Basic Degree Program in Specialty 33.08.01 Pharmaceutical Technology (Level of Top Qualification Personnel Training in Residency)

Terms, Workload of the Degree Program and Qualification of Graduates

Name	Qualification	Term of education including the holidays provided after the completion of the State Final Certification	Workload (in credits)
Residency program	Pharmacist- technologist	2 years	120

Purpose (Mission) of the Degree Program

The mission of the residency program in "Pharmaceutical Technology" is training of scientifically-oriented high-skilled top qualification personnel of new formation, who are able to carry out scientific research, production, organizational and managerial activities in the field of pharmaceutical, biomedical technologies, as well as undertake scientific activities in the context of global trends based on the application of breakthrough achievements in the field of pharmacy, additive technologies, protection and efficient use of nature resources.

The degree program is aimed at the implementation of the following principles, namely: application of the scientific research results in professional practices, professional activities based on the continuous development and innovation, independent carrying out of scientific research, analysis and aggregation of its results, making predictions; ability to arrange and carry out professional activities in the field of pharmacy, medicine, close to the degree program specialization.

Demand for Graduates

Graduates of the residency program in "Pharmaceutical Technology" are in demand with pharmaceutical organizations in St. Petersburg and the Northwestern Federal District. JSC "St. Petersburg Pharmacies", State Budgetary Healthcare Institution "Regional Clinical Oncologic Dispensary", CJSC "St. Petersburg Institute of Pharmacy", CJSC "BIOCAD", FSUE Saint Petersburg Scientific Research Institute of Vaccines and Serums of the FMBA of Russia, LLC "INTEKHPROEKT", Scientific and Technological Company "POLYSAN" LTD, JSC "PHARMPROJECT", JSC WERTEKS, ROSBIO LLC, JSC Ivanovo Pharmaceutical Factory and others are among them.

Requirements for Enrollment in the Degree Program

The persons with higher pharmaceutical education who have passed entrance examinations in accordance with the Regulations for Admission to Degree Programs, namely residency programs are allowed for enrollment.

Graduate's Qualification Characteristic Areas of Professional Activity

The area of professional activity of graduates who have completed the residency program includes circulation of medicinal products.

According to the register of professional standards (the list of types of professional activity approved by Order No. 667n of the Ministry of Labor of Russia dated 29.09.2014), the areas of professional activity and fields of professional activity which the graduates who have completed the residency program (hereinafter referred to as graduates) can be engaged in include:

02 Healthcare (in the field of circulation of medicinal products and other pharmacy goods).

Graduates can be engaged in professional activity in other areas and (or) fields of professional activity if their education level and acquired competences correspond to the employee's qualification.

Objects of Professional Activity

The objects of professional activity of graduates in the degree program in 33.08.01 Pharmaceutical Technology are:

medicinal products;

a set of facilities and technologies aimed at creating conditions for development, manufacturing, quality control, circulation of medicinal products as well as control in the field of circulation of medicinal products according to the established healthcare requirements and standards; individuals and legal entities.

Types of Professional Activity

Types of professional activity which graduates of the residency program are prepared for: engineering and manufacturing;

organizational and managerial.

Tasks of Professional Activity

The graduate who has completed the residency program is ready to carry out the following job tasks:

engineering and manufacturing activities:

production and manufacture of medicinal products;

organizational and managerial activities:

organization of production and manufacture of medicinal products;

organization and implementation of measures for storage, transportation, seizure and destruction of medicinal products;

maintenance of accounts and records in a pharmaceutical organization;

management of personnel labor in pharmaceutical organizations and their structural units proceeding from the health and safety requirements;

compliance with the basic requirements of information security.

