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 CONTROL AND SUPERVISION IN THE FIELD OF CIRCULATION 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 CONTROL AND SUPERVISION IN THE FIELD OF CIRCULATION OF MEDICINES (hereinafter – the discipline):

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

– professional competences (PC-4 (4.4), PC-5 (5.5), PC-10).

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 a specialist skills in carrying out control and permitting procedures related to the circulation of medicines.
5. Development of organizational measures for storage, transportation, seizure and destruction of medicines.

1.3. Requirements to the deliverables of mastering the discipline

As a result of completing the discipline, the student should

Know:

– the basics of the organization of state control and supervision, licensing control, quality control of medicines and medicinal plant raw materials in accordance with the legislation of the Russian Federation and the EAEU on circulation;

– international standards that ensure the quality of medicines, medicinal raw materials (rules for the practice of production, cultivation and harvesting of medicinal plants - GACP, rules for the proper production of medicines - GMP), foreign pharmacopoeias, their basic principles and requirements;

– the main regulatory documents (GENERAL Pharmacopoeia Monograph, FSP, GOST) and methodological materials on standardization and quality control of medicines and medicinal raw materials;

– the regulatory framework governing the rules for the import into the territory of the Russian Federation and the rules for the export of medicines;

– organization of quality control of medicines and medicinal plant raw materials in quality control centers, control and analytical laboratories, pharmacy warehouses, pharmaceutical enterprises, pharmacy organizations;

– requirements of regulatory legal acts of the Russian Federation to the quality of medicines; the concepts of falsified, substandard and counterfeit medicines.

Be able to:

– draw up documentation on the compliance of the quality of drugs with the requirements of the GF and other regulatory documents;

– use the State Pharmacopoeia and other regulatory enactments to search for information on the conditions of storage and transportation of medicines;

– place drugs at storage sites, observing all the necessary conditions (depending on their physicochemical properties and pharmacological affiliation);

– assess the conditions in which medicines and medicinal plant raw materials are stored;

– organize work on compliance with the requirements for the conditions of medicines and medicinal plant raw materials;

– draw up documentation on the conditions of storage and transportation of medicines;
– carry out the import /export of medicines in accordance with the current legislation;
– check the documentation for medicines;
– make a conclusion on the possibility / impossibility of import / export of medicines
– organize the receipt of reports of counterfeit and falsified drugs;
– timely identify medicines that have become unusable, medicines with an expired shelf life, falsified and poor-quality medicines;
– be able to carry out the withdrawal of these medicines from circulation for the purpose of further destruction in accordance with applicable law;
– document procedures for the seizure and destruction of falsified, substandard and counterfeit medicines.

Possess:

– skills in assessing the satisfactory compliance with the storageconditions of medicinal products and medicinal plant raw materials, methods for determining the main parameters proving the correctness of storage and transportation conditions;
– skills in organizing, ensuring and conducting quality control of medicines and medicinal plant raw materials in the conditions of a pharmacy organization and a pharmaceutical enterprise;
– skills in checking documentation and skills in the preparation of documentation for medicines in accordance with the current legislation in accordance with the established procedure;
– skills in taking measures for the timely detection of medicines that have become unusable, medicines with expired shelf life, falsified and poor-quality medicines and their withdrawal from circulation for the purpose of further destruction in accordance with the current legislation;
– skills in documenting the withdrawal from circulation and destruction of falsified, substandard and counterfeit medicines.

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-4	Able to participate in monitoring the quality, effectiveness and safety of medicines and medicinal plant raw materials	PC-4.4. Informs in accordance with the procedure established by law about the non-compliance of the medicinal product for medical use with the established requirements or about the non-compliance of the data on the effectiveness and safety of the medicinal product with the data on the medicinal product contained in the instructions for its use	– the basics of the organization of state control and supervision, licensing control, quality control of medicines and medicinal plant raw materials in accordance with the legislation of the Russian Federation and the EAEU on circulation; – international standards that ensure the quality of medicines, medicinal raw materials (rules for the practice of production, cultivation and harvesting of medicinal plants - GACP, rules for the proper production of medicines - GMP), foreign pharmacopoeias, their basic principles and requirements; – the main regulatory documents (GENERAL Pharmacopoeia Monograph, FSP, GOST) and methodological materials on	– draw up documentation on the compliance of the quality of drugs with the requirements of the GF and other regulatory documents; – use the State Pharmacopoeia and other regulatory enactments to search for information on the conditions of storage and transportation of medicines; – place drugs at storage sites, observing all the necessary conditions (depending on their physicochemical properties and pharmacological affiliation); – assess the conditions in which medicines and medicinal plant raw materials are stored; – organize work on compliance with the requirements for the conditions of medicines and	– skills in assessing the satisfactory compliance with the storage conditions of medicines and medicinal plant raw materials, methods for determining the main parameters proving the correctness of storage and transportation conditions; – skills in organizing, ensuring and conducting quality control of medicines and medicinal plant raw materials in the conditions of a pharmacy organization and a pharmaceutical enterprise; – skills in checking documentation and skills in the preparation of documentation for medicines in accordance with the current legislation in accordance with the established procedure; – skills in taking measures for the

