#### **Abstract**

### of Master's Degree Program in Field of Education 19.04.01 Biotechnology, Discipline (Specialization) "Production of Immunobiological Products"

## (Internal Study Mode)

### Terms, Workload of the Degree Program and Qualification of Graduates

| Name                    | Qualification | Term of education including the holidays provided after the completion of the State Final Certification | Workload<br>(in credits) |
|-------------------------|---------------|---|--------------------------|
| Master's degree program | Master        | 2 years   | 120                      |

### Purpose (Mission) of the Degree Program

The purpose of the master's degree program is developing student personal qualities and forming general cultural, general professional and professional competences in accordance with the requirements to mandatory minimum of the degree program content in field of education 19.04.01 Biotechnology (qualification (degree) – master), as well as the student acquisition of additional professionally specialized competences in the field of research and production and engineering and manufacturing activities.

### **Demand for Graduates**

The graduates of the master's program in "Production of Immunobiological Products" are in demanded with manufacturers of immunobiological products. Knowledge and skills acquired by students in creating regulatory technical and design and engineering documentation, familiarity with the basics of developing and introducing GMP standards into industry makes them competitive in the modern labor market. The graduates are trained engineers who are able to create regulations for biotechnological and pharmaceutical manufacturing, design production areas, develop and introduce modern technologies.

The graduates of the master's program can continue their study in postgraduate program of SPCPU and other institutions of higher education.

### 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 of the master's degree program in "Production of Immunobiological Products" includes:

- research, generation and application of ferments, viruses, microorganisms, animal and plant cell cultures, products of their biosynthesis and biotransformation;
- creation of technologies to produce new types of products, including products obtained with the use of microbiological synthesis, biocatalysis, genetic engineering and nanobiotechnologies;
- development of scientific and technical documentation, and process regulations for production of biotechnological products;
- implementation of biotechnological processes and production operations in accordance with the compliance of legislative and regulatory national and international acts;
- arrangement and performance of quality control of raw materials, intermediate products and finished products.

The master's professional activities are carried out at enterprises and scientific research institutions in the field of pharmaceutical and biotechnological production, educational institutions of secondary and higher vocational education that train personnel in the field of production of medicine and biotechnological products.

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 activity, the objects of professional activity of graduates of the master's degree program "Production of Immunobiological Products" are:

microorganisms, animal and plant cell cultures, viruses, ferments, biologically active chemical substances; instruments and equipment for studying of properties of used microorganisms, cell cultures obtained by biosynthesis of substances obtained in laboratory and industrial conditions; biomasses, installations and equipment for biotechnological processes; means of quality control of raw materials, semi-finished and finished products; regulations for production of biotechnology products, international standards.

### Types of Professional Activity

- scientific research activities;
- engineering and manufacturing activities.

### 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:

- 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;
- search and development of new effective ways to produce biotechnological products, creation of modern biotechnologies, including nanobiotechnologies, technologies of recombinant DNA, cell technologies;
- recovery, identification and analysis of biosynthesis and biotransformation products, deriving of new producer strains of biological preparations;
- creation of composite forms and optimal ways of biological preparations use;
- validation of engineering processes and analytical procedures;
- study of biochemical and biological regularities of biosynthesis processes, micro- and macrostoichiometry, micro- and macrokinetics of micropopulation and cell culture growth, interaction of microorganisms, viruscell interaction, metabolic fates and specifics of substrate disposal and synthesis of metabolism products;
- creation of theoretical models that allow predicting the nature of change in properties of raw materials in the process of their biotransformation and producing of products with the set qualitative characteristics;
- experimental research of biological and physical and chemical kinetics at every stage of engineering process and their mathematical description;
- 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.

