

**Abstract  
of Master's Degree Program  
in Field of Education 18.04.01 Chemical Technology,  
Discipline (Specialization) "Organization and Management of Pharmaceutical Manufacturing"  
(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 "Organization and Management of Pharmaceutical Manufacturing" is training of high-skilled personnel who are able to solve job tasks of scientific research, organizational and managerial activities at enterprises of the pharmaceutical industry including fields of research and developments, registration of medicinal products, pharmaceutical manufacturing, quality assurance and quality control, human resources management, marketing activities, strategic planning and innovation development.

The basic professional degree program is aimed at forming graduates' critical understanding and ability for comprehensive assessment of external and internal environment of pharmaceutical manufacturing companies in order to reach managerial decisions providing strategic competitive advantages and successful long-term growth; readiness to analyze main and supporting business processes of pharmaceutical manufacturing companies in order to make managerial decisions providing their effective implementation; comprehensive understanding and ability to use various management styles and techniques, leadership qualities promoting achievement of business goals, individual and collective goals of corporate employees; abilities to make reasoned decisions using different means of communication, apply analysis, reflection, self-assessment for the purpose of maximum use of their own opportunities for self-development and development of business.

***Demand for Graduates***

Graduates of the master's degree program "Organization and Management of Pharmaceutical Manufacturing" are in demand with pharmaceutical manufacturing companies, scientific research organizations dealing with the development of medicinal products, specialized companies providing services and performing works against the order of pharmaceutical manufacturers.

***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 the field of pharmaceutical manufacturing and circulation of medicinal products the regulation of which is carried out in accordance with applicable statutory and regulatory requirements, industrial standards, principles of social responsibility of pharmaceutical business, strict ethical standards in the pharmaceutical industry.

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.

40 Cross-cutting types of professional activity in 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***

In accordance with the types of professional activities, the objects of professional activities of graduates of the master's degree program "Organization and Management of Pharmaceutical Manufacturing", are:

- pharmaceutical manufacturing company as a set of facilities and technologies, material and financial resources, product portfolio, innovation and scientific and technical potential, organizational structure and management system, human resources, etc.;
- main and supporting business processes of pharmaceutical manufacturing companies;
- forms and methods of organization and management of various types of main and supporting activities of pharmaceutical enterprises;
- methods and techniques for design, evaluation and scientific research in the field of medicinal products development;
- regulatory legal acts and industrial standards in the field of pharmaceutical manufacturing and circulation of medicinal products;
- accounts and records, planning, technical documents of pharmaceutical enterprises;
- input and output information flows;
- mathematical, information, technical and process, economical and organizational support of main and auxiliary business processes;
- production and research teams of pharmaceutical companies;
- methods and techniques for design and implementation of systems for organization and remuneration of employees' labor.

### ***Types of Professional Activity***

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

- scientific research;
- organizational and managerial.

### ***Tasks of Professional Activity***

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

- organization of research works and experimentation
- arrangement of work of the personnel who are engaged in the production of medicinal products
- search for organizational and managerial decisions regarding development, production and sales of produced products

### ***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		

Item No.	Code of professional standard	Name of professional standard.
1	02.016	Specialist in industrial pharmacy in the field of production of medicinal products
40 Cross-cutting types of professional activity in industry		
2	40.033	Specialist for strategic and tactical planning of the production organization

***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 tasks of the professional activity, the graduate of the master's program in "Organization and Management of 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

Code and name of competence	Code and name of indicator of competence achievement
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
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	GPC-2.1. Organizes experiments and tests using state-of-the-art instruments and techniques for experiments and tests

Code and name of competence	Code and name of indicator of competence achievement
results	
	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
PC-5. Able to organize research works and experimentation to improve efficiency of pharmaceutical manufacturing, including through the introduction of scientific and technical achievements, advanced domestic and foreign experience	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, improvement of pharmaceutical manufacturing efficiency
	PC-5.2. Organizes works on study and implementation of scientific and technical achievements, advanced domestic and foreign experience in production of medicinal products
PC-7. Able to arrange work of the personnel who are engaged in the production of medicinal products	PC-7.1. Assesses the professional qualification level and effectiveness of activities of the production unit personnel, draws up competence development programs, determines forms and methods of training
	PC-7.2. Distributes tasks and works among employees of production units, controls their performance
	PC-7.3. Assesses the demand of the production unit for personnel, conducts search, recruitment and adaptation of new employees

Code and name of competence	Code and name of indicator of competence achievement
	PC-7.4. Develops effective incentive system of labor for personnel of the production unit and selects optimal forms of labor stimulation
	PC-7.5. Applies modern methods for preventing and resolving conflicts when designing interpersonal, group and organizational communications
PC-8 Able to make reasoned organizational and managerial decisions regarding development, production and sales of produced products	PC-8.1. Arranges work and effective interaction of all structural units of the industrial organization in order to develop and improve production taking into account social and market priorities, increase operational efficiency of the organization, increase sales volume of products and profits, improve quality and competitive ability of produced products
	PC-8.2. Suggests measures aimed at rhythmical organization of production and continuous output of products in accordance with the production programs and schedules
	PC-8.3. Applies methods of strategic analysis for development and implementation of organizational and managerial decisions aimed to improve efficiency and competitive ability of production
	PC-8.4. Conducts a comprehensive study on sector wide market of industrial products, consumers of goods, suppliers of raw materials, other materials and components, competitive manufacturers of substitute products, assesses the level of competitive struggle
	PC-8.5. Organizes production and commercial activities based on wide use of progressive forms of management and organization of labor in order to increase production efficiency, rational use of production reserves and conservation of all types of resources
	PC-8.6. Applies knowledge of advanced domestic and foreign experience in strategic and tactical planning and organization of production when developing and making organizational and managerial decisions

