (texts, spreadsheets, databases, etc.);

2. 7Zip 16.04 is a free file archiver with a high compression ratio;

3. Adobe Acrobat XI Pro – a software package for creating and viewing electronic publications in PDF format;

4. AutoCAD Electrical 2015 – three-dimensional computer-aided design and drafting system;

5. ESET Endpoint Security 5 – comprehensive protection for Windows-based workstations. Virtualization support + new technologies;

6. WinDjView 2.0.2 – a program for recognizing and viewing files with the same DJV and DjVu formats; SolidWorks 2016 is a CAD software package for automating the work of an industrial enterprise at the stages of design and technological preparation of production

7. Compass-3D LT V12 – Three-Dimensional Simulation System

8. Notepad++ 6.68 – Text Editor

IX. METHODICAL INSTRUCTIONS FOR MASTERING THE DISCIPLINE

Lecture

A lecture is the main active form of classroom classes, an explanation of the fundamental and most difficult theoretical sections of molecular biology and the theory of genetic engineering, which involves intensive mental activity of the student and is especially important for mastering the subject. A lecture should

always be cognitive, developmental, educational and organizing. Lecture notes help to assimilate the theoretical material of the discipline. When listening to a lecture, you need to Take notes of the main information, preferably with your own wording, which allows you to remember the material better. An outline is useful when it is written by the student independently.

In the lecture, the teacher gives only a small part of the material on certain topics that are presented in the textbooks. In addition, the instructor informs students about what additional information can be obtained on the topics discussed, and from what sources. Therefore, when working with lecture notes, it is always necessary to use the main textbooks, additional literature and other recommended sources on this discipline. It is this serious work of the student with the lecture material that allows him to achieve success in mastering new knowledge.

To present a lecture course on the discipline "Drug Development", the following are used as forms of active learning: lecture-conversation, lecture-visualization, which are built on the basis of knowledge received by students in the framework of subjects preceding the course. Electronic presentations, tables, video files, and blackboard diagrams are used to illustrate verbal information. In the course of the lecture material, problematic questions or questions with elements of discussion are posed.

Lecture – visualization

The lecture is accompanied by the demonstration of tables, electronic presentations, video files - such a combination of ways of presenting information significantly simplifies its mastering by students. Verbal presentation of the material should be accompanied and combined with the visual form. The information presented in the form of diagrams on the board, tables, slides allows you to form problematic questions, and contribute to the development of professional thinking of future specialists.

Lecture-conversation

Lecture-conversation, "dialogue with the audience", is the most common form of active learning and allows students to be involved in the educational process, since there is direct contact between the teacher and the audience. Such contact is achieved during the lecture, when students are asked questions of a problematic or informational nature, or when they are invited to ask the teacher questions themselves. Questions are offered to the entire audience, and any of the students can offer their own answer; another can complement it. In the course of the educational process, this allows you to identify the most active students and activate those who do not participate in the work. This form of lecture allows you to involve students in the work process, attract their attention, stimulate thinking, gain collective experience, and learn how to form questions. The advantage of a lecture-

conversation is that it allows you to draw students' attention to the most important issues of the topic, determine the content and pace of the presentation of educational material, as well as determine the topics that are most interesting to students, in order to possibly adjust the form of the material taught.

An extended conversation involves the preparation of students on each issue of the lesson plan with a single list of recommended mandatory and additional literature. Reports are prepared by students on a pre-proposed topic.

A dispute in a group has a number of advantages. A dispute can be caused by the teacher during the lesson or planned by him in advance.

Press conference. The teacher assigns several students to prepare short (thesis) reports. After the presentations, students ask questions, which are answered by the speakers and other members of the expert group. Based on the questions and answers, a creative discussion unfolds together with the teacher.

Case study method**.**The case-study method is a method of active problem-situational analysis based on learning by solving specific problems (case solving). The method of specific situations (case-study method) refers to non-game imitation active teaching methods and is considered as a tool that allows you to apply theoretical knowledge to solving practical problems. At the end of the lesson, the teacher tells a series of situations and offers to find solutions for those problems that are voiced in them. At the same time, the problem itself does not have unambiguous solutions. Students must analyze the situation, understand the essence of the problems, propose possible solutions and choose the best one. Thanks to the knowledge gained at the lecture, it is easy for the student to correlate the theoretical knowledge received with a real practical situation. As an interactive teaching method, it gains a positive attitude from students, who see it as an opportunity to take the initiative, feel independent in mastering theoretical provisions and mastering practical skills. No less important is the fact that the analysis of situations has a strong impact on the professionalization of students, contributes to their maturation, forms interest and positive motivation for learning. The method is aimed not so much at mastering specific knowledge or skills, as at developing the general intellectual and communicative potential of the student and the teacher.

It is a learning method designed to improve skills and gain experience in the following areas:

- identifying, selecting and solving problems;
- working with information – comprehending the meaning of the details described in the situation;
- analysis and synthesis of information and arguments;
- working with assumptions and conclusions;
- evaluation of alternatives;

- decision-making;
- Listening to and understanding other people is a group work skill. The main function of the case method is to teach students to solve complex unstructured problems that cannot be solved in an analytical way. The case activates students, develops analytical and communicative skills, leaving students face to face with real situations.

