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

Mu \_ I.V. Spitskaya (signature)

29.04.2021

AGREED Deputy Head of EMA ph.d. of biology

that 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 controlpermitting 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 storage conditions 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

	Compe-	The content of the	Code and name of the	the As a result of mastering the discipline, the students should:		
№	tence code	competence (or its part)	competence acquisition metric	know	be able to	possess
1.	PC-4	Able to participate in monitoring the quality, effectiveness s 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	<ul> <li>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;</li> <li>international standards that ensure the quality of medicines, medicinal raw materials (rules for the practice of production, cultivation and harvesting of medicinal plants</li> <li>GACP, rules for the proper production of medicines - GMP), foreign pharmacopoeias, their basic principles and requirements;</li> <li>the main regulatory documents (GENERAL Pharmacopoeia Monograph, FSP, GOST) and methodological materials on</li> </ul>	<ul> <li>draw up documentation on the compliance of the quality of drugs with the requirements of the GF and other regulatory documents;</li> <li>use the State Pharmacopoeia and other regulatory enactments to search for information on the conditions of storage and transportation of medicines;</li> <li>place drugs at storage sites, observing all the necessary conditions</li> <li>(depending on their physicochemical properties and pharmacological affiliation);</li> <li>assess the conditions in which medicines and medicinal plant raw materials are stored;</li> <li>organize work on compliance with the requirements for the conditions of medicines and</li> </ul>	<ul> <li>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;</li> <li>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;</li> <li>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;</li> <li>skills in taking measures for the</li> </ul>