				standardization and quality control of medicines and medicinal raw materials; – the regulatory framework governing the rules for the import into the territory of the Russian Federation and the rules for the export of medicines; – organization of quality control of medicines and medicinal plant raw materials in quality control centers, control and analytical laboratories, pharmacy warehouses, pharmaceutical enterprises, pharmacy organizations; – requirements of regulatory legal acts of the Russian Federation to the quality of medicines; the concepts of falsified, substandard and counterfeit medicines.	medicinal plant raw materials; – draw up documentation on the conditions of storage and transportation of medicines; – carry out the import /export of medicines in accordance with the current legislation; – check the documentation for medicines; – make a conclusion on the possibility / impossibility of import / export of medicines – organize the receipt of reports of counterfeit and falsified drugs; – timely identify medicines that have become unusable, medicines with an expired shelf life, falsified and poor-quality medicines; – be able to carry out the withdrawal of these medicines from circulation for the purpose of further destruction in accordance with applicable law; – document procedures for the seizure and destruction of falsified, substandard and counterfeit medicines.	timely detection of medicines that have become unusable, medicines with expired shelf life, falsified and poor-quality medicines and their withdrawal from circulation for the purpose of further destruction in accordance with the current legislation; – skills in documenting the withdrawal from circulation and destruction of falsified, substandard and counterfeit medicines.
2.	PC-5	Able to take	PC-5.5. Carries out	– the basics of	– draw up	– skills in

		part in planning and organizing the resource provision of a pharmaceutical organization	the withdrawal from circulation of medicines and pharmacy assortment goods that have fallen into disrepair, expired, falsified, counterfeit and substandard products	the organization of state control and supervision, licensing control, quality control of medicines and medicinal plant raw materials in accordance with the legislation of the Russian Federation and the EAEU on circulation; – international standards that ensure the quality of medicines, medicinal raw materials (rules for the practice of production, cultivation and harvesting of medicinal plants - GACP, rules for the proper production of medicines - GMP), foreign pharmacopoeias, their basic principles and requirements; – the main regulatory documents (GENERAL Pharmacopoeia Monograph, FSP, GOST) and methodological materials on standardization and quality control of medicines and medicinal raw materials; – the regulatory framework governing the rules for the import into the territory of the Russian	documentation on the compliance of the quality of drugs with the requirements of the GF and other regulatory documents; – use the State Pharmacopoeia and other regulatory enactments to search for information on the conditions of storage and transportation of medicines; – place drugs at storage sites, observing all the necessary conditions (depending on their physicochemical properties and pharmacological affiliation); – assess the conditions in which medicines and medicinal plant raw materials are stored; – organize work on compliance with the requirements for the conditions of medicines and medicinal plant raw materials; – draw up documentation on the conditions of storage and transportation of medicines; – carry out the import /export of medicines in accordance with the current	assessing the satisfactory compliance with the storage conditions of medicines and medicinal plant raw materials, methods for determining the main parameters proving the correctness of storage and transportation conditions; – skills in organizing, ensuring and conducting quality control of medicines and medicinal plant raw materials in the conditions of a pharmacy organization and a pharmaceutical enterprise; – skills in checking documentation and skills in the preparation of documentation for medicines in accordance with the current legislation in accordance with the established procedure; – skills in taking measures for the timely detection of medicines that have become unusable, medicines with expired shelf life, falsified and poor-quality medicines and their withdrawal from circulation for the purpose of further

