Abstract
of Master's Degree Program
in Field of Education 19.04.01 Biotechnology,
Discipline (Specialization) "Organization and Management of Biotechnological Production"
(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 Biotechnological Production" is training of high-skilled personnel who are able to solve job tasks of scientific research, organizational and managerial activities at enterprises of the biotechnological pharmaceutical industry including fields of research and developments, registration of medicinal products, biotechnological production, 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 biopharmaceutical 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 biopharmaceutical 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 in "Organization and Management of Biotechnological Production" are in demand with biopharmaceutical manufacturing companies, representatives of other areas of biotechnological production, scientific research organizations engaged in development of medicinal products and other biotechnological products, specialized companies providing services and performing works against the order of pharmaceutical manufacturing companies.

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 biopharmaceutical 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 pharmaceutic 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.

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 in "Organization and Management of Biotechnological Production", are:

– biopharmaceutical manufacturing company as a set of facilities and technologies, material and financial recourses, product portfolio, innovation and scientific and technical potential, organizational structure and management system, human resources, etc.;

– main and supporting business processes of biopharmaceutical manufacturing companies;

– forms and methods of organization and management of various types of main and supporting activities of biotechnological pharmaceutical enterprises;

– methods and techniques for design, evaluation and scientific research in the field of biotechnological products development;

– regulatory legal acts and industrial standards in the field of pharmaceutical manufacturing and circulation of medicinal products;

– accounts and records, 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 biopharmaceutical companies;

– methods and techniques for design and implementation of systems for organization and renumeration of employees' labor;

– organization and management of innovation activities at enterprise;

– social aspects of production and labor organization at enterprise.

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:

Scientific Research Activity:

– selection, processing and analysis of scientific and technical, and patent information according to the area of research using specialized databases and IT solutions;

– development of research programs, assessment and analysis of obtained results;

– preparation of scientific and technical reporting documentation, analytical reviews and reports, documentation for participation in competitions of scientific projects, projects of pharmacopoeial monographs (state standards), publication of scientific results, protection of intellectual property.

– development of new engineering, organizational and marketing decisions based on the results of scientific researches in accordance with the corporate development plan;

– coordination of operations on maintenance of work results implementation in the field of main and supporting business processes in biopharmaceutical manufacturing companies;

– analysis, synthesis and optimization of processes of tests quality assurance, certification of products with the use of problem-oriented methods.

Organizational and Managerial Activities:

– arrangement of team's work in conditions of existing production, planning of personnel's work and payroll budgets;

– conduct of technical and economic analysis of production and drawing up of technical and economic documentation;

– development and implementation of quality management system of biotechnological products:

– development of the system of local regulatory acts of enterprise in accordance with the requirements of international standards;

– arrangement of works related to innovation in the field of biotechnology;

– arrangement of compliance with the health and safety regulations in production and environment protection;

– assurance of professional confidentiality;

– search of optimal solutions in the field of main and supporting business processes of biopharmaceutical manufacturing companies taking into account the requirements of quality assurance, economic efficiency and risk management;

– marketing and preparation of business plans for producing and sale of promising and competitive 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		
1	02.010	Specialist in industrial pharmacy in the field of research of medicinal products
2	02.013	Specialist in industrial pharmacy in the field of quality control of medicinal products
3	02.014	Specialist in industrial pharmacy in the field of quality assurance of medicinal products
4	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 tasks of the professional activity, the graduate of the master's program in "Organization and Management of Biotechnological Production" shall have the following competences characterized by the indicators of their achievement:

Codes	Competences, indicators of competence achievement
GCC-1	**Ability to think abstractly, analyze, synthesize**
GCC-1.1	analyzes the available information and synthesizes their own judgments regarding professional activity
GCC-1.2	analyzes the results of works performed, synthesizes conclusions and new ideas on their basis
GCC-2	**Readiness to take actions in abnormal situations, to bear social and ethical responsibility for the decisions made**
GCC-2.1	takes social responsibility for the decisions made
GCC-2.2	takes ethical responsibility for the decisions made
GCC-3	**Ability to enhance and develop their intellectual and general cultural level, to acquire knowledge in the field of modern problems of science, engineering and technology, human, social and economic sciences**

