Abstract
of Master's Degree Program
in Field of Education 18.04.01 Chemical Technology,
Discipline (Specialization) "Industrial Manufacturing and Quality Assurance of Medicinal Products"
(Internal 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	120

Purpose (Mission) of the Degree Program

The mission of the master's degree program in "Industrial Manufacturing and Quality Assurance of Medicinal Products" is training of personnel who are able to solve tasks of professional activity in the field of organization of engineering processes at pharmaceutical production units and production and quality assurance of finished products, as well as validation (qualification) of engineering processes and equipment.

The degree program is aimed at training of the personnel who have competences in the field of medicines production, maintenance of the engineering process, quality assessment and quality control of manufactured products, validation of processes and qualification of production equipment.

Demand for Graduates

Graduates of the master's degree program in "Industrial Manufacturing and Quality Assurance of Medicinal Products" are in demand with scientific centers and enterprises engaged in the production of medicinal products; with organizations dealing with maintenance and design of chemical pharmaceutical manufacturing.

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 graduates who have completed the master's degree program includes: review and approval of production documentation of pharmaceutical manufacturing of finished dosage forms, herbal medicinal products, and pharmaceutical and cosmetic products and organization of its implementation, organization of production and storage of finished products in accordance with the approved documentation to achieve the required quality, monitoring of premises maintenance, operation and maintenance of equipment, arrangement of status monitoring of objects and processes that have passed validation, engineering process validation management, organization of investigation on detected deviations and nonconformities in production of medicinal products to the established requirements, quality risk analysis and quality risk management for manufactured products at all stages of production, conducting of comprehensive audit of the unit activities, organization of development and implementation of new process solutions, management of design and creation of new production areas and reconstruction of the existing ones, technical re-equipping of pharmaceutical production units, development and approval of measures on quality improvement of manufactured products and reduction of their prime cost, management of development of plans on efficiency improvement in pharmaceutical manufacturing, elimination of defects in the organization, organization of works on study and introduction of scientific and technical achievements, best domestic and foreign practices in production of medicinal products, planning and management of the set of works on analysis of engineering processes in pharmaceutical manufacturing and their improvement in accordance with the established requirements, task and work distribution among employees of the unit, performance monitoring and a number of other related fields.

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 master's degree program (hereinafter referred to as graduates) can be engaged in include:

02 Healthcare.

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

In accordance with the types of professional activity, the objects of professional activity of graduates in degree program in 18.04.01 Chemical Technology. Industrial Manufacturing and Quality Assurance of Medicinal Products are:

- chemical substances and materials;
- methods, ways and means of obtaining substances and materials using physical, physical and chemical, chemical processes, production of items of various purpose on their basis;
- equipment, engineering processes and industrial systems of process media preparation for industrial manufacturing;
- equipment, engineering processes and industrial systems of obtaining substances (including medicinal substances) and products (finished dosage forms, herbal medicinal products and pharmaceutical and cosmetic products);
- statistical methods of engineering process and finished product quality control;
- documentation of pharmaceutical enterprises in the field of production, quality assurance of medicinal products and validation of production processes;
- pharmaceutical quality system of medicinal products.

Types of Professional Activity

Types of professional activity which graduates of the master's degree program are prepared for:

- engineering;
- scientific research.

Tasks of Professional Activity

The graduate who has completed the master's degree program according to the types of tasks of professional activities which the master's degree program is aimed at, is ready to solve the following job tasks:

- arrangement of the production of medicinal products;
- organization of a pharmaceutical quality system of production of medicinal products;
- organization of research works and experimentation.

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	02.011	Specialist in validation (qualification) of pharmaceutical manufacturing
2	02.014	Specialist in industrial pharmacy in the field of quality assurance of medicinal products
3	02.016	Specialist in industrial pharmacy in the field of production 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 types of tasks of professional activity, the graduate of the master's degree program "Industrial Manufacturing and Quality Assurance of Medicinal Products" 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
	UC-2.2. Determines and calculates the process and economic resources required for process implementation and production
	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 research 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	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

