Abstract
of Master's Degree Program
in Field of Education 18.04.01 Chemical Technology,
Discipline (Specialization) "Processes and Equipment in Pharmaceutical Manufacturing"
(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 program in "Processes and Equipment in Pharmaceutical Manufacturing" is training of personnel who are able to solve tasks of professional activity in the field of organization of engineering processes in pharmaceutical manufacturing and production of finished products, as well as validation (qualification) of engineering processes and equipment.

The main degree program is aimed at training of the personnel who have competences in the field of medicine 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 "Processes and Equipment in Pharmaceutical Manufacturing" are in demand with scientific centers and enterprises engaged in synthesis of chemical substances, medicinal substances, production of finished dosage forms; 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 and organization of its implementation, organization of production and storage of finished products in accordance with approved documentation to achieve required quality, maintenance of operation, premises and equipment, arrangement of status monitoring of objects and processes that have passed validation, validation management of engineering processes, organization of investigation on detected deviations and nonconformities of production of medicinal products to the established requirements, risk analysis and risk management for quality assurance of manufactured products, conducting of comprehensive analysis of the unit activities, organization of the relevant validation, review and approval of documentation related to production of medicinal products and organization of its implementation, organization of development and implementation of new process engineering solutions, management of design and creation of new reconstructions of the existing production areas, technical re-equipping of pharmaceutical manufacturing, development and approval of measures on quality improvement of manufactured products and reduction of their costs, 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, advanced domestic and foreign experience 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 established requirements, task and work distribution among employees of the unit,

performance control and other adjacent 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 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 activities, the objects of professional activities of graduates of the master's degree program "Processes and Equipment in Pharmaceutical Manufacturing", are:

- chemical substances and materials;
- methods, ways and means of obtaining substances and materials using physical, physical and chemical, chemical processes, production of devices of different 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);
- statistical methods of engineering process control and finished product quality;
- documentation of pharmaceutical enterprises in the field of production and validation of engineering processes.

Types of Professional Activity

Types of professional activities 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 medicinal product production process;
- 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	02.016	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 type of tasks of professional activities, the graduate of the master's degree program "Processes and Equipment in Pharmaceutical Manufacturing" 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 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

Code and name of competence	Code and name of indicator of competence achievement
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
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	GPC-3.1. Develops production standards, engineering standards for the consumption of materials, blanks, fuel and electricity

Code and name of competence	Code and name of indicator of competence achievement
standards for the consumption of materials, blanks, fuel and electricity, control the parameters of the engineering process, select equipment and engineering tooling	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
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 approved documentation to achieve required quality
	PC-1.3. Carries out analysis of production activities, as well as organization of investigation on detected deviations and nonconformities of production of medicinal products to the established requirements; carries out risk analysis and risk management for quality assurance of 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 registration 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-5. Able to organize research works and experimentation to improve efficiency of pharmaceutical manufacturing,	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 cost, efficiency improvement of pharmaceutical manufacturing

Code and name of competence	Code and name of indicator of competence achievement
including through the introduction of scientific and technical achievements, advanced domestic and foreign experience	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 Master's Degree Program "Processes and Equipment in Pharmaceutical Manufacturing"

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 in Pharmaceutical Manufacturing – 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. Economics and Innovation – 3 credits (108 hours), in-class work – 36 hours, examination, course work
6. Processes and Equipment in the Production of Finished Products and Pharmaceutical Substances – 6 credits (216 hours), in-class work – 76 hours, examination, graded test, course project

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

7. Philosophical Problems of Science and Technology – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
8. Project Management – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
9. Proper Maintenance of Equipment – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
10. Design of Process Flow Diagrams in Pharmaceutical Manufacturing – 3 credits (108 hours), in-class work – 38 hours, pass-fail test, course project
11. Computer Modeling of Process Systems – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
12. Foreign Language – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
13. Science Team Management – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
14. Mass Exchange Processes – 3 credits (108 hours), in-class work – 40 hours, graded test, course project
15. Basics of Pharmaceutical Manufacturing Design – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
16. Validation of Purification – 3 credits (108 hours), in-class work – 40 hours, pass-fail test
17. Qualification of Process Equipment and Validation of Engineering Processes – 3 credits (108 hours), in-class work – 40 hours, pass-fail test