### Engineering and Manufacturing Activity:

- organization, planning and control of existing biotechnological processes and production;
- ensuring of stability of production performance and quality of manufactured products in accordance with local acts of enterprise (engineering regulations, duty regulations, analysis techniques);

- provision of effective operation of means of control, automation and automated management of biotechnological production;
- organization and performance of energy-efficiency and resource-saving measures, measures on assurance of environmental safety of biotechnological processes;
- provision of chemical and technical, biochemical and microbiological control;
- development of measures for improving economic and production performance of the process, provision of production efficiency and obtaining of the product of needed quality;
- organization of production operations metrology support;
- organization of external and internal audit system;
- coordination of operations on implementation of results of scientific researches into production;
- operation of experimental and industrial installations;
- operation of instruments and equipment, means of analytical control and production control in accordance with technical data sheets and instructions for instruments and equipment

# List of Professional Standards Corresponding to the Professional Activity of Graduates Who Have Completed the Degree Program

| Item<br>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   | 02.011                        | Specialist in validation (qualification) of pharmaceutical manufacturing                       |  |
| 3   | 02.013                        | Specialist in industrial pharmacy in the field of quality control of medicinal products        |  |
| 4   | 02.014                        | Specialist in industrial pharmacy in the field of quality assurance of medicinal products      |  |
| 5   | 02.016                        | Specialist in industrial pharmacy in the field of production of medicinal products             |  |
| 40 Cross-cutting types of professional activity in industry |                               |  |  |
| 6   | 40.010                        | Products quality control specialist  |  |
| 7   | 40.008                        | Specialist in organization and management of scientific research and experimental design works |  |
| 8   | 40.062                        | Product quality specialist   |  |

### General Characteristic of the Degree Program

Planned results of completing of the degree program (competences) and indicators of their achievement

In accordance with the aims of the degree program and type of tasks of professional activity, the graduate of the master's degree program "Production of Immunobiological Products" 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-2.1 takes social responsibility for the decisions made GCC-3.2 takes ethical responsibility for the decisions made 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 professional activity GCC-3.3 generates new ideas when solving research and practical problems GCC-4.1 doi: GCC-4.1 doi: GCC-4.1 doi: GCC-4.2 doi: GCC-4.2 doi: GCC-5.3 doi: GCC-6.2 doi: GCC-6.3 doi: GCC-6.3 doi: GCC-6.4 doi: GCC-6.1 doi: GCC-7 doi: GCC-8 doi: GCC-8 doi: GCC-9 doi: G | GCC-2   | Readiness to take actions in abnormal situations, to bear social and ethical                      |
|--|---------|---|
| GCC-3.2  GCC-3.1  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.3  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.3  GCC-3.2  GCC-3.2  GCC-3.2  GCC-3.3  GCC-3.2  GCC-3.2  GCC-3.3  GCC-3.2  GCC-3.2  GCC-3.3  GCC-3.2  GCC-3.3  GCC-3.2  GCC-3.3  GCC-3.2  GCC-3.3  GCC-4.1  GCC-4.1  GCC-4.1  GCC-4.1  GCC-4.1  GCC-5  GCC-5  GCC-5  GCC-5  GCC-5  GCC-5  GCC-6  GCC-6  GCC-6  GCC-6  GCC-7  Ability to enhance and develop their intellectual and general cultural level, performs a search, critically analyzes and synthesizes information  GCC-4.1  GCC-4.1  GCC-4.1  GCC-4.1  GCC-4.1  GCC-4.2  Ability for professional growth, individual study of new research methods, change of scientific and scientific production profile of their professional activity works out individual techniques for practical solving of training and job tasks, including with the use of creative potential  GCC-4.1  GCC-5  GCC-5  GCC-5  Ability to use skills in the organization of research and project works, in team management on a practical level 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 applies skills for effective performance of works  GCC-6.1  GCC-6.1  GCC-6.1  GCC-6.2  GCC-6.2  GCC-6.3  GCC-6.3  GCC-6.4  GCC-6.5  GCC-6.5  GCC-6.5  GCC-6.6  GCC-6.7  GCC-6.7  GCC-7  GCC-7  GCC-7  GCC-8  GCC-8  GCC-8  GCC-9  GCC-9  GCC-9  GCC-9  GCC-9  GCC-1  GCC-2  GCC-2  GCC-3  GCC-3  GCC-3  GCC-4  GCC-4  GCC-5  GCC-6  GCC-6  GCC-6  GCC-6  GCC-6  GCC-7  GCC-7  GCC-7  GCC-8  GCC-8  GCC-8  GCC-9  GCC-9  GCC-9  GCC-9  GCC-9  GCC-9  GCC-9  GCC-1  GCC |         |   |
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| GCC-5.1 their rights and obligations, as well as regulatory legal acts regulating the relations between individuals in the practical implementation of research and project works applies skills for effective performance of works  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  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-2.1 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 Readiness to manage the team in the field of their professional activity, perceive social, ethnic, religious and cultural differences in a non-judgmental manner  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  CPC-3.1 manages the team considering peculiarities of behavior and interests of individual   | GCC-5   | management on a practical level   |
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| GPC-3.1  Readiness to manage the team in the field of their professional activity, perceive social, ethnic, religious and cultural differences in a non-judgmental manner  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  | GPC-2.1 | presents the results of their activities in a foreign language                                    |
| social, ethnic, religious and cultural differences in a non-judgmental manner  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  CPC 2.2  manages the team considering peculiarities of behavior and interests of individual  | GPC-2.2 | produces and edits scientific, business and professional texts in a foreign language              |
| GPC-3.1 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  | GPC-3   |   |
| ( 'D( ' '2 ')   = = = = = = = = = = = = = = = = = =  | GPC-3.1 | behavior, interests and opinions of its members, appropriately distributes authority and          |
|  | GPC-3.2 |   |

