Federal State Budgetary Educational Institution of Higher Education
"Privolzhsky Research Medical University"
Ministry of Health of the Russian Federation

APPROVED
Vice-Rector for Academic Affairs
E.S. Bogomolova
31 August 2021

WORKING PROGRAM

Name of the academic discipline: **STATE REGISTRATION AND EXPERTISE OF MEDICINES**

Specialty: **33.05.01 PHARMACY**

Qualification: **PHARMACIST**

Department: **MANAGEMENT AND ECONOMICS OF PHARMACY AND PHARMACEUTICAL TECHNOLOGY**

Mode of study: **FULL-TIME**

Labor intensity of the academic discipline: **36 academic hours**

Nizhny Novgorod
2021

The working program has been developed in accordance with the Federal State Educational Standard for the specialty 33.05.01 PHARMACY, approved by Order by Order of the Ministry of Science and Higher Education of the Russian Federation No. 219 of March 27, 2018.

Developers of the working program:
Maxim Alekseevich Mishchenko, PhD in pharmaceutical sciences, associate professor of the Department of management and economics of pharmacy and pharmaceutical technology.

The program was reviewed and approved at the department meeting (protocol No. 9 of 29.04.2021).

Acting head of the Department,
PhD in pharmaceutical sciences _____ I.V. Spitskaya
(signature)

29.04.2021

AGREED
Deputy Head of EMA ph.d. of biology _____ Lovtsova L.V.
(signature)

29.04.2021

1. The purpose and objectives of mastering the academic discipline STATE REGISTRATION AND EXPERTISE OF MEDICINES (hereinafter – the discipline):

1.1. The purpose of mastering the discipline – participation in forming the following competencies:

– professional competences (PC-10, PC-11 (11.1)).

1.2. Tasks of the discipline:

1. Formation of basic, fundamental pharmaceutical knowledge in the specialty 33.0 5.01 Pharmacy.

2. Training of a specialist pharmacist with analytical thinking, well oriented in control-permitting and organizational-managerial activities in the field of circulation of medicines, having in-depth knowledge of related disciplines.

3. Formation of skills in mastering the latest technologies and techniques in the field of their professional interests.

4. Formation of competences of a specialist pharmacist in carrying out control and permitting procedures related to the circulation of medicines.

5. Mastering of organizational measures for storage, transportation, release and sale of medicines.

1.3. Requirements to the deliverables of mastering the discipline

As a result of completing the discipline, the student should

Know:

– current requirements of domestic and foreign legislation in the field of development, registration and examination of drugs;

– key features of the procedure for registration and examination of drugs, taking into account their origin, type and level of novelty;

– the structure of the state register of medicinal products for medical use and other official sources of information in the field of circulation of medicines;

– principles, rules and procedure for state registration of medicinal products;

– the procedure for planning the preparatory stages of the state registration of medicinal products;

– the structure and procedure for the formation of a registration dossier for various drugs;

– domestic and foreign requirements for conducting and presenting the results of the study of bioequivalence and biosimilarity of drugs;

– requirements for the execution of an application for state registration of medicinal products;

– the procedure for examination within the framework of the state registration of medicinal products;

– the procedure for making changes to the dossiers of registered medicinal products;

– the procedure for suspending and canceling the state registration of medicinal products;

– basic principles and procedure for conducting examinations in the process of state registration of medicinal products;

– the procedure for inclusion in the state register of pharmaceutical substances;

– rules for registration of medicinal products in accordance with the requirements of the Eurasian Economic Union.

Be able to:

– develop a program of preclinical and clinical studies for various drugs;

– analyze the data of (pre-)clinical trials to assess the quality, efficacy and safety of drugs in order to subsequently develop programs of measures for the registration and examination of drugs in order to obtain a registration certificate or obtain permission to conduct a clinical trial;

– develop documents submitted for state registration and examination of medicinal products.

