Abstract
of Master's Degree Program
in Field of Education 19.04.01 Biotechnology,
Discipline (Specialization) "Environmental Risks at Enterprises of the Pharmaceutical Industry"
(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 degree program in "Environmental Risks at Enterprises of the Pharmaceutical Industry" is training of high-skilled personnel who are able to perform scientific research in the sphere of biological, biomedical and environmental technologies at high professional level as well as undertake scientific, organizational and managerial activities in the context of global trends based on the application of breakthrough achievements in the field of biology, ecology, for business and medical purposes, environmentally sound technologies, protection and efficient use of nature resources.

The degree program is aimed at the implementation of the following principles, namely: application of the scientific research results in professional and pedagogical practices; undertaking of professional activities based on the continuous development and innovation; independent carrying out of scientific research, analysis and aggregation of its results, making predictions; ability to arrange and carry out professional research, organizational and managerial activities in the field of biology and ecology.

Demand for Graduates

Graduates of the master's degree program in "Environmental Risks at Enterprises of the Pharmaceutical Industry" are in demand with biotechnological and immunobiological enterprises, environmental safety departments of enterprises or entities of pharmaceutical industry, scientific laboratories of development of biopharmaceutical medicinal products, microbiological laboratories of analysis of biologically active supplements, cosmetics, foodstuffs and other enterprises of pharmaceutical industry.

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 "Environmental Risks at Enterprises of the Pharmaceutical Industry" 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 degree program (hereinafter referred to as graduates) can be engaged in include:

02 Healthcare (in the field of study of new medicinal products, quality assurance of medicinal products, production of medicinal products);

40 Cross-cutting types of professional activity in industry (in the field of products quality control, environmental safety in industry, medical and biological waste management).

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 "Environmental Risks at Enterprises of the Pharmaceutical Industry" are:

– biopharmaceutical manufacturing company as a set of facilities and technologies affecting the environment;

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

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

– accounts and records, planning, technical documents of enterprises dealing with pharmaceutical manufacturing and environmental safety;

– means of quality control of raw materials, semi-finished and finished products;

– organization and management of activity related to environmental safety assurance at the enterprise;

– regulations for production of biotechnology products, international standards.

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 activity which the master's degree program is aimed at, is ready to solve the following job tasks:

Scientific Research Activity:

- scientific and practical application of risk management processes and implementation of integrated risk management approach aimed at expansion and improvement of organization prospects;

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

– analysis of engineering process performance for the compliance with scientific developments;

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

Organizational and Managerial Activity:

- improvement of opportunities to achieve the goals of enterprise's quality management system
- maintaining and improvement of active corporate management
- realization of the need to identify and treat process risks of the enterprise;
- improved identification of common opportunities and threats;
- evaluation of environmental risks, risks of negative impact of economic activities, man-made and natural emergency risks as well as risk management
- compliance with the relevant legislation and other mandatory requirements and international standards;
- improvement of mandatory and management reporting;
- strengthening the trust of interested parties;

- creation of firm basis to make decisions and plan in the process of professional activity;
- effective resource distribution and use to treat risks;
- improvement of functional efficiency and effectiveness;
- improvement of health, safety and environment level;
- improvement of loss prevention and incident management;
- improvement of studies in organization;
- improvement of organization sustainability;
- preparation and implementation of internal ecological audit;

– arrangement of team's work in conditions of existing production, planning of personnel's work and payroll budgets;
– realization of cooperation with the leading scientific centers of the industry to optimize the enterprise functionality, the development of effectiveness evaluation criteria and plan for its improvement;
– 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 and implementation of strategies for environment protection – in the end of production cycle (end-of-pipe test) and preventive ones (based on low-waste and resource-saving technologies); comparing of their advantages in various situations and contexts;
– 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;
– application of the best technologies available;
– organization of facilities and resources supply for biotechnological production units, storage and accounting of raw material, supplies and finished product in the prescribed manner;
– production and consumption waste management, environmental responsibility of the manufacturer;
– ensure process discipline, sanitary and hygiene mode of enterprise operation, maintenance of the process equipment in appropriate technical condition;
– arrangement of compliance with the health and safety regulations in production and environment protection;
– assurance of professional confidentiality;

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	02.014	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
40 Cross-cutting types of professional activity in industry		
4	40.010	Products quality control specialist
5	40.117	Specialist in environmental safety in industry
6	40.134	Medical and biological waste engineering technologist

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 degree program in "Environmental Risks at Enterprises of the Pharmaceutical Industry" 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**
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 and 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

Codes	Competences, indicators of competence achievement
	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
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"**
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
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**

Codes	Competences, indicators of competence achievement
	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**
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

Codes	Competences, indicators of competence achievement
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 the Master's Degree Program in "Environmental Risks at Enterprises of the Pharmaceutical Industry"

Mandatory part (name, workload, final discipline assessment)

1. Foreign Language - 3 credits (108 hours), in-class work – 16 hours, examination
2. Philosophical Problems of Science and Technology – 3 credits (108 hours), in-class work – 18 hours, examination
3. Management of Human Resources – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
4. Information Technology in Professional Activity – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
5. Economics and Innovation – 3 credits (108 hours), in-class work – 18 hours, examination, course work
6. Modern Problems of Biotechnology – 3 credits (108 hours), in-class work – 18 hours, examination