| 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" (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-13   | Readiness to organize, plan and control the existing biotechnological processes and production  |

| PC-13.1 | develops measures to improve and intensify the existing production using achievements of science and technology                                       |
|---------|---|
| PC-13.2 | organizes project works for biopharmaceutical manufacturing   |
| PC-13.3 | designs process flow diagrams of biotechnological stages in accordance with the rules of  |
|         | production organization as per GMP  |
| PC-14   | Ability to use type methods and develop new methods of engineering calculations of process parameters and equipment for biotechnological production   |
| PC-14.1 | makes calculations of process parameters and equipment for biotechnological production  |
| PC-14.2 | uses type methods and develops new ones in the course of engineering calculations of process parameters in production                                 |
| PC-14.3 | assesses and takes into account hazards in calculations of the equipment and modes of its operation   |
| PC-15   | Readiness to provide the stability of production performance and quality of manufactured products   |
| PC-15.1 | conducts reviews of quality of biotechnological products using tools and methods of risk analysis   |
| PC-15.2 | provides the stability of production process performance with the aim to produce products of appropriate quality                                      |
| PC-15.3 | ensures the stability of production performance in the course of practical and scientific activities upon the receipt of biopharmaceutical substances |
|         | Ability to perform effective operation of means of control, automation and  |
| PC-16   | automated management of production, chemical and technical, biochemical and   |
|         | microbiological control   |
| PC-16.1 | justifies the selection of methods of microbiological, chemical and technical,  |
|         | biochemical control of production items and finished products uses current regulatory documents to analyze the results of microbiological control,    |
| PC-16.2 | draws conclusions   |
| PC-17   | Readiness to carry out experimental industrial elaboration of the technology and simulation of processes  |
| PC-17.1 | knows the approaches for carrying out the experimental industrial elaboration of the technology   |
| PC-17.2 | carries out the experimental-industrial elaboration of the technology and simulation of processes in practice   |
| PC-18   | Ability to develop and scientifically justify schemes for optimal integrated certification of biotechnological products                               |
| PC-18.1 | develops scientifically grounded programs for integrated certification of biotechnological products taking into account the risk analysis             |
| PC-18.2 | takes into account safety requirements in the risk analysis   |
| PC-19   | Ability to analyze engineering process performance for the compliance with initial scientific developments  |
| PC-19.1 | analyzes engineering process performance in practice considering the compliance with safety requirements  |
| PC-19.2 | assesses technology efficiency and suggests measures aimed at improvement of production and quality of finished products                              |