				Federation and the rules for the export of medicines; – organization of quality control of medicines and medicinal plant raw materials in quality control centers, control and analytical laboratories, pharmacy warehouses, pharmaceutical enterprises, pharmacy organizations; – requirements of regulatory legal acts of the Russian Federation to the quality of medicines; the concepts of falsified, substandard and counterfeit medicines.	legislation; – check the documentation for medicines; – make a conclusion on the possibility / impossibility of import / export of medicines – organize the receipt of reports of counterfeit and falsified drugs; – timely identify medicines that have become unusable, medicines with an expired shelf life, falsified and poor-quality medicines; – be able to carry out the withdrawal of these medicines from circulation for the purpose of further destruction in accordance with applicable law; – document procedures for the seizure and destruction of falsified, substandard and counterfeit medicines.	destruction in accordance with the current legislation; – skills in documenting the withdrawal from circulation and destruction of falsified, substandard and counterfeit medicines.
3.	PC-10	Able to carry out measures to control (supervise) the activities of legal entities and individuals licensed for pharmaceutical activities, to comply	PC-10.1. Supervises the activities of legal 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	– the basics of the organization of state control and supervision, licensing control, quality control of medicines and medicinal plant raw materials in accordance with the legislation of the Russian Federation and the EAEU on circulation;	– draw up documentation on the compliance of the quality of drugs with the requirements of the GF and other regulatory documents; – use the State Pharmacopoeia and other regulatory	– skills in assessing the satisfactory compliance with the storage conditions of medicines and medicinal plant raw materials, methods for determining the main parameters proving the correctness of storage and

		with mandatory requirements	on its safety and effectiveness	– international standards that ensure the quality of medicines, medicinal raw materials (rules for the practice of production, cultivation and harvesting of medicinal plants - GACP, rules for the proper production of medicines - GMP), foreign pharmacopoeias, their basic principles and requirements; – the main regulatory documents (GENERAL Pharmacopoeia Monograph, FSP, GOST) and methodological materials on standardization and quality control of medicines and medicinal raw materials; – the regulatory framework governing the rules for the import into the territory of the Russian Federation and the rules for the export of medicines; – organization of quality control of medicines and medicinal plant raw materials in quality control centers, control and analytical laboratories, pharmacy	enactments to search for information on the conditions of storage and transportation of medicines; – place drugs at storage sites, observing all the necessary conditions (depending on their physicochemical properties and pharmacological affiliation); – assess the conditions in which medicines and medicinal plant raw materials are stored; – organize work on compliance with the requirements for the conditions of medicines and medicinal plant raw materials; – draw up documentation on the conditions of storage and transportation of medicines; – carry out the import /export of medicines in accordance with the current legislation; – check the documentation for medicines; – make a conclusion on the possibility / impossibility of import / export of medicines – organize the receipt of reports of counterfeit	transportation conditions; – skills in organizing, ensuring and conducting quality control of medicines and medicinal plant raw materials in the conditions of a pharmacy organization and a pharmaceutical enterprise; – skills in checking documentation and skills in the preparation of documentation for medicines in accordance with the current legislation in accordance with the established procedure; – skills in taking measures for the timely detection of medicines that have become unusable, medicines with expired shelf life, falsified and poor-quality medicines and their withdrawal from circulation for the purpose of further destruction in accordance with the current legislation; – skills in documenting the withdrawal from circulation and destruction of falsified, substandard and counterfeit medicines.

				warehouses, pharmaceutical enterprises, pharmacy organizations; – requirements of regulatory legal acts of the Russian Federation to the quality of medicines; the concepts of falsified, substandard and counterfeit medicines.	and falsified drugs; – timely identify medicines that have become unusable, medicines with an expired shelf life, falsified and poor-quality medicines; – be able to carry out the withdrawal of these medicines from circulation for the purpose of further destruction in accordance with applicable law; – document procedures for the seizure and destruction of falsified, substandard and counterfeit medicines.	

