Abstract
of Master's Degree Program
in Field of Education 18.04.01 Chemical Technology,
Discipline (Specialization) "Qualified Person"
(Internal-External Study Mode)

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)
Master's degree program	Master	2 years and 3 months	120

Purpose (Mission) of the Degree Program

The mission of the master's program in "Qualified Person" is training of personnel who are able to solve tasks of organizational and managerial activities at pharmaceutical enterprises in the course of confirmation of compliance of medicinal products with the regulatory requirements.

The degree program is aimed at the implementation of the following principles, namely: application of the results of theoretical education in professional practices, professional activities based on the continuous development and innovation; ability to arrange and carry out professional activities in the field corresponding to the degree program specialization.

Demand for Graduates

Graduates of the master's degree program in "Qualified Person" are in demand with pharmaceutical enterprises and the state regulation system for circulation of medicinal products.

Requirements for Enrollment in the Degree Program

The persons with appropriate education confirmed by the document of higher education and qualification who have passed entrance examinations in accordance with the approved Regulations for Admission to Higher Education Programs, namely bachelor's degree programs, specialist's and master's degree programs, are allowed for enrollment.

Graduate's Qualification Characteristic

Areas of Professional Activity

The area of the professional activity of masters in field of education 18.04.01 "Chemical Technology", master's degree program "Qualified Person" includes organization, carrying out of works and management of works according to the pharmaceutical quality system involving drawing up of the permission for putting of medicinal products into circulation.

The professional activity which the graduates who have completed the master's degree program (hereinafter referred to as graduates) can be engaged in:

02 Healthcare (in the field of production, quality assurance and development of new medicinal products, in the field of quality control of raw materials and finished products of the pharmaceutical industry);

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 activities of graduates of the degree program in field of education 18.04.01 Chemical technology. "Qualified Person" are:

– processes of pharmaceutical quality system of production of medicinal products;

– requirements for production and quality control of medicinal products in pharmaceutical manufacturing;
– dossier for a batch of medicinal product and decisions on putting the products into circulation.

Types of Professional Activity

Types of professional activities which graduates of the master's degree program are prepared for:
– organizational and managerial activities.

Tasks of Professional Activity

The graduate who has completed the master's degree program according to the type of tasks of professional activities which the master's degree program is aimed at, is ready to solve the following job tasks:
– organization and management of works according to the pharmaceutical quality system.

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

General Characteristic of the Degree Program

Planned results of completing of the degree program (competences) and indicators of their achievement

In accordance with the aims of the degree program and type of tasks of professional activities, the graduate of the master's degree program "Qualified Person" shall have the following competences characterized by the indicators of their achievement:

Code and name of competence	**Code and name of indicator of competence achievement**
UC-1. Able to critically analyze problem situations based on a system approach, to elaborate an action strategy	UC-1.1. Uses logical-methodological tools to critically assess up-to-date philosophical and social concepts in their subject area
	UC-1.2. Analyzes a problem situation as a system, identifying its components and their interrelations
	UC-1.3. Critically assesses the reliability of information obtained from various sources
	UC-1.4. Develops and substantively argues a problem situation solving strategy in the professional field based on system and interdisciplinary approaches
UC-2. Able to manage the project at all stages of its life cycle	UC-2.1. Develops the concept of project implementation within the outlined problem: formulates the goal, tasks, justifies the relevance, significance, expected results and possible scope of their application

Code and name of competence	Code and name of indicator of competence achievement
	UC-2.2. Determines and calculates required engineering and economic resources for the implementation of production process
	UC-2.3. Develops a work implementation plan and monitors the project with the use of planning tools
UC-3. Able to organize and manage a team, developing a team strategy to achieve the set goal	UC-3.1. Develops a collaborative strategy and, on its basis, arranges the selection of team members to achieve the set goal in the field of researches of medicinal products
	UC-3.2. Plans and arranges the teamwork in the field of research of medicinal products proceeding from the interests, behaviors and opinions of team members
	UC-3.3. Arranges for discussions on a given topic and consideration of the results of the teamwork in the field of research of medicinal products
UC-4. Able to use state-of-the-art communication technologies, including in foreign language(s), for academic and professional interaction	UC-4.1. Establishes and develops professional contacts according to the needs of cooperation, including the exchange of information and the elaboration of a single strategy of cooperation
	UC-4.2. Draws up, translates and edits materials of the field of professional activity, including those in a foreign language
UC-5. Able to analyze and take into account the cultural diversity in the process of inter-cultural collaboration	UC-5.1. Analyzes the most important ideological and value systems formed in the course of historical development; justifies the relevance of their use in social and professional interactions in the field of research of medicinal products
	UC-5.2. Makes social and professional interaction, given the peculiarities of main forms of scientific and religious consciousness, culture and professional ethics in the field of research of medicinal products
UC-6. Able to determine and implement priorities of their activities and ways to improve them based on self-esteem	UC-6.1. Assesses and optimally uses their resources (personal, situational, temporary) for successful completion of the tasks
	UC-6.2. Determines the priorities of professional growth and ways to improve their own activities based on self-esteem according to the selected criteria
	UC-6.3. Makes a flexible professional trajectory using tools of continuing education, given the accumulated experience of professional activities and dynamically changing requirements of the labor market