List of Professional Standards Corresponding to the Professional Activity of Graduates Who Have Completed the Degree Program

Item No.	Code of professional standard	Name of professional standard		
	02 Healthcare			
1.	02.014	Specialist in industrial pharmacy in the field of quality assurance of medicinal products		
2.	02.016	Specialist in industrial pharmacy in the field of manufacturing of medicinal products		

General Characteristic of the Degree Program

<u>Planned results of completing of the degree program (competences) and indicators of their achievement</u>

In accordance with the aims of the degree program and types of tasks of professional activity, the graduate of the degree program in 33.08.01 Pharmaceutical Technology shall have the following competences characterized by the indicators of their achievement:

Codes	Competences, indicators of competence achievement		
UC-1	readiness to think abstractly, analyze, synthesize		
UC-1.1	Develops and substantively argues a problem situation solving strategy based on system and interdisciplinary approaches		
UC-1.2	Logically analyzes, systematizes and summarizes information, uses methods and techniques of argumentation culture in communication		

members to achieve the set goal, assigning roles in the team UC-2.2 Settles conflicts and contradictions in business communication proceeding from interests of all parties Treadiness to participate in teaching activities under programs of secondary higher medical education or secondary and higher pharmaceutical education, as as under additional training programs for persons with secondary vocational higher education, according to the procedure prescribed by the federal execute body responsible for the development of public policy and statutory regulation in field of healthcare UC-3.1 Participates in the development and update of working programs, learning and teachin materials for programs of secondary and higher pharmaceutical education based on the requirements of federal and local regulatory legal acts regulating activity in the field of secondary vocational and higher education UC-3.2 Makes educational process for students with different forms of disability taking account their needs and capabilities based on the application of technologies and teaching account their needs and capabilities based on the application of technologies and teaching disability taking account their needs and capabilities based on the application of technologies and teaching disability taking account their needs and capabilities based on the application of technologies and teaching disability taking account their needs and capabilities based on the application of technologies and teaching disability taking account their products PC-1.1 Selects best available technologies for production and manufacture of medicinal products PC-1.2 Justifies the selection and selects excipients to obtain various medicinal products PC-1.3 Performs auxiliary processing operations in the production of medicinal products PC-2.1 Manages the documentation of the quality assurance system PC-2.2 Prepares internal audits (self-inspections) of the quality assurance system PC-3.2 Prepares internal audits (self-inspections) of the quality assurance syst	UC-2	readiness to manage a team, perceive social, ethnic, religious and cultural differences in a non-judgmental manner	
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PC-6 readiness to organize engineering processes in the production and manufacture of medicinal products	PC-5.1	Applies basic principles of organization and HR design when planning the activities of structural units of a pharmaceutical organization	
medicinal products	PC-5.2		
	PC-6	readiness to organize engineering processes in the production and manufacture of medicinal products	
PC-6.1 Develops process documentation in the production of medicinal products	PC-6.1	Develops process documentation in the production of medicinal products	

PC-6.2	Draws up process documentation in the manufacture of various medicinal products
PC-6.3	Arranges for the provision of the engineering process of medicinal products with the necessary raw materials and supplies
PC-6.4	Analyzes process documentation in a foreign language

Mandatory part (name, workload, final discipline assessment)

- 1. Business Communication Conflict Resolution Studies 3 credits (108 hours), in-class work 28 hours, pass-fail test
- 2. Pedagogy 3 credits (108 hours), in-class work 28 hours, pass-fail test
- 3. Logic and Theory of Argumentation 3 credits (108 hours), in-class work 30 hours, pass-fail test
- 4. Pharmacy Innovation Management 3 credits (108 hours), in-class work 36 hours, pass-fail test, course project
- 5. Corporate Management 3 credits (108 hours), in-class work 32 hours, graded test
- 6. Excipients in Formulation of Dosage Forms 6 credits (216 hours), in-class work 58 hours, examination
- 7. Quality Assurance System in Formulation 6 credits (216 hours), in-class work 58 hours, examination
- 8. Good Manufacturing Practice (GMP) 3 credits (108 hours), in-class work 22 hours, pass-fail test
- 9. Modern Formulations of Dosage Forms 3 credits (108 hours), in-class work 32 hours, graded test <u>Optional part</u>
- 10. Foreign Language 3 credits (108 hours), in-class work 28 hours, pass-fail test
- 11. Modern Approaches to Assessment of Medicinal Product Interchangeability 3 credits (108 hours), in-class work 30 hours, pass-fail test