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

				standardization	medicinal plant	timely detection
				and quality	raw materials;	of medicines that
				control of	– draw up	have become
				medicines and	documentation	unusable,
				medicinal raw	on the conditions	medicines with
				materials;	of storage and	expired shelf
				<ul> <li>the regulatory</li> </ul>	transportation of	life, falsified and
				framework	medicines;	poor-quality
				governing the	<ul> <li>carry out the</li> </ul>	medicines and
				rules for the	import /export of	their withdrawal
				import into the	medicines in	from circulation
				territory of the	accordance with	for the purpose
				Russian	the current	of further
				Federation and	legislation;	destruction in
				the rules for the	<ul> <li>check the</li> </ul>	accordance with
				export of	documentation	the current
				medicines;	for medicines;	legislation;
				– organization	– make a	– skills in
				of quality control	conclusion on	documenting the
				of medicines and	the possibility /	withdrawal from
				medicinal plant	impossibility of	circulation and
				raw materials in	import / export	destruction of falsified,
				quality control	of medicines	substandard and
				centers, control	<ul> <li>organize the</li> </ul>	counterfeit
				and analytical	receipt of reports	medicines.
				laboratories,	of counterfeit	medicines.
				pharmacy	and falsified	
				warehouses, pharmaceutical	drugs;	
				enterprises,	<ul> <li>timely identify</li> </ul>	
				pharmacy	medicines that	
				organizations;	have become	
				- requirements	unusable, medicines with	
				of regulatory		
				legal acts of the	an expired shelf life, falsified and	
				Russian		
				Federation to the	poor-quality medicines;	
				quality of	<ul> <li>be able to</li> </ul>	
				medicines; the	carry out the	
				concepts of	withdrawal of	
				falsified,	these medicines	
				substandard and	from circulation	
				counterfeit	for the purpose	
				medicines.	of further	
					destruction in	
					accordance with	
					applicable law;	
					- document	
					procedures for	
					the seizure and	
					destruction of	
					falsified,	
					substandard and	
					counterfeit	
					medicines.	
2.	PC-5	Able to take	PC-5.5. Carries out	– the basics of	– draw up	<ul> <li>skills in</li> </ul>
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part in	the withdrawal from	the organization	documentation	assessing the
planning	circulation of	of state control	on the	satisfactory
and	medicines and	and supervision,	compliance of	compliance with
organizing	pharmacy	licensing control,	the quality of	the storage
the resource	assortment goods	quality control of	drugs with the	conditions of
provision of	that have fallen into	medicines and	requirements of	medicines and
a	disrepair, expired,	medicinal plant	the GF and other	medicinal plant
pharmaceuti	falsified, counterfeit	raw materials in	regulatory	raw materials,
cal	and substandard	accordance with	documents;	methods for
organizatio	products	the legislation of	– use the State	determining the
n	products	the Russian	Pharmacopoeia	main parameters
11		Federation and	and other	proving the
		the EAEU on		correctness of
			regulatory	
		circulation;	enactments to	storage and
		<ul> <li>international</li> </ul>	search for	transportation
		standards that	information on	conditions;
		ensure the	the conditions of	<ul> <li>skills in</li> </ul>
		quality of	storage and	organizing,
		medicines,	transportation of	ensuring and
		medicinal raw	medicines;	conducting
		materials (rules	<ul> <li>place drugs at</li> </ul>	quality control of
		for the practice	storage sites,	medicines and
		of production,	observing all the	medicinal plant
		cultivation and	necessary	raw materials in
		harvesting of	conditions	the conditions of
		medicinal plants	(depending on	a pharmacy
		- GACP, rules	their	organization and
		for the proper	physicochemical	a pharmaceutical
		production of	properties and	enterprise;
		medicines -		- skills in
			pharmacological	
		GMP), foreign	affiliation);	checking
		pharmacopoeias,	– assess the	documentation
		their basic	conditions in	and skills in the
		principles and	which medicines	preparation of
		requirements;	and medicinal	documentation
		– the main	plant raw	for medicines in
		regulatory	materials are	accordance with
		documents	stored;	the current
		(GENERAL	<ul> <li>organize work</li> </ul>	legislation in
		Pharmacopoeia	on compliance	accordance with
		Monograph,	with the	the established
		FSP, GOST) and	requirements for	procedure;
		methodological	the conditions of	– skills in taking
		materials on	medicines and	measures for the
		standardization	medicinal plant	timely detection
		and quality	raw materials;	of medicines that
		control of		have become
		medicines and	- draw up	unusable,
		medicinal raw	documentation	medicines with
		materials;	on the conditions	
			of storage and	expired shelf
		- the regulatory	transportation of	life, falsified and
		framework	medicines;	poor-quality
		governing the	<ul> <li>carry out the</li> </ul>	medicines and
		rules for the	import /export of	their withdrawal
		import into the	medicines in	from circulation
		territory of the	accordance with	for the purpose
		Russian	the current	of further
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				Federation and	legislation;	destruction in
				the rules for the	<ul> <li>check the</li> </ul>	accordance with
				export of	documentation	the current
				medicines;	for medicines;	legislation;
				– organization	– make a	– skills in
				of quality control	conclusion on	documenting the
				of medicines and	the possibility /	withdrawal from
					1 V	circulation and
				medicinal plant	impossibility of	
				raw materials in	import / export	destruction of
				quality control	of medicines	falsified,
				centers, control	<ul> <li>organize the</li> </ul>	substandard and
				and analytical	receipt of reports	counterfeit
				laboratories,	of counterfeit	medicines.
				pharmacy	and falsified	
				warehouses,	drugs;	
				pharmaceutical	- timely identify	
				enterprises,	medicines that	
				pharmacy	have become	
				organizations;	unusable,	
				- requirements	medicines with	
				of regulatory		
				legal acts of the	an expired shelf	
					life, falsified and	
				Russian	poor-quality	
				Federation to the	medicines;	
				quality of	– be able to	
				medicines; the	carry out the	
				concepts of	withdrawal of	
				falsified,	these medicines	
				substandard and	from circulation	
				counterfeit	for the purpose	
				medicines.	of further	
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					accordance with	
					applicable law;	
					<ul> <li>document</li> </ul>	
					procedures for	
					the seizure and	
					destruction of	
					falsified,	
					substandard and	
					counterfeit	
					medicines.	
3.	PC-10	Able to	PC-10.1. Supervises	– the basics of	- draw up	– skills in
5.	1010	carry out	the activities of legal	the organization	documentation	assessing the
		measures to	entities and	of state control	on the	Ũ
			individuals who			satisfactory
		control		and supervision,	compliance of	compliance with
		(supervise)	have licenses for	licensing control,	the quality of	the storage
		the	pharmaceutical	quality control of	drugs with the	conditions of
		activities of	activity	medicines and	requirements of	medicines and
		legal	PC-10.2. Monitors	medicinal plant	the GF and other	medicinal plant
		entities and	the procedure	raw materials in	regulatory	raw materials,
		individuals	established by law	accordance with	documents;	methods for
		licensed for	regarding the	the legislation of	– use the State	determining the
		pharmaceuti	compliance of	the Russian	Pharmacopoeia	main parameters
		cal	available medicines	Federation and	and other	proving the
		activities, to	for medical use,	the EAEU on	regulatory	correctness of
		comply	instructions and data	circulation;	regulatory	
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mandatory requirement s       effectiveness       standards that casure the medicines, medicines, storage and medicines, storage and medicines, storage and medicines, cultivation and harvesting of medicines and pharwacopocia, diffuitation);       - skills in organizing, cultivation and harvesting of medicines, cultivation and harvesting of medicines and for the proper their       - nake a pharmacological medicines and pharmacopocia, storage and requirements;       - nakes a pharmacological medicines and pharmacopocia, storage and requirements;       - skills in conductions a pharmacological medicines and pharmacological medicines and pharmacopocia, storage and requirements;       - skills in conductions a pharmacological medicines and pharmacological medicines and pharmacological medicines and pharmacological medicines and pharmacological medicines and medicines and medined phar medicines and medicines and medined ph	with	on its sofety and	internetional	anastmants to	transportation
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<ul> <li>organization</li> <li>organization</li> <li>of quality control</li> <li>of medicines and</li> <li>of medicines and</li> <li>conclusion on</li> <li>withdrawal from</li> <li>the possibility /</li> <li>circulation and</li> <li>destruction of</li> <li>impossibility of</li> <li>destruction of</li> <li>import / export</li> <li>and analytical</li> <li>organize the</li> <li>receipt of reports</li> </ul>					
of quality control of medicines and medicinal plant raw materials in quality control centers, control and analytical laboratories, documenting the conclusion on the possibility / impossibility of import / export of medicines substandard and counclusion on the possibility of import / export of medicines substandard and counterfeit medicines.					-
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i receipt of reports			-	U U	
Dharmacy of counterfait					medicines.
			pnarmacy	of counterfeit	