Code and name of competence	Code and name of indicator of competence achievement
interaction	UC-4.2. Draws up, translates and edits materials in 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 the 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-assessment	UC-6.1. Assesses and optimally uses their resources (personal, situational, temporary) for successful completion of the tasks.
	UC-6.2. Determines priorities for professional growth and ways to improve their own activities based on self-assessment by the selected criteria
	UC-6.3. Makes a flexible professional path using lifelong learning tools, given the accumulated experience of professional activities and dynamically changing requirements of the labor market
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 feasibility of scientific research works and the possibility of commercial use of new developments at domestic pharmaceutical enterprises
GPC-2. Able to use modern instruments and current techniques, organize experiments and tests, handle them and analyze the results	GPC-2.1. Organizes experiments and tests using relevant modern instruments and techniques
	GPC-2.2. Handles and analyzes the results of experiments and tests, including with the use of state-of-the-art software

Code and name of competence	Code and name of indicator of competence achievement
GPC-3. Able to develop production rates, process standards for the consumption of materials, blanks, fuel and electricity, control the parameters of the engineering process, select equipment and process tooling	GPC-3.1. Develops production rates, process standards for the consumption of materials, blanks, fuel and electricity
	GPC-3.2. Justifies the selection of type equipment 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, health and wellness and environmental friendliness	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
PC-1. Able to arrange and manage the production process of medicinal products	PC-1.1. Agrees upon and approves production documentation of pharmaceutical manufacturing and arranges its implementation
	PC-1.2. Arranges production and storage of finished products in accordance with the approved documentation to achieve the required quality
	PC-1.3. Carries out analysis of production activities, as well as organization of investigation on detected deviations and nonconformities in production of medicinal products to the established requirements; carries out quality risk analysis and quality risk management for manufactured products
PC-2. Able to organize and control the engineering process and equipment operation	PC-2.1. Plans validation (qualification) of pharmaceutical manufacturing
	PC-2.2. Organizes the development of controlling and registering documentation for validation (qualification) of pharmaceutical manufacturing
	PC-2.3. Organizes the relevant validation and controls compliance with the requirements and deadlines for validation and performs measures based on the results of validation
	PC-2.4. Organizes status monitoring of objects and processes that have passed validation and analyzes and assesses the significance of deviations from the established requirements
PC-4. Able to organize the functioning of the processes of pharmaceutical system of production quality of medicinal products	PC-4.1. Conducts audit of quality of pharmaceutical production unit and analyzes quality risks of medicinal products
	PC-4.2. Analyzes the causes of deviations and nonconformities, organizes investigation processes on deviations, nonconformities, quality reclamations in accordance with the established procedures and monitors corrective and preventive actions at the pharmaceutical production unit

Code and name of competence	Code and name of indicator of competence achievement
	PC-4.3. Analyzes and systematizes information in the field of pharmaceutical quality and pharmaceutical manufacturing, also analyzes the reports (reviews) on the quality of medicinal products
PC-5. Able to organize research works and experimentation to improve efficiency of the pharmaceutical production unit, including through the introduction of scientific and technical achievements, best domestic and foreign practices	PC-5.1. Able to organize research works and experimentation on the development and optimization of engineering processes, quality improvement of products and reducing their prime cost, improvement of pharmaceutical manufacturing efficiency
	PC-5.2. Able to organize works on study and implementation of scientific and technical achievements, advanced domestic and foreign experience in production of medicinal products

Curriculum of the Master's Degree Program in "Industrial Manufacturing and Quality Assurance of Medicinal Products"

Mandatory part (name, workload, final discipline assessment)

1. Information Technology in Professional Activity – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
2. Processes of Pharmaceutical Production Units – 3 credits (108 hours), in-class work – 38 hours, examination
3. Statistical Methods and Experiment Planning – 3 credits (108 hours), in-class work – 40 hours, graded test
4. Safety of Engineering Processes in Pharmaceutical Manufacturing – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
5. Organization of Production of Medicinal Products – 3 credits (108 hours), in-class work – 40 hours, graded test
6. Economics and Innovation – 3 credits (108 hours), in-class work – 36 hours, examination, course work
7. Quality Management and Confirmation of Conformity of Products – 3 credits (108 hours), in-class work – 40 hours, graded test

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

8. Philosophical Problems of Science and Technology – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
9. Project Management – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
10. Foreign Language – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
11. Science Team Management – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
12. Production of Parenteral Medicinal Products – 3 credits (108 hours), in-class work – 40 hours, graded test
13. Quality Risk Management in Production of Medicinal Products – 3 credits (108 hours), in-class work – 40 hours, pass-fail test