Elective disciplines (name, workload, final discipline assessment)

- 12. Formulation of Pharmaceutical and Cosmetic Products 3 credits (108 hours), in-class work 32 hours, pass-fail test
- 13. Formulation of Homeopathic Medicinal Products 3 credits (108 hours), in-class work 32 hours, pass-fail test
- 14. Principles of Medicinal Products for Veterinary Use 3 credits (108 hours), in-class work 30 hours, passfail test
- 15. Formulation of Age-specific Medicinal Products 3 credits (108 hours), in-class work 30 hours, pass-fail test

Optional subjects (name, workload, final discipline assessment)

- 16. Equipment for Pharmaceutical Retail and Hospital Pharmacy 2 credits (72 hours), in-class work 20 hours, pass-fail test
- 17. Packaging of Medicinal Products 2 credits (72 hours), in-class work 20 hours, pass-fail test *Practices (name, workload, final assessment)*
- 18. Practice in Formulation of Soft Dosage Forms 14 credits (432 hours), in-class work 14 hours, graded test
- 19. Pedagogical Practice 3 credits (108 hours), in-class work 8 hours, pass-fail test
- 20. Practice in Formulation of Sterile Dosage Forms 18 credits (648 hours), in-class work 20 hours, graded test
- 21. Practice in Formulation of Solid Dosage Forms 15 credits (540 hours), in-class work 17 hours, graded test
- 22. Practice in Formulation of Liquid Dosage Forms 17 credits (540 hours), in-class work 17 hours, graded test

Elective disciplines (name, workload, final discipline assessment)

- 23. Practice in Formulation of Pharmaceutical and Cosmetic Products 6 credits (216 hours), in-class work 8 hours, pass-fail test
- 24. Practice in Formulation of Pediatric Dosage Forms 3 credits (108 hours), in-class work 5 hours, pass-fail test

25. Practice in Formulation of Homeopathic Medicinal Products – 3 credits (108 hours), in-class work – 5 hours, pass-fail test

State final certification

26. Preparation for and Passing of State Examination—3 credits (108 hours), in-class work—6 hours, pass-fail test

Resources Provision of the Degree Program

The degree program is provided with learning and teaching documentation, as well as materials in all disciplines (modules) and practices, including electronic educational-methodical complexes posted in electronic information and educational environment of the University.

The University has facilities and resources that are in compliance with applicable fire safety rules and regulations and ensure all types of the disciplinary and interdisciplinary preparation, practical and scientific research works of students, provided for by the curriculum.

The list of facilities and resources, learning and teaching support, required for implementation of the degree program, includes the following: special rooms in the form of classrooms for conducting lecture-type activities, seminar-type activities, course work development (course work execution), group and individual tutorials, current control and midterm assessment. There are also rooms for independent work and rooms for storage and preventative maintenance of training equipment. Special rooms are equipped with designated furniture and teaching aids intended for presentation of teaching information to a large audience. Laboratories are equipped with laboratory equipment depending on the degree of complexity. Sets of demonstration equipment and illustrative study guides providing for topic-based illustrations and corresponding to discipline (module) programs, working educational programs of disciplines (modules), are offered for lecture-type activities.

Rooms for students' independent work are equipped with computer hardware with the possibility of connecting to the Internet network and access to electronic information and educational environment of the organization. Furthermore, students' independent work is arranged with the use of electronic resources of the University.

The library fund is provided with the required number of printed publications, moreover, there is an access to electronic library systems.