Elective disciplines (name, workload, final discipline assessment)

18. Foreign Language for Business Contacts – 3 credits (108 hours), in-class work – 32 hours, pass-fail test

19. Foreign Language for Scientific Work – 3 credits (108 hours), in-class work – 32 hours, pass-fail test
20. Process Media– 3 credits (108 hours), in-class work – 32 hours, graded test
21. Engineering Thermodynamics – 3 credits (108 hours), in-class work – 32 hours, graded test
22. Statistical Analysis of Production Data– 3 credits (108 hours), in-class work – 32 hours, pass-fail test
23. Statistical Methods in Quality Management – 3 credits (108 hours), in-class work – 32 hours, pass-fail test

Optional subjects (name, workload, final discipline assessment)

24. Bioethics – 2 credits (72 hours), in-class work – 20 hours, pass-fail test
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

Practices (name, workload, final assessment)

26. Academic practical training: scientific research work (obtaining primary skills in scientific research) – 3 credits (108 hours), in-class work – 12 hours, pass-fail test
27. SRW 1 (Scientific Research Work) – 21 credits (756 hours), in-class work – 30 hours, pass-fail test
28. Production (process engineering) practice – 6 credits (216 hours), in-class work – 24 hours, graded test
29. SRW 2 (Scientific Research Work) – 15 credits (540 hours), in-class work – 15 hours, pass-fail test

State final certification

30. Execution and preparation for presentation of graduate qualification work – 6 credits (216 hours), in-class work – 30 hours, graded test
31. 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 "Processes and Equipment in Pharmaceutical Manufacturing" 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 "Processes and Equipment in Pharmaceutical Manufacturing" 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 "Processes and Equipment in Pharmaceutical Manufacturing"

The degree program "Processes and Equipment in Pharmaceutical Manufacturing" is relevant and aimed at training of the engineers for pharmaceutical manufacturing units who are able to solve tasks facing employees of enterprises producing medicinal products and pharmaceutical substances, food production facilities and chemical industry enterprises.

The graduates who have completed the program are ready 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, which is relevant and modern in the conditions of dynamic development of pharmaceutical industry. Study of course materials by masters allows the student to acquire knowledge in the field of physical and chemical essence and theory of medicinal product and substance production processes, peculiarities of their conduct in type and non-standard apparatus of chemical technology, methods of calculations and selection of modern equipment intended for conducting these processes.

It should be noted that the program contains a range of professional disciplines that have no analogues in the curricular program of other institutions of higher education: validation of purification, qualification of process equipment and validation of engineering processes, statistical analysis of production data, etc. Profession-oriented disciplines of the degree program give the opportunity for graduates to implement engineering, manufacturing and organizational measures at enterprises specialized in the production of medicinal products and pharmaceutical substances.

Employers are actively involved in the implementation of the program. Engagement of the employer in organization of the educational process is characterized by the availability of large number of cooperation contracts in the field of organizing students' practice. In order to acquire important skills, the students undertake training as part of practice at leading enterprises of the industry – JSC Werteks, Scientific and Technological Company "Polysan", LLC "Novartis Neva", JSC "PharmProject", LLC "Pharma Gene", etc.

Scientific works are executed in collaboration with employers in the course of implementing scientific research activities and executing graduate qualification works. The students, within the collaborative work, develop methodologies for control and assessment of engineering process and product quality, improve formulations and technologies of medicinal products, develop and simulate operations of new designs of industrial equipment.

The involvement of employers' representatives to participate in the state final certification is provided.