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

7. Basics of Governmental Management for Environment Protection – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
8. Basics of Environmental Safety and Nature Management – 3 credits (108 hours), in-class work – 18 hours, examination
9. Medical and Biological Waste Management – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
10. Ecotoxicology in Pharmaceutical Industry – 3 credits (108 hours), in-class work – 18 hours, examination
11. Occupational Safety at Enterprises of the Pharmaceutical Industry – 3 credits (108 hours), in-class work – 18 hours, pass-fail test
12. Metrological Support of Technoecological Measurements – 3 credits (108 hours), in-class work – 18 hours, graded test
13. Environmental Risks at Enterprises of the Pharmaceutical Industry – 6 credits (216 hours), in-class work – 36 hours, examination, pass-fail test, course work
14. Environmental Management at Enterprises of the Pharmaceutical Industry – 3 credits (108 hours), in-class work – 18 hours, examination

Elective disciplines (name, workload, final discipline assessment)

15. Nature Management Practice at Enterprises of the Pharmaceutical Industry – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
16. Medical and Biological Waste Management Practice – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
17. Nature Management Practice at Enterprises of the Pharmaceutical Industry – 3 credits (108 hours), in-class work – 10 hours, pass-fail test

18. Medical and Biological Waste Management Practice – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
19. Occupational Health and Safety at Enterprises of Pharmaceutical Industry – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
20. Human Ecology – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
21. General Hygiene – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
22. Organization of Special Assessment of Working Conditions at Enterprises of the Pharmaceutical Industry – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
23. Economic Security of Pharmaceutical Enterprises – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
24. Energy and Resource Efficiency of Pharmaceutical Enterprises – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
25. Energy and Resource Efficiency of Pharmaceutical Production Units – 3 credits (108 hours), in-class work – 10 hours, pass-fail test
26. Foreign Language for Scientific Work – 3 credits (108 hours), in-class work – 6 hours, pass-fail test
27. Foreign Language for Business Contacts – 3 credits (108 hours), in-class work – 6 hours, pass-fail test

Optional subjects (name, workload, final discipline assessment)

28. *Latin – 2 credits (72 hours), in-class work – 4 hours, pass-fail test*
29. *Bioethics– 2 credits (72 hours), in-class work – 4 hours, pass-fail test*
30. *Digital Literacy – 2 credits (72 hours), in-class work – 10 hours, pass-fail test*
31. *Digital Culture – 2 credits (72 hours), in-class work – 10 hours, pass-fail test*
32. *Cognitive Management Systems – 2 credits (72 hours), in-class work – 10 hours, pass-fail test*

Practices (name, workload, final assessment)

33. Academic Practical Training: Practice in Obtaining Primary Professional Abilities and Skills – 6 credits (216 hours), in-class work – 8 hours, pass-fail test
34. SRW 1 (Scientific Research Work) – 30 credits (1,080 hours), in-class work – 60 hours, pass-fail test
35. SRW 2 (Scientific Research Work) – 6 credits (216 hours), in-class work – 15 hours, pass-fail test
36. Practice in Obtaining Professional Abilities and Experience of Professional Activities (Including Production Practice) – 6 credits (216 hours), in-class work – 8 hours, graded test
37. Pre-graduation Practice – 6 credits (216 hours), in-class work – 8 hours, graded test

State Final Certification

38. 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 "Ecological Risks in Enterprises of Pharmaceutical Industry" 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 in "Environmental Risks at Enterprises of the Pharmaceutical Industry" 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 Degree Program

The master degree program in 19.04.01 Biotechnology, specialization – "Environmental Risks at Enterprises of the Pharmaceutical Industry" ensures training of high-skilled personnel who are able to carry out the following at high professional level:

- scientific research activities in the sphere of biological sciences;
- as well as to undertake organizational and managerial activities on environmental and social aspects in organizations of pharmaceutical and related industries

The provided master's degree program in field of education 19.04.01 Biotechnology, specialization: "Environmental Risks at Enterprises of the Pharmaceutical Industry" is at the junction of biotechnology and industrial ecology and deals with environmental safety of organizations in the industry.

It is aimed at training of specialists who are able to make and fulfill environmental safety decisions at manufacturing facilities of organizations in the pharmaceutical industry (official, head of environmental management department), to introduce integrated environmental management, quality management and risk management systems to ensure continuity and safe operations of manufacturers of medical products in the pharmaceutical industry and in pharmaceutical entities (official, head of environmental management department)

Graduates will be able to take part in management of pharmaceutical corporations and medical product manufacturers and circulation of medical products at every stage of production management, taking into account:

a set of facilities and technologies affecting the environment; forms and methods of organization and management of various types of main and supporting activities of biotechnological pharmaceutical enterprises on environment protection;

relevant regulatory legal acts and industrial standards in the field of pharmaceutical manufacturing and circulation of medicinal products. accounts and records, planning, technical documents of enterprises dealing with pharmaceutical manufacturing and environmental safety; means of quality control of raw materials, semi-finished and finished products;

organization and management of activity related to environmental safety assurance at the enterprise;

regulations for production of biotechnology products, international standards.