14. Formulation of Phytosubstances in Production of Medicinal Products – 3 credits (108 hours), in-class work – 40 hours, graded test
15. Formulation of Pharmaceutical and Cosmetic Products – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
16. Qualification of Process Equipment and Validation of Engineering Processes – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
17. Formulation of Innovative Medicinal Products – 3 credits (108 hours), in-class work – 38 hours, examination
18. Validation of Purification – 3 credits (108 hours), in-class work – 22 hours, pass-fail test

Elective disciplines (name, workload, final discipline assessment)

19. Technology of Cultivation of Plant Cells – 3 credits (108 hours), in-class work – 32 hours, pass-fail test
20. Chemistry and Formulation of Biologically Active Substances of Natural Origin – 3 credits (108 hours), in-class work – 32 hours, pass-fail test
21. Foreign Language for Business Contacts – 3 credits (108 hours), in-class work – 32 hours, pass-fail test
22. Foreign Language for Scientific Work – 3 credits (108 hours), in-class work – 32 hours, pass-fail test
23. Physical and Chemical Methods of Analysis in Production of Medicinal Products – 3 credits (108 hours), in-class work – 32 hours, pass-fail test
24. Colloid Chemistry of Surface-Active Substances and High-Molecular Compounds – 3 credits (108 hours), in-class work – 32 hours, pass-fail test

Optional subjects (name, workload, final discipline assessment)

25. Analysis of Scientific and Production Data with the Use of Microsoft Excel – 2 credits (72 hours), in-class work – 20 hours, pass-fail test
26. Bioethics – 2 credits (72 hours), in-class work – 20 hours, pass-fail test

Practices (name, workload, final assessment)

27. Academic Practical Training: Scientific Research Work (Obtaining Primary Skills in Scientific Research) – 3 credits (108 hours), in-class work – 12 hours, pass-fail test
28. SRW 1 (Scientific Research Work) – 21 credits (756 hours), in-class work – 30 hours, pass-fail test
29. Production (Process Engineering) Practice – 6 credits (216 hours), in-class work – 24 hours, graded test
30. SRW 2 (Scientific Research Work) – 15 credits (540 hours), in-class work – 15 hours, pass-fail test

State final certification

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

Resources Provision of the Degree Program

The master's degree program in "Industrial Manufacturing and Quality Assurance of Medicinal Products" 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 "Industrial Manufacturing and Quality Assurance of Medicinal Products" 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 in "Industrial Manufacturing and Quality Assurance of Medicinal Products"

Significant changes have occurred in the pharmaceutical market of the Russian Federation in the last decade. There has been an increase in the number of pharmaceutical industry enterprises. Requirements for the quality and safety of medicinal products have been tightened. It is impossible to imagine the functioning of a pharmaceutical enterprise without introduction of quality management systems, including organization, production and quality assurance of manufactured products in accordance with the requirements of GxP, ISO, ICH.

The master's degree program in "Industrial Manufacturing and Quality Assurance of Medicinal Products" is aimed at training of the personnel who are able to introduce innovative approaches into production of medicines, to organize and maintain the engineering process of production of medicinal products, to take responsibility for the quality of manufactured products, to carry out validation of processes and qualification of equipment, to perform designing of pharmaceutical enterprises etc., which is relevant and modern in the conditions of dynamic development of pharmaceutical industry.

The area of the professional activity of graduates who have completed the master's degree program includes: review and approval of production documentation of a pharmaceutical production unit and organization of its implementation, organization of production and storage of finished products in accordance with the approved documentation to achieve the required quality, monitoring of premises maintenance, operation and maintenance of equipment, organization of investigation on detected deviations and nonconformities in production of medicinal products to the established requirements, quality risk analysis and quality risk management for manufactured products, performance of the transfer procedure at pharmaceutical enterprise, organization of development and implementation of new process solutions, development and approval of measures on quality assurance of manufactured products, planning and management of the set of works on analysis of engineering processes in pharmaceutical manufacturing and their improvement in accordance with the established requirements.

Types of professional activity which graduates of the master's degree program are prepared for:

- engineering and manufacturing;

- scientific research.
  Graduates of the degree program “Industrial Manufacturing and Quality Assurance of Medicinal Products” are in demand with scientific centers and enterprises engaged in the production of medicinal products; with organizations dealing with maintenance and design of chemical pharmaceutical manufacturing.