Codes	Competences, indicators of competence achievement
GCC-3.1	develops their intellectual and general cultural level, performs a search, critically analyzes and synthesizes information
GCC-3.2	finds solutions to the worldview and methodological problems in public field and professional activity
GCC-3.3	generates new ideas when solving research and practical problems
GCC-4	**Ability for professional growth, individual study of new research methods, change of scientific and scientific production profile of their professional activity**
GCC-4.1	works out individual techniques for practical solving of training and job tasks, including with the use of creative potential
GCC-4.2	outlines the path of their professional growth and personal development
GCC-5	**Ability to use skills in the organization of research and project works, in team management on a practical level**
GCC-5.1	able to be involved in interpersonal collaboration with due regard to the knowledge of their rights and obligations, as well as regulatory legal acts regulating the relations between individuals in the practical implementation of research and project works
GCC-5.2	applies skills for effective performance of works
GCC-6	**Readiness to use legal and ethical standards in the assessment of consequences of their professional activity, in the development and implementation of socially important projects**
GCC-6.1	considers ethical requirements in the course of scientific research practice, development and implementation of socially important projects
GCC-6.2	applies normative legal documents in their professional activity
GPC-1	**Ability to skillfully operate modern biotechnological equipment and scientific instruments**
GPC-1.1	takes into account the requirements for biotechnological process safety when selecting biotechnological equipment and scientific instruments
GPC-1.2	operates modern biotechnological equipment used in production and laboratories.
GPC-2	**Readiness to communicate in oral and written form using the official language of the Russian Federation and a foreign language to solve job tasks**
GPC-2.1	presents the results of their activities in a foreign language
GPC-2.2	produces and edits scientific, business and professional texts in a foreign language
GPC-3	**Readiness to manage the team in the field of their professional activity, perceive social, ethnic, religious and cultural differences in a non-judgmental manner**
GPC-3.1	plans and organizes the work of the team taking into account the peculiarities of behavior, interests and opinions of its members, appropriately distributes authority and responsibility based on the basic principles of delegation
GPC-3.2	manages the team considering peculiarities of behavior and interests of individual employees
GPC-4	**Readiness to use methods of mathematical modeling of materials and engineering processes, readiness for theoretic analysis and experimental test of theoretical hypothesis**
GPC-4.1	uses mathematical methods for analysis and modeling of processes and materials
GPC-4.2	performs theoretical analysis and experimental check of theoretical hypothesis

Codes	Competences, indicators of competence achievement
GPC-5	**Ability to use state-of-the-art IT solutions for collection, processing and distribution of scientific information in the field of biotechnology and linked industries, ability to use databases, software programs and resources of information and telecommunications network "Internet" (hereinafter referred to as network "Internet") to solve job tasks**
GPC-5.1	uses databases and resources of information and telecommunications network "Internet" in scientific activities
GPC-5.2	uses databases, software programs and resources of information and telecommunications network "Internet" to solve job tasks
GPC-6	**Readiness to protect intellectual property objects and commercialize intellectual property rights**
GPC-6.1	Assesses potential patentability of new developments and determines the possibility of their commercial use
GPC-6.2	determines the possibility of commercial use of new developments
PC-1	**Readiness to plan, organize and conduct scientific research works in the field of biotechnology, ability to correctly handle the results of experiments and make reasonable deductions and conclusions**
PC-1.1	searches scientific information and develops plans to conduct scientific researches within the selected scientific direction
PC-1.2	set goals of the experiment, draws up plans of the experiment with due regard to set goals, develops plans for performers
PC-1.3	takes into account the interests of all participants of the process when playing their role in a teamwork and social interaction
PC-2	**Ability to analyze scientific and technical information in the field of biotechnology and linked disciplines with the purpose of scientific, patent and marketing support of conducted fundamental researches and engineering developments**
PC-2.1	conducts a critical analysis and assessment of modern scientific achievements
PC-2.2	searches scientific and technical information in today's databases
PC-2.3	draws up reports and abstracts containing scientific, business and professional information required for organizing and conducting scientific researches in the field of biotechnology, in a foreign language
PC-3	**Ability to present the results of the work performed in the form of scientific and technical reports, reviews, scientific presentations and publications using state-of-the-art capabilities of IT solutions and taking into account the requirements of intellectual property protection**
PC-3.1	uses information and communication technologies when handling experimental results
PC-3.2	handles the results of experiments and tests, analyzes obtained results, presents the results in the form comprehensible for others
PC-3.3	executes analysis reports, draws conclusions
PC-7	**Readiness to arrange performers' work, make decisions for performing in conditions with a range of opinions, determine the procedure for performance of works**
PC-7.1	plans and arranges performers' work and determines procedure for performance of works
PC-7.2	makes decisions for performing in conditions with a range of opinions
PC-8	**Ability to conduct technical and economic analysis of production and draw up technical and economic documentation**

Codes	Competences, indicators of competence achievement
PC-8.1	conducts technical and economic analysis of production and assesses economic conditions and consequences of organizational and managerial decisions made
PC-8.2	assesses economic efficiency of investment projects of pharmaceutical manufacturing
PC-8.3	makes nonstandard organizational and managerial decisions to solve professional tasks related to organizational and managerial activities
PC-8.4	develops technical and economic documentation
PC-9	**Readiness to use basic principles of organization of production operations metrology support**
PC-9.1	uses knowledge of guidance and regulatory documents for production preparation, operating rules for the main systems and equipment of biotechnological production
PC-9.2	assesses the results of analysis of raw materials and starting materials for the compliance with the specification requirements
PC-10	**Ability to develop quality management systems of biotechnological products in accordance with the requirements of Russian and international quality standards**
PC-10.1	develops regulatory documentation of the enterprise's quality management system in accordance with the requirements of Russian and international standards
PC-10.2	assesses compliance of the quality management system of biotechnological products with the requirements of Russian and international standards
PC-11	**Ability to ensure process discipline, sanitary and hygiene mode of enterprise operation, maintenance of the process equipment in appropriate technical condition**
PC-11.1	ensures process discipline, sanitary and hygiene mode of operation, compliance with the health and safety regulations
PC-11.2	ensures carrying out of validation activities for equipment cleaning
PC-12	**Ability to plan and implement measures for ensuring the health and safety regulations in production, for monitoring and environment protection**
PC-12.1	ensures safety of production processes during the whole cycle of their functioning
PC-12.2	plans and implements measures for ensuring the health and safety regulations in biotechnological production

