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

making 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

29.04.2021

AGREED Deputy Head of EMA ph.d. of biology _

abot Lovtsova L.V.

29.04.2021

(signature)

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 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 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

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			into account their	programs of	within the
			origin, type and	measures for the	framework of
			level of novelty;	registration and	pre-registration
			– the structure	examination of	preparation and
			of the state	drugs in order to	in the process of
			register of	obtain a	state registration
			medicinal	registration certificate or	of medicinal
			products for	obtain	products;
			medical use and		– skills in
			other official sources of	permission to conduct a	issuing an
			information in	clinical trial;	application for
			the field of	– develop	state registration of medicinal
			circulation of	documents	products;
			medicines;	submitted for	 – skills in the
			 principles, 	state registration	development and
			rules and	and examination	execution of
			procedure for	of medicinal	documents for
			state registration	products.	the formation of
			of medicinal	F	a registration
			products;		dossier in
			- the procedure		accordance with
			for planning the		the current
			preparatory		legislation;
			stages of the		– skills of
			state registration		examination of
			of medicinal		documentation
			products;		included in the
			– the structure		registration
			and procedure		dossier of the
			for the formation		medicinal
			of a registration		product;
			dossier for		 skills in
			various drugs;		issuing an expert
			- domestic and		report on the
			foreign		results of
			requirements for		examinations
			conducting and		within the
			presenting the		framework of
			results of the		state registration;
			study of		– skills in
			bioequivalence		obtaining a
			and biosimilarity		marketing
			of drugs;		authorization for
			- requirements		a medicinal
			for the execution		product for

of an application	medical use
of an application for state	medical use
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.	

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

NO.	Compete nce code	Section name of the discipline	The content of the section in teaching units	
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	PC-10	State registration	Fundamentals of the state policy in the field of drug
	PC-11	and expertise of	provision to the population. General characteristics of the drug
	10-11	medicines	supply system of the Russian Federation. Organization and
		medicines	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
1			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 t	the academic	discipline and	types of academ	ic work
	v oranic or e	me acaacime	and and and	ypes of academ	

	Labor	Labor intensity	
Type of educational work	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)*	Laborato	ry 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

N⁰	Name of the section of the	Types of academic work* (in AH)					
	academic discipline	L	LP	Р	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	Nome of lasture tonics	Volume in AH
INO	Name of lecture topics	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

N		Volume in AH
No	Name of the topics of practicals	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
	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 of academic discipline	Assessment formats			
Nº	Semes ter No.	Types of control		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	Credit	3	40
		assessment			

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 literature 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 medicines: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova, S.V. Kononova. – Nizhny Novgorod, 2021. – 77 p.	electronic r	esource					
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 r						
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 r						
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 r	esource					
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.	A.						
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.	A.						
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 r	esource					
10	Planning of distribution costs of a pharmaceutical organization: Textbook / M.A. Mishchenko, E.V. Shalenkova, A.A. Ponomareva, N.N. Chesnokova,	electronic r	esource					

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

8.2. Further reading

	8.2. Further reading						
N⁰	Name according to bibliographic requirements	Number of	copies				
		at the department	in the library				
1	The medicine lifecycle concept: Textbook / M.A.	electronic re	esource				
	Mishchenko, S.V. Kononova, A.A Ponomareva. –						
	Nizhny Novgorod, 2020. – 80 p.						
2	Information technologies in the medicine lifecycle	electronic re	esource				
	management: Textbook / M.A. Mishchenko, S.V.						
	Kononova, A.A Ponomareva. – Nizhny Novgorod, 2020. – 99 p.						
3	Evaluating the quality of pharmaceutical information:	electronic re	esource				
	Textbook / M.A. Mishchenko, S.V. Kononova, A.A						
	Ponomareva. – Nizhny Novgorod, 2020. – 98 p.						
4	Analysis and processing of pharmaceutical	electronic re	esource				
	information: Textbook / M.A. Mishchenko, S.V.						
	Kononova, A.A Ponomareva. – Nizhny Novgorod,						
	2020. – 95 p.						
5	Post-marketing evaluation of medicinal products –	electronic re	esource				
	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 re	esource				
	pharmacoeconomics: Textbook / M.A. Mishchenko,						
	S.V. Kononova, A.A Ponomareva. – Nizhny						
	Novgorod, 2020. – 107 p.						
7	Post-marketing evaluation of medicinal products –	electronic re	esource				
	pharmacovigilance: Textbook / M.A. Mishchenko,						
	S.V. Kononova, A.A Ponomareva. – Nizhny						
	Novgorod, 2020. – 70 p.						
8	Fundamentals of the state regulation of	electronic re	esource				
	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)

Nº	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 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.cons ultant.ru/	Not limited Term of validity: Unlimited

8.3.3 Open access resources

N⁰	Name of the electronic	Brief description (content)	Access conditions
	resource		
1	PubMed	US National Library of	From any computer and
	https://www.ncbi.nlm.nihgov	Medicine search engine for	mobile device.
	/pubmed	Medline, PreMedline	Access mode:
		databases	https://www.ncbi.nlm.nihgov
			/pubmed
			Not limited
2	Scopus database	International abstract	Access mode:
	www.scopus.com	database of scientific citation	www.scopus.com
		From university computers,	Not limited
		from any computer by	
		individual login and	
		password	
3	Web of Science Core	International abstract	Access mode:
	Collection	database of scientific	https://www.webofscience.co
	https://www.webofscience.co	citation. From university	m
	m	computers, from any	Not limited
		computer by individual login	

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"

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	

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

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: _____

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

(code, name)