Code and name of competence	Code and name of indicator of competence achievement
GPC-1. Able to arrange independent and collective scientific research work, develop plans and programs for conducting scientific research and technical developments	GPC-1.1. Arranges independent scientific research work in the field of research of medicinal products, including using state-of-the-art software technologies
	GPC-1.2. Arranges collective scientific research work in the field of research of medicinal products
	GPC-1.3. Develops plans for scientific research and technical developments in the field of production and quality assurance of medicinal products
	GPC-1.4. Develops research and technical development programs, taking into account the expediency of conducting scientific research works and the possibility of commercial use of new developments at domestic pharmaceutical enterprises
GPC-2. Able to use state-of-the-art instruments and techniques, organize experiments and tests, process them and analyze the results	GPC-2.1. Organizes experiments and tests using state-of-the-art instruments and techniques for experiments and tests
	GPC-2.2. Performs processing and analysis of the results of experiments and tests, including with the use of state-of-the-art software
GPC-3. Able to develop production standards, engineering standards for the consumption of materials, blanks, fuel and electricity, control the parameters of the engineering process, select equipment and engineering tooling	GPC-3.1. Develops production standards, engineering standards for the consumption of materials, blanks, fuel and electricity
	GPC-3.2. Justifies the selection of type apparatus and tooling for process
	GPC-3.3. Controls the parameters of the engineering process
GPC-4. Able to find optimal solutions when creating products taking into account the requirements of quality, reliability and cost, as well as deadlines, life safety and environmental cleanliness	GPC-4.1. Finds optimal parameters and ways of carrying out of the engineering process in order to improve its efficiency, safety and environmental friendliness of pharmaceutical manufacturing
	GPC-4.2. Finds optimal solutions when creating pharmaceutical products taking into account the requirements of quality and reliability
	GPC-4.3. Finds optimal solutions when creating pharmaceutical products taking into account the cost and deadlines

Code and name of competence	Code and name of indicator of competence achievement
PC-9. Able to arrange, plan and enhance processes of the pharmaceutical quality system of production of medicinal products including improvement of the work of personnel of the units for quality assurance of medicinal products	PC-9.1. Arranges and controls works on ensuring functioning of the pharmaceutical quality system of medicinal products and assesses its effectiveness
	PC-9.2. Monitors compliance of pharmaceutical manufacturing with the established requirements, the relevant procedure for circulation of medical products, principles of the good manufacturing practice
	PC-9.3. Agrees upon and approves documentation of the pharmaceutical quality system
	PC-9.4. Determines forms and methods of personnel training
PC-10. Able to perform control of compliance with the established requirements for production and quality control of medicinal products in pharmaceutical manufacturing as well as carry out assessment of documentation of pharmaceutical enterprise to confirm the conformity of a batch of medicinal product to the requirements of the registration dossier and the relevant rules of production	PC-10.1 Performs control of personnel's compliance with the internal documents of the pharmaceutical quality system
	PC-10.2. Applies knowledge in fields of physics, chemistry, biochemistry, physiology, pharmacology, microbiology, toxicology, pharmaceutical technology, pharmacognosy to solve practical tasks in assessment of compliance of products with the requirements
	PC-10.3. Makes decision on putting the products into circulation
	PC-10.4. Uses interdisciplinary approach in the analysis of the causes of deviations and nonconformities, analysis of risks for quality of finished products, validation of processes and procedures

Curriculum of Master's Degree Program "Qualified Person"

Mandatory part (name, workload, final discipline assessment)

1. Information Technology in Professional Activity – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
2. Processes in Pharmaceutical Manufacturing – 3 credits (108 hours), in-class work – 16 hours, examination
3. Biological Chemistry – 2 credits (72 hours), in-class work – 16 hours, pass-fail test
4. Project Management – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
5. Economics and Innovation – 3 credits (108 hours), in-class work – 16 hours, examination, course work
6. Pharmaceutical Technology and Production of Dosage Forms – 3 credits (108 hours), in-class work – 18 hours, examination
7. Pharmaceutical Chemistry and Analysis of Medicinal Products – 3 credits (108 hours), in-class work – 18 hours, examination
8. Pharmacognosy – 3 credits (108 hours), in-class work – 19 hours, pass-fail test

The part formed by participants of educational relations (name, workload, final discipline assessment)