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

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

N⁰	Compete nce code	Section name of the discipline	The content of the section in teaching units
	PC-4	State control and	State control in the field of circulation of medicines.
	PC-5	supervision in the	Regulatory framework regulating state control in the field
	PC-10	field of circulation	of circulation and quality of medicines.
		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
1			control of drugs (express control on the basis of mobile express
1			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
	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
I	

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.
	reporting documentation.

5. Volume of the academic discipline	e and types of academic work
5. Volume of the academic discipling	c and types of academic work

	V L	Labor intensity		
Trans of a data of a national seconds	volume in	volume in	(AH) in	
Type of educational work	credit units	academic	semesters	
	(CU)	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)	Se	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

N₂	Name of the section of the	Types of academic work* (in AH)					
	academic discipline	L	LP	Р	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
INU	Name of lecture topics	9
1.	State control in the field of circulation of medicines. Regulatory	
	framework regulating state control in the field of circulation and quality	1
	of medicines.	
2.	Import of medicines into the Russian Federation and export of	1
	medicines from the Russian Federation.	1
3.	The procedure for introducing medicines into civil circulation on the	1
	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	1
	pharmaceutical specialists in the pharmacovigilance system.	
5.	Testing laboratories for quality control of medicines. Functions,	
	regulatory framework governing state regulation of the work of testing	1
	laboratories for quality control of medicines.	
6.	Principles of organization and functioning of quality control	1
	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
NO	Name of the topics of practicals	9
1.	State control in the field of circulation of medicines. Regulatory	
	framework regulating state control in the field of circulation and quality	2
	of medicines.	
2.	Import of medicines into the Russian Federation and export of	4
	medicines from the Russian Federation.	4
3.	The procedure for introducing medicines into civil circulation on the	2
	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	2
	pharmaceutical specialists in the pharmacovigilance system.	
5.	Testing laboratories for quality control of medicines. Functions,	
	regulatory framework governing state regulation of the work of testing	2
	laboratories for quality control of medicines.	
6.	Principles of organization and functioning of quality control	2
	departments.	۷
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
	Types and topics of SIW	9
1.	Working with literature and other sources of information on	6
	the studied section	
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