Curriculum of Master's Degree Program "Organization and Management of Biotechnological Production"

Mandatory part (name, workload, final discipline assessment)

1. Foreign Language – 3 credits (108 hours), in-class work – 22 hours, examination, test
2. Philosophical Problems of Science and Technology – 3 credits (108 hours), in-class work – 24 hours, examination, test
3. Management of Human Resources – 3 credits (108 hours), in-class work – 22 hours, pass-fail test, test
4. Information Technology in Professional Activity – 3 credits (108 hours), in-class work – 22 hours, pass-fail test, test
5. Economics and Innovation – 3 credits (108 hours), in-class work – 25 hours, examination, course work, test

6. Modern Problems of Biotechnology – 3 credits (108 hours), in-class work – 24 hours, examination, test

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

7. General and Strategic Management – 3 credits (108 hours), in-class work – 22 hours, graded test, course work, test
8. Business Planning in the Field of Pharmaceutical Manufacturing – 3 credits (108 hours), in-class work – 22 hours, pass-fail test, test
9. Industrial Biotechnology – 3 credits (108 hours), in-class work – 22 hours, pass-fail test, test
10. Financial and Investment Management – 3 credits (108 hours), in-class work – 26 hours, examination, test
11. Production Management – 3 credits (108 hours), in-class work – 22 hours, graded test, test
12. Quality Management in Production of Biotechnological Medicinal Products – 3 credits (108 hours), in-class work – 20 hours, graded test, test
13. Pharmaceutical Innovation Management – 3 credits (108 hours), in-class work – 24 hours, examination, test
14. Strategic Marketing in the Pharmaceutical Market – 3 credits (108 hours), in-class work – 25 hours, examination, course work, test
15. Safety of Engineering Processes in Pharmaceutical Manufacturing – 3 credits (108 hours), in-class work – 20 hours, pass-fail test, test

Elective disciplines (name, workload, final discipline assessment)

16. State Control in the Field of Circulation of Medicinal Products – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
17. Basics of Registration of Medicinal Products – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
18. Team Conflict Resolution – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
19. Labor Law – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
20. Economic Law – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
21. Commercial Law – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
22. Risk Management – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
23. Pricing in the Pharmaceutical Market – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
24. Economic Security of Pharmaceutical Enterprises – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
25. Money, Credit, Banking – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
26. Statutory Regulation of GxP Standards Assurance – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
27. Pharmacoeconomics of Innovative Medicinal Products – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test
28. Analytical Studies in the Pharmaceutical Market – 3 credits (108 hours), in-class work – 14 hours, pass-fail test, test

Optional subjects (name, workload, final discipline assessment)

29. Foreign Language for Business Contacts– 2 credits (72 hours), in-class work – 8 hours, pass-fail test, test
30. Bioethics – 2 credits (72 hours), in-class work – 8 hours, pass-fail test, test

31. Digital Literacy – 2 credits (72 hours), in-class work – 18 hours, pass-fail test
32. Digital Culture – 2 credits (72 hours), in-class work – 18 hours, pass-fail test
33. Cognitive Management Systems – 2 credits (72 hours), in-class work – 18 hours, pass-fail test

Practices (name, workload, final assessment)

34. Academic Practical Training, Practice in Obtaining Primary Professional Abilities and Skills – 6 credits (216 hours), in-class work – 10 hours, pass-fail test
35. SRW 1 (Scientific Research Work) – 30 credits (1080 hours), in-class work – 68 hours, pass-fail test
36. SRW 2 (Scientific Research Work) – 6 credits (216 hours), in-class work – 17 hours, pass-fail test
37. Practice in Obtaining Professional Abilities and Experience of Professional Activities (Including Production Practice) – 6 credits (216 hours), in-class work – 10 hours, graded test
38. Pre-graduation Practice – 6 credits (216 hours), in-class work – 10 hours, graded test

State final certification

39. Presentation of Graduate Qualification Work – 6 credits (216 hours), in-class work – 4 hours, GQW presentation.

Resources Provision of the Degree Program

Master's degree program "Organization and Management of Biotechnological Production" 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 data bases 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 mastering the degree program;
- the formation of electronic portfolio of the student, including the preservation of student's works and marks 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 Biotechnological Production" 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

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 participate 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.