The case study is designed to increase the effectiveness of educational activities: as an illustration for solving a certain problem, explaining a particular phenomenon, studying the features of its manifestations in real life, developing competence aimed at solving various life and work situations (the use of the case involves individual and group work of students).

Brainstorming is a widely used way of generating new ideas to solve scientific and practical problems. Its goal is to organize collective thinking to find non-traditional ways to solve problems.

The use of the brainstorming method in the educational process allows you to solve the following tasks:

- creative assimilation of educational material by students;
- connection of theoretical knowledge with practice;
- • activation of educational and cognitive activities of students;
- formation of the ability to concentrate attention and mental efforts on the solution of an urgent task;
- formation of the experience of collective thinking activity.

The problem formulated in the brainstorming class should have theoretical or practical relevance and arouse the active interest of students. A common requirement that must be taken into account when choosing a problem for brainstorming is the possibility of many ambiguous solutions to the problem, which is put forward to students as a learning task.

Quizzes & Testing

Current control of material assimilation is assessed by oral answers, tests, as well as paper testing.

Assessments of laboratories, colloquiums, tests and testing mainly form the grade for this discipline.

LOGISTICAL SUPPORT FOR DISCIPLINE

Training sessions on the discipline are held in rooms equipped with appropriate equipment and software.

The list of logistical and software of the discipline is given in the table.

Logistical and software of the discipline

Name of special rooms and rooms for independent work	Equipment special rooms and rooms for self-study	List of licensed software. Details of the supporting document
690922, Primorsky Krai, Vladivostok, Russky Island, Saperny Peninsula, Ajax village, 10, aud. M 605	Multimedia audience: Electric Screen 236*147cm Trim Screen Line; DLP Projector, 3000 ANSI Lm, WXGA 1280x800, 2000:1 EW330U Mitsubishi; CORSA-2007 Tuarex Specialized Equipment Fastening Subsystem; Video Switching Subsystem: Extron DXP 44 DVI Pro DVI Matrix Switcher; Extron DVI 201 Tx/Rx twisted-pair DVI extender Audio switching and sound amplification subsystem; Extron SI 3CT LP ceiling mount speaker system; Extron DMP 44 LC Digital Audio Processor; Extension for IPL T CR48 control controller;Wireless LAN for students is provided by a system based on 802.11a/b/g/n 2x 2 MIMO (2SS) access points. Моноблок HP ProOne 400 All-in-One 19.5 (1600x900), Core i3-4150T, 4GB DDR3-1600 (1x4GB), 1TB HDD 7200 SATA, DVD+/-RW, GigEth, Wi-Fi, BT, usb kbd/mse, Win7Pro (64-bit) +Win8.1Pro(64-bit), 1-1-1 Wty	-
690922, Primorsky Krai, Vladivostok, Russky Island, Saperny Peninsula, Ajax village, 10, aud. M 422	Multimedia audience: HP ProOne 400 G1 AiO 19.5" Intel Core i3-4130T 4GB DDR3-1600 SODIMM (1x4GB)500GB; Projection screen Projecta Elpro Electrol, 300x173 cm; Multimedia projector, Mitsubishi FD630U, 4000 ANSI Lumen, 1920x1080; Mortise interface with TLS TAM 201 Stan automatic cable retraction; Avervision CP355AF visualizer; Sennheiser EW 122 G3 UHF microphone lavalier radio system consisting of wireless microphone and receiver; Video conferencing codec LifeSizeExpress 220- Codeconly-Non-AES; Multipix MP-HD718 Network Video Camera; Two 47" Full HD LG M4716CCBA LCD panels; Audio switching and sound reinforcement subsystem; Centralized	-

	uninterrupted power supply	
690922, Primorsky Krai, Vladivostok, Russky Island, Saperny Peninsula, Ajax village, 10, aud. M 627	Light microscope Carl Zeiss GmbH Primo Star 3144014501 (13 pcs.); Light microscope with digital camera Altami BIO8 (2 pcs.).	-
Computer class of the School of Biomedicine aud. M723, 15 workplaces	Electric Screen 236*147cm Trim Screen Line; DLP projector, 3000 ANSI Lm, WXGA 1280x800, 2000:1 EW330U Mitsubishi; CORSA-2007 Tuarex Specialized Equipment Fastening Subsystem; Video Switching Subsystem: Extron DXP 44 DVI Pro DVI Matrix Switcher; Extron DVI 201 Tx/Rx twisted-pair DVI extender Audio switching and sound amplification subsystem; Extron SI 3CT LP Ceiling Mount Speaker System Extron DMP 44 LC Digital Audio Processor; extension for IPL T CR48 control controller; Wireless LAN for students is provided by a system based on 802.11a/b/g/n 2x2 MIMO(2SS) access points. Monoblock HP RgoOpe 400 All-in-One 19.5 (1600x900), Core and3-4150T, 4GB DDR3-1600 (1x4GB), 1TB HDD 7200 SATA, DVD+/-RW, GigEth, Wi- Fi, VT, usb kbd/mse, Win7Pro (64-bit)+Win8.1Pro(64-bit), 1-1-1 Wty	-