Possess:

– skills in working with the state register of medicines for medical use;

– skills in working with the state register of issued licenses for the right to manufacture medicines;

– skills in organizing procedures within the framework of pre-registration preparation and in the process of state registration of medicinal products;

– skills in issuing an application for state registration of medicinal products;

– skills in the development and execution of documents for the formation of a registration dossier in accordance with the current legislation;

– skills of examination of documentation included in the registration dossier of the medicinal product;

– skills in issuing an expert report on the results of examinations within the framework of state registration;

– skills in obtaining a registration certificate for a medicinal product for medical use.

2. Position of the academic discipline in the structure of the General Educational Program of Higher Education (GEP HE) of the organization.

2.1. The discipline refers to the part formed by the participants of educational relations of Block 1 of GEP HE (B1.PER.E.7).

The discipline is taught in the 9 semester/5 year of study.

2.2. The following knowledge, skills and abilities formed by previous academic disciplines are required for mastering the discipline:

– introduction to the specialty;
– law;
– information support of the life cycle of medicines;
– information technologies in pharmacy;
– medical and pharmaceutical commodity science;
– management and economics of pharmacy;
– pharmaceutical propaedeutic practice.

2.3. Mastering the discipline is required for forming the following knowledge, skills and abilities for subsequent academic disciplines:

– management and economics of pharmacies.

3. Deliverables of mastering the academic discipline and metrics of competence acquisition

Mastering the discipline aims at acquiring the following professional (PC) competence

№	Compe-tence code	The content of the competence (or its part)	Code and name of the competence acquisition metric	As a result of mastering the discipline, the students should:		
				know	be able to	possess
1.	PC-10	Able to carry out	PC-10.1. Supervises the activities of legal	– current	– develop a	– skills in

		measures to control (supervise) the activities of legal entities and individuals licensed for pharmaceutical activities, to comply with mandatory requirements	entities and individuals who have licenses for pharmaceutical activity PC-10.2. Monitors the procedure established by law regarding the compliance of available medicines for medical use, instructions and data on its safety and effectiveness	requirements of domestic and foreign legislation in the field of development, registration and examination of drugs; – key features of the procedure for registration and examination of drugs, taking into account their origin, type and level of novelty; – the structure of the state register of medicinal products for medical use and other official sources of information in the field of circulation of medicines; – principles, rules and procedure for state registration of medicinal products; – the procedure for planning the preparatory stages of the state registration of medicinal products; – the structure and procedure for the formation of a registration dossier for various drugs; – domestic and foreign requirements for conducting and presenting the results of the study of bioequivalence and biosimilarity	program of preclinical and clinical studies for various drugs; – analyze the data of (pre-)clinical trials to assess the quality, efficacy and safety of drugs in order to subsequently develop programs of measures for the registration and examination of drugs in order to obtain a registration certificate or obtain permission to conduct a clinical trial; – develop documents submitted for state registration and examination of medicinal products.	working with the state register of medicines for medical use; – skills in working with the state register of issued licenses for the right to manufacture medicines; – skills in organizing procedures within the framework of pre-registration preparation and in the process of state registration of medicinal products; – skills in issuing an application for state registration of medicinal products; – skills in the development and execution of documents for the formation of a registration dossier in accordance with the current legislation; – skills of examination of documentation included in the registration dossier of the medicinal product; – skills in issuing an expert report on the results of examinations within the framework of state registration; – skills in obtaining a marketing

				of drugs; – requirements for the execution of an application for state registration of medicinal products; – the procedure for examination within the framework of the state registration of medicinal products; – the procedure for making changes to the dossiers of registered medicinal products; – the procedure for suspending and canceling the state registration of medicinal products; – basic principles and procedure for conducting examinations in the process of state registration of medicinal products; – the procedure for inclusion in the state register of pharmaceutical substances; – rules for registration of medicinal products in accordance with the requirements of the Eurasian Economic Union.		authorization for a medicinal product for medical use
2.	PC-11	Able to take part in measures to ensure the quality of	PC-11.1. Participates in events, including the preparation and verification of	– current requirements of domestic and foreign	– develop a program of preclinical and clinical studies	– skills in working with the state register of medicines for