			Name of section	Ass	essment forr	nats
N⁰	Semes ter	Types of control	of academic discipline	types	number of test	number of test task
	No.		unserprine.		questions	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

	8.1. Key interature references						
N⁰	Name according to bibliographic requirements	Number of	copies				
		at the department	in the library				
1	The system of legislative regulation of circulation of	electronic re	esource				
	medicines: Textbook / M.A. Mishchenko, E.V.						
	Shalenkova, A.A. Ponomareva, N.N. Chesnokova,						
	S.V. Kononova. – Nizhny Novgorod, 2021. – 77 p.						
2	Fundamentals of state legislation on manufacturing of	electronic re	esource				
	medicines: Textbook / M M.A. Mishchenko, E.V.						
	Shalenkova, A.A. Ponomareva, N.N. Chesnokova,						
	S.V. Kononova. – Nizhny Novgorod, 2021. – 56 p.						
3	Fundamentals of state legislation on pharmaceutical	electronic re	esource				
	activities: Textbook / M.A. Mishchenko, E.V.						
	Shalenkova, A.A. Ponomareva, N.N. Chesnokova,						
	S.V. Kononova. – Nizhny Novgorod, 2021. – 50 p.						
4	The concept of good practices in the pharmaceutical	electronic re	esource				

<ul> <li>regulatory system: Textbook / M.A. Mishchenko,</li> <li>E.V. Shalenkova, A.A. Ponomareva, N.N.</li> <li>Chesnokova, S.V. Kononova. – Nizhny Novgorod,</li> <li>2021. – 57 p.</li> <li>5 Fundamentals of pharmaceutical economics:</li> <li>Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A.</li> <li>Ponomareva, N.N. Chesnokova, S.V. Kononova. –</li> <li>Nizhny Novgorod, 2021. – 125 p.</li> <li>6 Prices and pricing in the pharmaceutical market:</li> </ul>	e
Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 57 p.electronic resource5Fundamentals 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	e
2021 57 p.55Fundamentals of pharmaceutical economics: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova Nizhny Novgorod, 2021 125 p.	e
5Fundamentals 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 electronic resource	e
Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 125 p.	e
Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 125 p.	
Nizhny Novgorod, 2021. – 125 p.	
6 Prices and pricing in the pharmaceutical market electronic resource	
	e
Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A.	
Ponomareva, N.N. Chesnokova, S.V. Kononova. –	
Nizhny Novgorod, 2021. – 77 p.	
7 Product policy of a pharmaceutical organization: electronic resource	e
Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A.	
Ponomareva, N.N. Chesnokova, S.V. Kononova. –	
Nizhny Novgorod, 2021. – 90 p.	
8 Fundamentals of planning economic indicators: electronic resource	e
Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A.	
Ponomareva, N.N. Chesnokova, S.V. Kononova. –	
Nizhny Novgorod, 2021. – 78 p.	
9 Planning of trade turnover of a pharmaceutical electronic resource	e
organization: Textbook / M.A. Mishchenko, E.V.	
Shalenkova, A.A. Ponomareva, N.N. Chesnokova,	
S.V. Kononova. – Nizhny Novgorod, 2021. – 78 p.	
10Planning of distribution costs of a pharmaceuticalelectronic resource	e
organization: Textbook / M.A. Mishchenko, E.V.	
Shalenkova, A.A. Ponomareva, N.N. Chesnokova,	
S.V. Kononova. – Nizhny Novgorod, 2021. – 60 p.	
11Income and profit planning of a pharmaceuticalelectronic resource	e
organization: Textbook / M.A. Mishchenko, E.V.	
Shalenkova, A.A. Ponomareva, N.N. Chesnokova,	
S.V. Kononova. – Nizhny Novgorod, 2021. – 70 p.	
12Accounting of financial and economic activities of aelectronic resource	e
pharmacy organization: Textbook / M.A.	
Mishchenko, S.V. Kononova, N.N. Chesnokova, A.A.	
Ponomareva, E.V. Shalenkova. – Nizhny Novgorod,	
2022. – 74 p.	
13Specific issues of accounting for the property of aelectronic resource	e
pharmacy organization: Textbook / M.A.	
Mishchenko. – Nizhny Novgorod, 2022. – 50 p.	
14Basic principles of accounting of settlements with theelectronic resource	e
personnel of a pharmacy organization: Textbook /	
M.A. Mishchenko. – Nizhny Novgorod, 2022. – 50 p.	
15 The tax concept and tax management of electronic resource	e
pharmaceutical organizations: Textbook / M.A.	
Mishchenko. – Nizhny Novgorod, 2022. – 52 p.	