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-4 PC-5 PC-10	State control and supervision in the field of circulation of medicines	**State control in the field of circulation of medicines. Regulatory framework regulating state control in the field of circulation and quality of medicines.** Licensing control in the field of production of medicines and in the field of pharmaceutical activity. Federal state supervision in the field of circulation of medicines. Selective quality control of medicines. Scheduled and unscheduled inspections of the subjects of circulation of medicines. The system of state quality control of drugs (express control on the basis of mobile express laboratories; examination of the quality of drugs for compliance with the requirements of ND on the basis of laboratory complexes). The procedure for the withdrawal from circulation and destruction of poor-quality, falsified and counterfeit medicines. Information letters of the Federal Service for Surveillance in Healthcare of the Russian Federation addressed to participants of the pharmaceutical market. Federal Law of December 26, 2008 N 294-FZ "On the Protection of the Rights of Legal Entities and Individual Entrepreneurs in the Exercise

			of State Control (Supervision) and Municipal Control". Federal Law of May 4, 2011 N 99-FZ "On Licensing of Certain Types of Activities". Federal Law of 12.04.2010 No. 61-FZ "On the Circulation of Medicines". Decree of the Government of the Russian Federation dated September 3, 2010 N 674 "On Approval of the Rules for the Destruction of Poor-Quality Medicines, Falsified Medicines and Counterfeit Medicines". "Agreement on Common Principles and Rules for the Circulation of Medicines within the Framework of the Eurasian Economic Union" (Concluded in Moscow on 23.12.2014). Order of Roszdravnadzor dated 27.04.2017 No. 4043 "On Approval of the List of Legal Acts and Their Individual Parts (Provisions) Containing Mandatory Requirements, Compliance with Which is Assessed When Carrying Out Control Measures within the Framework of a Separate Type of State Control (Supervision)". Order of Roszdravnadzor dated 27.04.2017 No. 4043 "On Approval of the List of Legal Acts and Their Individual Parts (Provisions) Containing Mandatory Requirements, Compliance with Which is Assessed When Carrying Out Control Measures within the Framework of a Separate Type of State Control (Supervision)". Resolution of the Government of the Russian Federation dated 30.06.2004 N 323 "On Approval of the Regulations on the Federal Service for Supervision in the Field of Health and Social Development". Order of the Ministry of Health of Russia N 682n of 07.09.2016 "On approval of the form of the document containing the results of monitoring the efficacy and safety of a medicinal product for medical use, carried out by the holder or holder of the registration certificate of the medicinal product or a legal entity authorized by him". Order of the Ministry of Health of the Russian Federation dated October 26, 2015 No. 751n "On Approval of the Rules for the Manufacture and Release of Medicines for Medical Use by Pharmacy Organizations, Individual Entrepreneurs Licensed for Pharmaceutical Activities". Order of the Ministry of Health of the Russian Federation dated August 31, 2016 No. 647n "On Approval of the Rules of Good Pharmacy Practice of Medicines for Medical Use". **Import of medicines into the Russian Federation and export of medicines from the Russian Federation. The procedure for introducing medicines into civil circulation on the territory of the Russian Federation.** The procedure for the import of medicines into the Russian Federation and the export of medicines from the Russian Federation. Import of medicines into the Russian Federation for personal use and other non-commercial purposes, as well as for use in the territory of an international medical cluster. Documents submitted to the customs authorities of the Russian Federation when importing medicines into the Russian Federation. Cooperation of the federal executive body authorized in the field of customs affairs and other authorized federal executive bodies. Features of the import and export of medicinal plant raw materials. Decree of the Government of the Russian Federation dated

			November 26, 2019 N 1510 "On the procedure for introducing medicines for medical use into civil circulation".. **Monitoring the efficacy and safety of medicines in circulation in the territory of the Russian Federation. Pharmacovigilance and the role of pharmaceutical specialists in the pharmacovigilance system.** The main types of adverse reactions of drugs (adverse adverse reaction, serious adverse reaction, unforeseen adverse reaction). Organization of receiving reports of adverse reactions. Obtaining information about adverse reactions through spontaneous messages. Obtaining information about adverse reactions through stimulated messages. Obtaining information about adverse reactions through active safety monitoring. Methods and timing of presentation of information on various types of adverse reactions. Periodic report on the safety of the medicinal product. Federal Law of 12.04.2010 No. 61-FZ "On the Circulation of Medicines". Rules of Good Pharmacovigilance Practice (GVP) of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission No. 87 of 03.11.2016. Order of the Ministry of Health and Social Development of Russia dated 26.08.2010 N 758n "On Approval of the Procedure for Suspending the Use of a Medicinal Product for Medical Use". Order of the Ministry of Health of Russia N 682n of 07.09.2016 "On approval of the form of the document containing the results of monitoring the efficacy and safety of a medicinal product for medical use, carried out by the holder or holder of the registration certificate of the medicinal product or a legal entity authorized by him". **Testing laboratories for quality control of medicines. Functions, regulatory framework governing state regulation of the work of testing laboratories for quality control of medicines.** Testing laboratories operating in the system of confirmation of conformity of medicines, their functions. Federal laboratory complexes, their functions. Centers for quality control of medicines of the constituent entities of the Russian Federation, their functions. Federal expert organizations, their functions. Methods of quality control of medicines in testing laboratories. Modern non-destructive methods of rapid analysis of medicines. Raman spectroscopy (Raman spectroscopy). Theoretical basis of the method. Stationary and portable Raman spectrometers. The principle of their work. Use of the Raman spectroscopy method in quality control. Limitations of the method. NIR spectroscopy (diffuse scattering). Theoretical basis of the method. Stationary and portable BIC spectrometers. The principle of their work. Use of the NIR spectroscopy method in pharmaceutical analysis. Limitations of the method. Libraries of spectra for the implementation of state quality control of medicines by non-destructive method. **Principles of organization and functioning of quality control departments.**