		medicines in industrial production	documents responsible for the quality of medicines	legislation in the field of development, registration and examination of drugs; – key features of the procedure for registration and examination of drugs, taking into account their origin, type and level of novelty; – the structure of the state register of medicinal products for medical use and other official sources of information in the field of circulation of medicines; – principles, rules and procedure for state registration of medicinal products; – the procedure for planning the preparatory stages of the state registration of medicinal products; – the structure and procedure for the formation of a registration dossier for various drugs; – domestic and foreign requirements for conducting and presenting the results of the study of bioequivalence and biosimilarity of drugs; – requirements for the execution	for various drugs; – analyze the data of (pre-)clinical trials to assess the quality, efficacy and safety of drugs in order to subsequently develop programs of measures for the registration and examination of drugs in order to obtain a registration certificate or obtain permission to conduct a clinical trial; – develop documents submitted for state registration and examination of medicinal products.	medical use; – skills in working with the state register of issued licenses for the right to manufacture medicines; – skills in organizing procedures within the framework of pre-registration preparation and in the process of state registration of medicinal products; – skills in issuing an application for state registration of medicinal products; – skills in the development and execution of documents for the formation of a registration dossier in accordance with the current legislation; – skills of examination of documentation included in the registration dossier of the medicinal product; – skills in issuing an expert report on the results of examinations within the framework of state registration; – skills in obtaining a marketing authorization for a medicinal product for

				of an application for state registration of medicinal products; – the procedure for examination within the framework of the state registration of medicinal products; – the procedure for making changes to the dossiers of registered medicinal products; – the procedure for suspending and canceling the state registration of medicinal products; – basic principles and procedure for conducting examinations in the process of state registration of medicinal products; – the procedure for inclusion in the state register of pharmaceutical substances; – rules for registration of medicinal products in accordance with the requirements of the Eurasian Economic Union.		medical use

4. Sections of the academic discipline and competencies that are formed when mastering them

№	Competence code	Section name of the discipline	The content of the section in teaching units

1	PC-10 PC-11	State registration and expertise of medicines	Fundamentals of the state policy in the field of drug provision to the population. General characteristics of the drug supply system of the Russian Federation. Organization and provision of drug care in the Russian Federation. Programs to improve drug supply based on the list of essential medicines. State regulation of pricing for medicines. Problems and prospects for the development of the pharmaceutical industry of the Russian Federation. Legislative basis of drug provision to the population. Regulatory and legal framework in the field of organization of drug provision to the population at the present stage. Federal Regulations "On the Circulation of Medicines", "On Licensing certain types of activities", "On Narcotic Drugs and Psychotropic Substances", "On the Basics of Protecting the Health of Citizens in the Russian Federation".. The system of drug supply to the population in the Russian Federation. Medical and pharmaceutical organizations in the system of drug provision. Types of consumers. Characteristics of types of medical care and types of medical organizations. Types and characteristics of pharmaceutical organizations in the system of drug provision. Types and characteristics of consumers of medicines. Organization of drug provision to end users. Organization of drug provision in outpatient and polyclinic treatment. Organization of work of pharmacies. Organization of drug provision for citizens who have the right to receive drugs free of charge or on preferential terms for outpatient treatment. Programs and state guarantees of free medical care for citizens. Procedure for providing citizens with the necessary medicines. Organization of drug provision for medical organizations. The procedure for drug provision of inpatients. Fundamentals of the formulary system in the health care of the Russian Federation. Modern models of drug provision for inpatient patients. The appointment of drugs in the provision of medical care in stationary conditions. The procedure for the release of goods from the pharmacy to the departments and offices of the Ministry of Defense. Accounting for released goods. Pharmacoeconomic aspects of providing drug care to the population. Characteristics of drug consumption. Methods for determining the need for medicines. Types of demand for medicines. Concepts of need, demand, consumption. Types of consumption and factors affecting the consumption of medicines. Methods for determining the need for medicines. Types of demand. Types of demand.

