

*Summary of the working program of the academic discipline*

**«LEGAL ASPECTS OF ORGANIZATION OF PHARMACEUTICAL ACTIVITIES (ADDITIONAL DISCIPLINE)»**

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 competencies (PC-10 (10.1, 10.2)).

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

**2.1.** The discipline is taught in the 8 semester/4 year of study.

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

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

№	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	<ul style="list-style-type: none"> <li>– the structure of the modern health care system of the Russian Federation, the basics of the legislation of the Russian Federation on the protection of public health, the main regulatory and legal documents regulating relations in the field of circulation of medicines;</li> <li>– legal status of pharmaceutical entities: individual entrepreneurs and legal entities, types of legal entities;</li> <li>– regulatory framework for the creation, reorganization and liquidation of individual entrepreneurs and legal entities engaged in pharmaceutical activities;</li> <li>– regulatory framework for the creation,</li> </ul>	<ul style="list-style-type: none"> <li>– organize the creation, reorganization, liquidation of pharmaceutical entities;</li> <li>– carry out types of work or services constituting pharmaceutical activities, and activities in the field of circulation of medicines in compliance with the requirements of the legislation of the Russian Federation in the field of health protection;</li> <li>– use modern information technologies in solving problems of professional activity.</li> </ul>	<ul style="list-style-type: none"> <li>– regulatory and legal documentation regulating the procedure for the creation, reorganization, liquidation of pharmaceutical entities;</li> <li>– regulatory documentation regulating the procedure for carrying out pharmaceutical activities and activities in the field of circulation of medicines</li> <li>– regulatory and legal reference systems, as well as professional databases for solving problems of professional activity</li> </ul>

				<p>reorganization and liquidation of corporations engaged in pharmaceutical activities and other activities related to the circulation of medicines;</p> <ul style="list-style-type: none"><li>– norms of legislation relating to state control and supervision in the field of pharmaceutical activities and other activities related to the circulation of medicines;</li><li>– procedure and requirements for the implementation of pharmaceutical activities.</li><li>– legal regime of property of subjects of pharmaceutical activity;</li><li>– the procedure for recognizing the insolvency (bankruptcy) of pharmaceutical entities;</li><li>– fundamentals of antimonopoly regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices;</li><li>– methods of legal protection of the rights and legitimate interests of subjects of pharmaceutical activity;</li><li>– fundamentals of regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices within the EAEU;</li><li>– modern information technologies for solving problems of professional activ-</li></ul>		
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#### 4. Volume of the academic discipline and types of academic work.

Type of educational work	Labor intensity		Labor intensity in semesters (AH)
	volume in credit units (CU)	volume in academic hours (AH)	8
Classroom work, including	1,22	44	44
Lectures (L)	0,28	10	10
Laboratory practicum (LP)*	Laboratory practicums are not stipulated		
Practicals (P)	0,94	34	34
Seminars (S)	Seminars are not stipulated		
Student's individual work (SIW)	0,78	28	28
Mid-term assessment: credit			
<b>TOTAL LABOR INTENSITY</b>	<b>2</b>	<b>72</b>	<b>72</b>

#### 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	Legal aspects of organization of pharmaceutical activities	<p>State regulation of pharmaceutical activity as an element of the system of public health protection in pharmaceutical activities.</p> <p>Legal status of subjects of pharmaceutical activity.</p> <p>The procedure for the creation, reorganization and liquidation of pharmaceutical entities.</p> <p>Corporations in pharmaceutical activities and other activities related to the circulation of medicines and medical devices.</p> <p>Licensing of pharmaceutical activities.</p> <p>The general legal regime of the property of subjects of pharmaceutical activity.</p> <p>Insolvency (bankruptcy) of pharmaceutical entities.</p> <p>Antimonopoly regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices.</p> <p>Protection of the rights and legitimate interests of subjects of pharmaceutical activity (jurisdictional and non-jurisdictional forms).</p> <p>Regulation of pharmaceutical activities and other activities related to the circulation of medicines and medical devices within the EAEU.</p>