### 8.2. Further reading

ſ	№	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	electronic resource
	management: Textbook / M.A. Mishchenko, S.V.	
	Kononova, A.A Ponomareva. – Nizhny Novgorod,	
	2020. – 99 p.	
3	Evaluating the quality of pharmaceutical information:	electronic resource
	Textbook / M.A. Mishchenko, S.V. Kononova, A.A	
	Ponomareva. – Nizhny Novgorod, 2020. – 98 p.	
4	Analysis and processing of pharmaceutical	electronic resource
	information: Textbook / M.A. Mishchenko, S.V.	
	Kononova, A.A Ponomareva. – Nizhny Novgorod,	
	2020. – 95 p.	
5	Post-marketing evaluation of medicinal products –	electronic resource
	pharmacoepidemiology: Textbook / M.A.	
	Mishchenko, S.V. Kononova, A.A Ponomareva. –	
	Nizhny Novgorod, 2020. – 53 p.	
6	Post-marketing evaluation of the medicinal products –	electronic resource
	pharmacoeconomics: Textbook / M.A. Mishchenko,	
	S.V. Kononova, A.A Ponomareva. – Nizhny	
	Novgorod, 2020. – 107 p.	
7	Post-marketing evaluation of medicinal products –	electronic resource
	pharmacovigilance: Textbook / M.A. Mishchenko,	
	S.V. Kononova, A.A Ponomareva. – Nizhny	
	Novgorod, 2020. – 70 p.	
8	Fundamentals of the state regulation of	electronic resource
	pharmaceutical information that is advertising:	
	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)

N⁰	Name of the electronic resource	Brief description (content)	Access conditions	Number of users
1	Internal electronic library system (IELS) http://nbk.pimunn.net/M egaPro/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.pimun n.net/MegaPro/ Web	Not limited

#### 8.3.2. Electronic educational resources acquired by the University

N⁰	Name of the electronic resource	Brief description (content)	Access conditions	Number of users
1	Electronic legal	Regulatory documents	Access mode:	Not limited

reference system	regulating the activities	http://www.cons	
"Consultant Plus"	of medical and	ultant.ru/	Term of validity:
(contract for free)	pharmaceutical		Unlimited
http://www.consultant.ru	institutions From the		
	scientific library		
	computers		

	8.5.5 Open access resources					
N⁰	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.co m	International abstract database of scientific citation. From university computers, from any computer by individual login and password.	Access mode: https://www.webofscience.co m Not limited			

#### 8.3.3 Open access resources

#### 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

Ite m no.	Software	number of licenses	Type of software	Manufacture r	Number in the unified register of Russian software	Contract No. and date
1	Wtware	100	Thin Client Operating System	Kovalev Andrey Alexandrovic h	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 TECHNOLO GIES"	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 Subscriptio n	
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/HN100 30 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