5. Volume of the academic discipline and types of academic work

Type of educational work	Labor intensity		Labor intensity (AH) in semesters
	volume in credit units (CU)	volume in academic hours (AH)	9
Classroom work, including	0,61	22	22

Lectures (L)	0,17	6	6
Laboratory practicum (LP)*	Laboratory practicums are not stipulated		
Practicals (P)	0,44	16	16
Seminars (S)	Seminars are not stipulated		
Student's individual work (SIW)	0,39	14	14
Mid-term assessment			
credit/exam *(specify the type)*			credit
TOTAL LABOR INTENSITY	1	36	1

6. Content of the academic discipline

6.1. Sections of the discipline and types of academic work

№	Name of the section of the academic discipline	Types of academic work* (in AH)					
		L	LP	P	S	SIW	total
1	State registration and expertise of medicines	6		16		14	36
	TOTAL	6		16		14	36

* - L – lectures; LP – laboratory practicum; P – practicals; S – seminars; SIW – student's individual work.

6.2. Thematic schedule of educational work types:

6.2.1 Thematic schedule of lectures

No	Name of lecture topics	Volume in AH
		9
1.	The main stages of development of pharmaceutical substances and drugs. Scientifically based program for the development of pharmaceutical substances and drugs. System Dclinical andclinical researchand.	1
2.	Regulatory and legal framework regulating the examination and registration of medicines in the Russian Federation, EurAsEC, OECD and the USA. Bioequivalence studies, taking into account current domestic and foreign requirements. The role of harmonization of requirements in the field of drug circulation.	1
3.	The procedure of state registration and examination of pharmaceutical substances and drugs. Registration dossier and general white paper. The main elements of OTD and the features of their development, taking into account the type of drugs	1
4.	Development, registration and examination of biological drugs. Development, registration and examination of biological cell products.	1
5.	Features of the development, registration and examination of drugs of natural origin in comparison with the procedure for registration of MI, dietary supplements and cosmetic products.	1
6.	Post-registration studies and pharmacovigilance.	1
	TOTAL (total – 6 AH)	6

6.2.2. The thematic plan of laboratory practicums

Laboratory practicums are not stipulated.

6.2.3. Thematic plan of practicals

No	Name of the topics of practicals	Volume in AH
		9
1.	The main stages of development of pharmaceutical substances and drugs. Scientifically based program for the development of pharmaceutical substances and drugs. System Dclinical andclinical researchand.	2
2.	Regulatory and legal framework regulating the examination and registration of medicines in the Russian Federation, EurAsEC, OECD and the USA. Bioequivalence studies, taking into account current domestic and foreign requirements. The role of harmonization of requirements in the field of drug circulation.	4
3.	The procedure of state registration and examination of pharmaceutical substances and drugs. Registration dossier and general white paper. The main elements of OTD and the features of their development, taking into account the type of drugs	2
4	Development, registration and examination of biological drugs. Development, registration and examination of biological cell products.	2
5.	Features of the development, registration and examination of drugs of natural origin in comparison with the procedure for registration of MI, dietary supplements and cosmetic products.	2
6.	Post-registration studies and pharmacovigilance.	2
7.	CREDIT	2
8	TOTAL (total – 16 AH)	16

6.2.4. Thematic plan of seminars
Seminars are not stipulated.

6.2.5. Types and topics of student's individual work (SIW)

No	Types and topics of SIW	Volume in AH
		9
1.	Working with literature and other sources of information on the studied section	6
2.	Assignments in the form of reports and speeches	4
3.	Working with electronic educational resources	4
4.	TOTAL (total – 14 AH)	14