The University has the necessary licensed software package the composition of which is given in working programs of disciplines (modules) and is subject to annual update.

The students are provided with an access (remote access), including in the event of doing electronic learning, applying distance learning technology, to today's professional databases and inquiry and communications systems the composition of which is determined in working programs of disciplines (modules) and is subject to annual update.

During the whole period of studying every student and a teacher are provided for with an unlimited access (including the remote one) to electronic library systems and to electronic information and educational environment of the University from any place with the available Internet connection.

Electronic information and educational environment of the University provides for:

- the access to curricula, working programs of disciplines (modules), practices, editions of electronic library systems and electronic learning resources specified in working programs;
- recording of progress of the educational process, results of midterm assessment and results of the degree program completion;
- the formation of electronic portfolio of the student, including the preservation of student's works and grades for these works by any participants of the educational process;
- interaction between participants of the educational process, as well as synchronous and (or) asynchronous communication via Internet.

Functioning of electronic information and educational environment complies with the requirements of the legislation of the Russian Federation in the field of education and is provided for with the relevant means of information and communication technologies and qualification of the University employees who use and maintain it.

Staffing of the Degree Program

Implementation of the residency program is ensured by the senior academic staff of the University, as well as by persons engaged in the implementation of the residency program under the terms of the civil contract.

The percentage of the academic staff (reduced to integer rates) having education that corresponds to the profile of the discipline (module) taught in the total number of the academic staff implementing the residency program is at least 70%.

The percentage of the academic staff (reduced to integer rates) having a degree and (or) an academic rank in the total number of the academic staff implementing the residency program is at least 65%.

The percentage of staff (reduced to integer rates) among the heads and employees of organizations whose activities are related to the specialization (profile) of the residency program (having at least 3 years of work experience in this professional field) in the total number of staff implementing the residency program is at least 10%.

Uniqueness and Competitive Advantages of the Program

This degree program has a relevant focus in the field of training practice-oriented personnel who are able to implement engineering, organization and management in the area of development, production, quality control and circulation of medicinal products according to the established requirements and standards.

The program has been created in cooperation with employers. As part of the practice, residents acquire professional skills and experience in professional activity based at pharmaceutical organizations in St. Petersburg, the Northwestern Federal District and other regions of the Russian Federation. The key employers engaged in the educational process are JSC "St. Petersburg Pharmacies", LLC "NEVIS Pharmacies", CJSC "St. Petersburg Institute of Pharmacy", CJSC "BIOCAD", FSUE Saint Petersburg Scientific Research Institute of Vaccines and Serums of the FMBA of Russia, LLC "INTEKHPROEKT", Scientific and Technological Company "POLYSAN" LTD, JSC "PHARMPROJECT", JSC WERTEKS, JSC Ivanovo Pharmaceutical Factory and others.

The program takes into account current scientific trends in innovative information and education technologies, flexible individual educational trajectories allowing for operative considering the global challenges of pharmacy, medicine and healthcare. The development of students' teamwork skills, interpersonal communication, decision-making, leadership is ensured in the process of academic studies (including interactive lectures, group discussions, role-playing games, trainings, case and simulation model studies). Disciplines are taught in the light of regional features of professional activities of graduates and the needs of employers. Case technologies and problem-based learning, business simulation games, portfolio method, as well as other education technologies stimulating students' cognitive activity are used within academic studies.

The content of the program represents the needs of today's labor market in organization of the production of medicinal products; quality assurance system in the formulation of medicinal products; organization of measures for seizure and destruction of medicinal products; maintenance of accounts and records in pharmaceutical organizations and their structural units; management of personnel labor in pharmaceutical organizations and their structural units proceeding from the health and safety requirements; compliance with the basic requirements of information security.

In addition, active career guidance counseling involving employers is carried out with students within the educational process. All graduates of the degree program in 33.08.01. Pharmaceutical Technology are in demand with pharmaceutical organizations.