***Curriculum of Master's Degree Program "Organization and Management of Pharmaceutical Manufacturing"***

***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 of Pharmaceutical Production Units – 3 credits (108 hours), in-class work – 16 hours, examination

3. Organization of Production of Medicinal Products – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
4. Safety of Engineering Processes in Pharmaceutical Manufacturing – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
5. General and Strategic Management – 3 credits (108 hours), in-class work – 18 hours, graded test, test
6. Economics and Innovation – 3 credits (108 hours), in-class work – 16 hours, examination, course work
7. Quality Management in Production of Medicinal Products – 3 credits (108 hours), in-class work – 18 hours, pass-fail 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 – 18 hours, pass-fail test
9. Business Planning in the Field of Pharmaceutical Manufacturing – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
10. Project Management – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
11. Financial and Investment Management – 3 credits (108 hours), in-class work – 18 hours, graded test
12. Foreign Language – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
13. Legal Basis of Organizational Activities – 3 credits (108 hours), in-class work – 18 hours, graded test
14. Strategic Marketing in the Pharmaceutical Market – 3 credits (108 hours), in-class work – 20 hours, examination
15. Production Management – 3 credits (108 hours), in-class work – 16 hours, examination
16. Incentive Management and Stimulation of Personnel – 3 credits (108 hours), in-class work – 18 hours, pass-fail test, course work
17. Analytical Studies and Pricing in the Pharmaceutical Market – 3 credits (108 hours), in-class work – 18 hours, pass-fail test, course work

*Elective disciplines (name, workload, final discipline assessment)*

18. Foreign Language for Business Contacts – 3 credits (108 hours), 14 hours, pass-fail test
19. Foreign Language for Scientific Work – 3 credits (108 hours), 14 hours, pass-fail test
20. State Control in the Field of Circulation of Medicinal Products – 3 credits (108 hours), 14 hours, pass-fail test
21. Basics of Registration of Medicinal Products – 3 credits (108 hours), 14 hours, pass-fail test
22. Statutory Regulation of GxP Standards Assurance – 3 credits (108 hours), 14 hours, pass-fail test
23. Economic Security of Pharmaceutical Enterprises – 3 credits (108 hours), 14 hours, pass-fail test
24. Risk Management – 3 credits (108 hours), 14 hours, pass-fail test
25. Money, Credit, Banking – 3 credits (108 hours), 14 hours, pass-fail test

*Optional subjects (name, workload, final discipline assessment)*

26. Bioethics – 2 credits (72 hours), 14 hours, pass-fail test
27. Team Conflict Resolution – 2 credits (72 hours), 14 hours, pass-fail test

*Practices (name, workload, final assessment)*

28. Academic practical training: scientific research work (obtaining primary skills in scientific research) – 3 credits (108 hours), 4 hours, pass-fail test
29. SRW 1 (Scientific Research Work) – 31 credits (1,116 hours), 45 hours, pass-fail test
30. Production (process engineering) practice – 6 credits (216 hours), in-class work – 24 hours, graded test
31. SRW 2 (Scientific Research Work) – 5 credits (180 hours), 15 hours, pass-fail test

### State final certification

32. Execution and preparation for presentation of graduate qualification work – 6 credits (216 hours), 30 hours, graded test
33. 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 "Organization and Management of 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 "Organization and Management of 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 "Organization and Management of Pharmaceutical Manufacturing"***

This master's degree program is relevant in today's pharmaceutical labor market and is aimed at forming of students' competences required for solving the wide range of job and managerial tasks in the field of pharmaceutical manufacturing, development and registration of medicinal products, control and quality assurance, personnel management, marketing activities, strategic planning, innovation development of enterprises of the pharmaceutical industry.

The special feature of the master's degree program is that it forms graduates' systematic understanding of the specifics of the field of circulation of medicinal products and pharmaceutical manufacturing, content of main phases of the life cycle of medicinal products, principles of arrangement and management of activities of pharmaceutical manufacturing companies, characteristic features of innovation activities and economics of pharmaceutical manufacturers.

The program is based on the professional standards of the specialist in industrial pharmacy in the field of production of medicinal products, in respect of managerial functions performance and the professional standards of the specialist for strategic and tactical planning of the production organization.

The program is implemented in cooperation with industrial employers engaged in the educational process (Scientific and Technological Company "POLYSAN" LTD, CJSC "BIOCAD", JSC Werteks, JSC "PharmProject", LLC "Groteks", LLC "GEROPHARM", LLC "Plant Medsintez").

The training in the program is provided with minimum separation from work because studying is arranged with applying distance learning technology and electronic learning.

Wide range of the program allows graduates participating in many main, supporting and managerial business processes in pharmaceutical companies, provides significant opportunities to choose the field of activity, ensures reliable start for building successful career in the pharmaceutical industry. Using the acquired knowledge and skills after having completed the master's degree program, the graduates can count on career advancement which will let them work in the leading domestic and foreign pharmaceutical companies in production departments, marketing departments, planning departments, HR management departments occupying positions of top and middle managers in future. Graduates can also continue with developing their professional careers in educational institutions of secondary and higher education carrying out scientific research activities.