7. Types of assessment formats for ongoing monitoring and mid-term assessment

№	Semester No.	Types of control	Name of section of academic discipline	Assessment formats		
				types	number of test questions	number of test task options
1	2	3	4	5	6	7
1.	9	Current monitoring: Control of mastering the topic Monitoring the student's	State registration and expertise of medicines	Test work	5	5

		individual work				
2.	9	Mid-term assessment		Credit	3	40

8. Educational, methodological and informational support for mastering the academic discipline (printed, electronic publications, the Internet and other network resources)

8.1. Key literature references

№	Name according to bibliographic requirements	Number of copies	
		at the department	in the library
1	The system of legislative regulation of circulation of medicines: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 77 p.	electronic resource	
2	Fundamentals of state legislation on manufacturing of medicines: Textbook / M M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 56 p.	electronic resource	
3	Fundamentals of state legislation on pharmaceutical activities: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 50 p.	electronic resource	
4	The concept of good practices in the pharmaceutical regulatory system: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 57 p.	electronic resource	
5	Fundamentals of pharmaceutical economics: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 125 p.	electronic resource	
6	Prices and pricing in the pharmaceutical market: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 77 p.	electronic resource	
7	Product policy of a pharmaceutical organization: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 90 p.	electronic resource	
8	Fundamentals of planning economic indicators: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 78 p.	electronic resource	
9	Planning of trade turnover of a pharmaceutical organization: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 78 p.	electronic resource	
10	Planning of distribution costs of a pharmaceutical organization: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova,	electronic resource	

	S.V. Kononova. – Nizhny Novgorod, 2021. – 60 p.	
11	Income and profit planning of a pharmaceutical organization: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 70 p.	electronic resource
12	Accounting of financial and economic activities of a pharmacy organization: Textbook / M.A. Mishchenko, S.V. Kononova, N.N. Chesnokova, A.A. Ponomareva, E.V. Shalenkova. – Nizhny Novgorod, 2022. – 74 p.	electronic resource
13	Specific issues of accounting for the property of a pharmacy organization: Textbook / M.A. Mishchenko. – Nizhny Novgorod, 2022. – 50 p.	electronic resource
14	Basic principles of accounting of settlements with the personnel of a pharmacy organization: Textbook / M.A. Mishchenko. – Nizhny Novgorod, 2022. – 50 p.	electronic resource
15	The tax concept and tax management of pharmaceutical organizations: Textbook / M.A. Mishchenko. – Nizhny Novgorod, 2022. – 52 p.	electronic resource

8.2. Further reading

№	Name according to bibliographic requirements	Number of copies	
		at the department	in the library
1	The medicine lifecycle concept: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 80 p.	electronic resource	
2	Information technologies in the medicine lifecycle management: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 99 p.	electronic resource	
3	Evaluating the quality of pharmaceutical information: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 98 p.	electronic resource	
4	Analysis and processing of pharmaceutical information: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 95 p.	electronic resource	
5	Post-marketing evaluation of medicinal products – pharmacoepidemiology: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 53 p.	electronic resource	
6	Post-marketing evaluation of the medicinal products – pharmacoeconomics: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 107 p.	electronic resource	
7	Post-marketing evaluation of medicinal products – pharmacovigilance: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 70 p.	electronic resource	
8	Fundamentals of the state regulation of pharmaceutical information that is advertising:	electronic resource	

	Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 109 p.	

8.3. Electronic educational resources for teaching academic subjects

8.3.1. Internal Electronic Library System of the University (IELSU)

№	*Name of the electronic resource*	*Brief description (content)*	*Access conditions*	*Number of users*
1	Internal electronic library system (IELS) http://nbk.pimunn.net/MegaPro/Web	Works of university teaching staff: textbooks, manuals, collections of tasks, teaching aids, laboratory works, monographs, collections of scientific works, scientific articles, dissertations, abstracts of dissertations, patents	From any computer and mobile device with individual login and password. Access mode: http://nbk.pimunn.net/MegaPro/Web	Not limited

