Summary of the working program of the academic discipline

«STATE CONTROL AND SUPERVISION IN THE FIELD OF CIRCULATION OF MEDICINES»

General Educational Program of higher education (specialist's degree programs): *33.05.01 Pharmacy*
Department: *Management and Economics of Pharmacy and Pharmaceutical Technology*

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).

2. Position of the academic discipline in the structure of the General Educational Program (GEP)

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).

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

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

№	Competence 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	– 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);	– 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

				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.	– 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	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.

					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 part in planning and organizing the resource provision of a pharmaceutical organization	PC-5.5. Carries out the withdrawal from circulation of medicines and pharmacy assortment goods that have fallen into disrepair, expired, falsified, counterfeit and substandard products	– 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	– 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;	– 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 timely detection

				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.	– 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.	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.
3.	PC-10	Able to carry out measures to control	PC-10.1. Supervises the activities of legal entities and individuals who have	– the basics of the organization of state control and supervision,	– draw up documentation on the compliance of the quality of	– skills in assessing the satisfactory compliance with

		(supervise) the activities of legal entities and individuals licensed for pharmaceuti cal activities, to comply with mandatory requirements	licenses for pharmaceutical activity PC-10.2. Monitors the procedure established by law regarding the compliance of available medicines for medical use, instructions and data on its safety and effectiveness	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;	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;	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 destruction in accordance with the current

				– 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.	– 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.	legislation; – skills in documenting the withdrawal from circulation and destruction of falsified, substandard and counterfeit medicines.

4. 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

5. 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.