Summary of the working program of the academic discipline

«STATE REGISTRATION AND EXPERTISE 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-10, PC-11 (11.1)).

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-10	Able to carry out measures to control (supervise) the activities of legal entities and individuals licensed for pharmaceutical activities, to comply with mandatory requirements	PC-10.1. Supervises the activities of legal entities and individuals who have licenses for pharmaceutical activity PC-10.2. Monitors the procedure established by law regarding the compliance of available medicines for medical use, instructions and data on its safety and effectiveness	– 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	– 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.	– 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

				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		formation of a registration dossier in accordance with the current legislation; – skills of examination of documentation included in the registration dossier of the medicinal product; – skills in issuing an expert report on the results of examinations within the framework of state registration; – skills in obtaining a marketing authorization for a medicinal product for medical use

				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.		
2.	PC-11	Able to take part in measures to ensure the quality of medicines in industrial production	PC-11.1. Participates in events, including the preparation and verification of documents responsible for the quality of medicines	– 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	– 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.	– 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;

				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		– skills of examination of documentation included in the registration dossier of the medicinal product; – skills in issuing an expert report on the results of examinations within the framework of state registration; – skills in obtaining a marketing authorization for a medicinal product for medical use

				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. 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-10 PC-11	State registration and expertise of medicines	Fundamentals of the state policy in the field of drug provision to the population. General characteristics of the drug supply system of the Russian Federation. Organization and provision of drug care in the Russian Federation. Programs to improve drug supply based on the list of essential medicines. State regulation of pricing for medicines. Problems and prospects for the development of the pharmaceutical industry of the Russian Federation. Legislative basis of drug provision to the population. Regulatory and legal framework in the field of organization of drug provision to the population at the present stage. Federal Regulations "On the Circulation of Medicines", "On Licensing certain types of activities", "On Narcotic Drugs and Psychotropic Substances", "On the Basics of Protecting the Health of Citizens in the Russian Federation".. The system of drug supply to the population in the Russian Federation. Medical and pharmaceutical organizations in the system of drug provision. Types of consumers. Characteristics of types of medical care and types of medical organizations.

			Types and characteristics of pharmaceutical organizations in the system of drug provision. Types and characteristics of consumers of medicines. Organization of drug provision to end users. Organization of drug provision in outpatient and polyclinic treatment. Organization of work of pharmacies. Organization of drug provision for citizens who have the right to receive drugs free of charge or on preferential terms for outpatient treatment. Programs and state guarantees of free medical care for citizens. Procedure for providing citizens with the necessary medicines. Organization of drug provision for medical organizations. The procedure for drug provision of inpatients. Fundamentals of the formulary system in the health care of the Russian Federation. Modern models of drug provision for inpatient patients. The appointment of drugs in the provision of medical care in stationary conditions. The procedure for the release of goods from the pharmacy to the departments and offices of the Ministry of Defense. Accounting for released goods. Pharmacoeconomic aspects of providing drug care to the population. Characteristics of drug consumption. Methods for determining the need for medicines. Types of demand for medicines. Concepts of need, demand, consumption. Types of consumption and factors affecting the consumption of medicines. Methods for determining the need for medicines. Types of demand. Types of demand.