8.3.2. Electronic educational resources acquired by the University

№	*Name of the electronic resource*	*Brief description (content)*	*Access conditions*	*Number of users*
1	Electronic legal reference system "Consultant Plus" (contract for free) http://www.consultant.ru	Regulatory documents regulating the activities of medical and pharmaceutical institutions From the scientific library computers	Access mode: http://www.consultant.ru/	Not limited Term of validity: Unlimited

8.3.3 Open access resources

№	*Name of the electronic resource*	*Brief description (content)*	*Access conditions*
1	PubMed https://www.ncbi.nlm.nihgov/pubmed	US National Library of Medicine search engine for Medline, PreMedline databases	From any computer and mobile device. Access mode: https://www.ncbi.nlm.nihgov/pubmed Not limited
2	Scopus database www.scopus.com	International abstract database of scientific citation From university computers, from any computer by individual login and password	Access mode: www.scopus.com Not limited
3	Web of Science Core Collection https://www.webofscience.com	International abstract database of scientific citation. From university computers, from any computer by individual login	Access mode: https://www.webofscience.com Not limited

		and password.	

9. Material and technical support for mastering an academic discipline

9.1. List of premises for classroom activities for the discipline

1. Classes for lectures and practical classes, equipped with multimedia and other means of training, allowing the use of simulation technologies, with standard sets of professional models (sets of protocols of clinical trials, formulary lists of LPU, price lists of distribution companies, sets of quality of life questionnaires), allowing students to master the skills and abilities, provided by professional activity, individually.

2. Simulation center "Educational pharmacy", equipped with simulation technics, which imitates the activity of pharmacy and its subdivisions (acceptance of goods, storage of goods, dispensing, pharmaceutical expertise of receipt) in the amount that allows students to master skills, provided by professional activity individually.

3. Rooms for students' independent work, equipped with computers with the ability to connect to the Internet and access to the electronic information and educational environment of the University.2.

9.2. List of equipment for classroom activities for the discipline

1. Multimedia complex (laptop, projector, screen, TV)
2. Computer class (15 computers) with installed applications and Internet access.

9.3. List of software

1. Online event platform "Webinar"
2. Yandex Browser
3. Reference system "Consultant Plus"

9.3. A set of licensed and freely distributed software, including domestic production

Item no.	**Software**	**number of licenses**	**Type of software**	**Manufacturer**	**Number in the unified register of Russian software**	**Contract No. and date**
1	Wtware	100	Thin Client Operating System	Kovalev Andrey Alexandrovich	1960	2471/05-18 from 28.05.2018
2	MyOffice is Standard. A corporate user license for educational organizations, with no expiration date, with the right to receive updates for 1 year.	220	Office Application	LLC "NEW CLOUD TECHNOLOGIES"	283	without limitation, with the right to receive updates for 1 year.
3	LibreOffice		Office Application	The Document Foundation	Freely distributed software	

4	Windows 10 Education	700	Operating systems	Microsoft	Azure Dev Tools for Teaching Subscription	
5	Yandex. Browser		Browser	«Yandex»	3722	
6	Subscription to MS Office Pro for 170 PCs for FGBOU VO "PIMU" of the Ministry of Health of Russia	170	Office Application	Microsoft		23618/HN10030 LLC "Softline Trade" from 04.12.2020

10. List of changes to the working program (to be filled out by the template)

Federal State Budgetary Educational Institution of Higher Education
"Privolzhsky Research Medical University"
Ministry of Health of the Russian Federation
(FSBEI HE "PRMU" of the Ministry of Health of Russia)

Department of
Name of the department

CHANGE REGISTRATION SHEET

working program for the academic discipline
NAME OF THE ACADEMIC DISCIPLINE

Field of study / specialty / scientific specialty: _____
(code, name)

Training profile: _____
(*name) - for master's degree programs*

Mode of study: _____
full-time/mixed attendance mode/extramural

Position	Number and name of the program section	Contents of the changes made	Effective date of the changes	Contributor's signature
1				

Approved at the department meeting
Protocol No. _____of _____20__

Head of the Department
_____ _____/_____
department name, academic title signature print name