9. Philosophical Problems of Science and Technology – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
10. General and Inorganic Chemistry – 3 credits (108 hours), in-class work – 16 hours, pass-fail test
11. Foreign Language – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
12. Science Team Management – -3 credits (108 hours), in-class work – 18 hours, pass-fail test
13. Pharmacology – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
14. Toxicology – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
15. State Control in the Field of Circulation of Medicinal Products – 3 credits (108 hours), in-class work – 18 hours, examination
16. Quality Assurance System at Pharmaceutical Enterprise – 3 credits (108 hours), in-class work – 18 hours, examination

Elective disciplines (name, workload, final discipline assessment)

17. Applied (Medical and Biological) Physics – 2 credits (72 hours), in-class work – 12 hours, pass-fail test
18. Physics – 2 credits (72 hours), in-class work – 12 hours, pass-fail test
19. Physiology with Basics of Anatomy – 2 credits (72 hours), in-class work – 14 hours, pass-fail test
20. Pathology – 2 credits (72 hours), in-class work – 14 hours, pass-fail test
21. Microbiology – 3 credits (108 hours), in-class work – 14 hours, pass-fail test
22. Industrial Aseptics – 3 credits (108 hours), in-class work – 14 hours, pass-fail test
23. Organic Chemistry – 3 credits (108 hours), in-class work – 14 hours, pass-fail test
24. Chemistry of Biologically Active Substances – 3 credits (108 hours), in-class work – 14 hours, pass-fail test
25. Analytical Chemistry – 3 credits (108 hours), in-class work – 14 hours, pass-fail test
26. Current Methods in Analytical Chemistry – 3 credits (108 hours), in-class work – 14 hours, pass-fail test

Optional subjects (name, workload, final discipline assessment)

27. Statistical Methods at Pharmaceutical Enterprise – 3 credits (108 hours), in-class work – 6 hours, pass-fail test
28. Production of Sterile Medicinal Products – 3 credits (108 hours), in-class work – 6 hours, pass-fail test

Practices (name, workload, final assessment)

29. Academic Practical Training: Scientific Research Work (Obtaining Primary Skills in Scientific Research) – 3 credits (108 hours), in-class work – 4 hours, pass-fail test
30. Manufacturing Practice – 31 credits (1116 hours), in-class work – 45 hours, pass-fail test
31. Practice in Quality Assurance – 9 credits (324 hours), in-class work – 12 hours, graded test
32. Practice in Arrangement of In-house Training of Personnel According to GMP – 5 credits (180 hours), in-class work – 8 hours, graded test

State Final Certification

33. Execution and Preparation for Presentation of Graduate Qualification Work – 6 credits (216 hours), in-class work – 30 hours, graded test
34. Presentation of Graduate Qualification Work – 6 credits (216 hours), in-class work 2 hours, GQW presentation.

Resources Provision of the Degree Program

Master's degree program "Qualified Person" 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 master's degree program "Qualified Person" is ensured by the senior academic staff of the organization, as well as by persons engaged in the implementation of the master's degree program under the terms of the civil contract in accordance with the requirements of the Federal State Educational Standard for this field of education.

The percentage of the employed academic staff (reduced to integer rates) is at least 60 % of the total number of the University academic staff. The percentage of the academic staff (reduced to integer rates) having education and (or) a degree that correspond to the profile of the discipline (module) taught in the total number of the academic staff implementing the master's degree program is at least 80 %. 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 master's degree program is at least 70 %. 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 master's degree program (having at least 3 years of work experience in this professional field) in the total number of staff implementing the master's degree program is at least 10%.

General management of the science based content of the master's degree program is responsibility of an employed academic of the University having the Doctor of Sciences degree, carrying out independent scientific research projects (involved in implementation of such projects) in the field of education, having annual publications of the results of the scientific research activities in leading domestic and (or) foreign peer reviewed scientific journals and editions, as well as taking part in annual evaluation of the results of the scientific research activities at national (departmental, industrial) and international conferences.

The list of the academic staff engaged in the implementation of the master's degree program is included in the certificate of staffing of the educational process.

Uniqueness and Competitive Advantages of the Master's Degree Program "Qualified Person"

The degree program has a relevant focus on forming of professional competences required for carrying out the duties of qualified person of manufacturers of medicinal products in confirming compliance of medicinal products with the requirements established during their state registration and ensuring guarantees that the medicinal products are manufactured in accordance with the Good Manufacturing Practice (GMP).

The content of the program represents the needs of today's labor market of specialists of pharmaceutical enterprises planning certification as qualified person and not corresponding to Decision No. 73 of Council of the Eurasian Economic Commission and Order No. 7n of the Ministry of Health of the Russian Federation in respect of requirements for basic education and studying of appropriate disciplines.

In the course of the educational process, there is active interaction involving employers within the practices, that allows graduates to get involved in the work processes of organizations more quickly. The training is provided with minimum separation from work because studying is arranged with applying distance learning technology and electronic learning. As part of the practice, there is realization of opportunity to make individual assignment corresponding to production tasks at the workplace of the student. Within the execution of graduate qualification work there is a possibility to choose a subject of the graduate qualification work aimed at solving of graduate's real production tasks.