			Requirements for the organization of the quality control department in accordance with the rules of GMP and GLP (requirements for visits; requirements for personnel; requirements for equipment; requirements for standard samples and comparison samples; requirements for reagents). Documentary support of the quality control department (instructions and SOPs for performing operations; job descriptions; methodological support). Processes implemented in the quality control department (input control; stage (operational) control; personnel control; environmental control; quality control of finished products; control of corrective actions; control during complaints). Principles of effective quality control. Interaction of the quality control department with other departments. The procedure for conducting and documenting various types of control. Material and technical base of the quality control department. Equipment of quality control departments (for testing medicines (physicochemical methods of analysis); for microbiological analysis; for determining the parameters of premises; for laboratory water treatment; auxiliary laboratory equipment). Storage of documents and research materials. Safety and rational equipment of workplaces. Assessment of operating conditions and selection of reagents and equipment. Control and measuring devices, their documentation and verification. Justification of the choice of the method of quality control of the medicinal product. Development and validation of control methods. Document the method. Conducting research, statistical processing and evaluating the results. Execution and storage of reporting documentation.

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 control and supervision in the field of circulation 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.	State control in the field of circulation of medicines. Regulatory framework regulating state control in the field of circulation and quality of medicines.	1
2.	Import of medicines into the Russian Federation and export of medicines from the Russian Federation.	1
3.	The procedure for introducing medicines into civil circulation on the territory of the Russian Federation.	1
4.	Monitoring the efficacy and safety of medicines in circulation on the territory of the Russian Federation. Pharmacovigilance and the role of pharmaceutical specialists in the pharmacovigilance system.	1
5.	Testing laboratories for quality control of medicines. Functions, regulatory framework governing state regulation of the work of testing laboratories for quality control of medicines.	1
6.	Principles of organization and functioning of quality control departments.	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.	State control in the field of circulation of medicines. Regulatory framework regulating state control in the field of circulation and quality of medicines.	2
2.	Import of medicines into the Russian Federation and export of medicines from the Russian Federation.	4
3.	The procedure for introducing medicines into civil circulation on the territory of the Russian Federation.	2
4	Monitoring the efficacy and safety of medicines in circulation on the territory of the Russian Federation. Pharmacovigilance and the role of pharmaceutical specialists in the pharmacovigilance system.	2
5.	Testing laboratories for quality control of medicines. Functions, regulatory framework governing state regulation of the work of testing laboratories for quality control of medicines.	2
6.	Principles of organization and functioning of quality control departments.	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 individual work	State control and supervision in the field of circulation of medicines	Test work	5	5
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	electronic resource	

	regulatory system: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 57 p.	
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, S.V. Kononova. – Nizhny Novgorod, 2021. – 60 p.	electronic resource
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.	electronic resource	

	Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 80 p.	
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: Textbook / M.A. Mishchenko, S.V. Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 109 p.	electronic resource

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	Regulatory documents	Access mode:	Not limited

	reference system "Consultant Plus" (contract for free) http://www.consultant.ru	regulating the activities of medical and pharmaceutical institutions From the scientific library computers	http://www.consultant.ru/	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 and password.	Access mode: https://www.webofscience.com Not limited

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