# Curriculum of Master's Degree Program "Production of Immunobiological Products" Mandatory part (name, workload, final discipline assessment)

- 1. Foreign Language 3 credits (108 hours), in-class work 32 hours, pass-fail test
- 2. Philosophical Problems of Science and Technology -3 credits (108 hours), in-class work -32 hours, pass-fail test
- 3. Management of Human Resources 3 credits (108 hours), in-class work 32 hours, pass-fail test
- 4. Information Technology in Professional Activity 3 credits (108 hours), in-class work 32 hours, pass-fail test

- 5. Economics and Innovation 3 credits (108 hours), in-class work 34 hours, examination, course work
- 6. Modern Problems of Biotechnology 3 credits (108 hours), in-class work 34 hours, examination

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

- 7. Design and Organization of Pharmaceutical Manufacturing According to GMP 3 credits (108 hours), in-class work -32 hours, pass-fail test, course project
- 8. Immunobiochemistry 3 credits (108 hours), in-class work 32 hours, pass-fail test, course work
- 9. Quality Assurance of Biotechnological Medicinal Products 3 credits (108 hours), in-class work 34 hours, pass-fail test
- 10. Fundamental and Applied Aspects of Modern Molecular Biology 3 credits (108 hours), in-class work 32 hours, graded test
- 11. Immunobiological Products Based on Microorganisms 3 credits (108 hours), in-class work 32 hours, passfail test
- 12. Technology of Immunobiological Products Production 3 credits (108 hours), in-class work 32 hours, passfail test, course project
- 13. Methods of Immunobiological Products Analysis 3 credits (108 hours), in-class work 32 hours, pass-fail test
- 14. Modern Equipment for Immunobiological Production 3 credits (108 hours), in-class work 32 hours, passfail test
- 15. Safety of Engineering Processes in Pharmaceutical Manufacturing 3 credits (108 hours), in-class work 32 hours, pass-fail test

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

- 16. Psychology of Professional Activity and Management 3 credits (108 hours), in-class work 24 hours, passfail test
- 17. Team Conflict Resolution 3 credits (108 hours), in-class work 24 hours, pass-fail test
- 18. Physical and Chemical Methods of Analysis 3 credits (108 hours), in-class work 24 hours, pass-fail test
- 19. Microbiological Control in Biotechnological Production 3 credits (108 hours), in-class work 24 hours, passfail test
- 20. Process Media in Pharmaceutical Manufacturing 3 credits (108 hours), in-class work 24 hours, graded test
- 21. Engineering Thermodynamics 3 credits (108 hours), in-class work 24 hours, graded test
- 22. Foreign Language for Scientific Work 3 credits (108 hours), in-class work 24 hours, pass-fail test
- 23. Foreign Language for Business Contacts 3 credits (108 hours), in-class work 24 hours, pass-fail test
- 24. Processes of Equipment Cleaning 3 credits (108 hours), in-class work 24 hours, pass-fail test
- 25. Validation of Purification 3 credits (108 hours), in-class work 24 hours, pass-fail test

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

- 26. Latin 2 credits (72 hours), in-class work 16 hours, pass-fail test
- 27. Bioethics 2 credits (72 hours), in-class work 16 hours, pass-fail test

### Practices (name, workload, final assessment)

- 28. Academic practical training: practice in obtaining primary professional abilities and skills 6 credits (216 hours), in-class work 12 hours, pass-fail test
- 29. Practice in obtaining professional abilities and experience of professional activities (including production practice) 6 credits (216 hours), in-class work 24 hours, graded test
- 30. SRW 1 (Scientific Research Work) 21 credits (756 hours), in-class work 45 hours, pass-fail test
- 31. SRW 2 (Scientific Research Work) 15 credits (540 hours), in-class work 15 hours, pass-fail test
- 32. Pre-graduation practice 6 credits (216 hours), in-class work 30 hours, graded test

#### State final certification

33. 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 "Production of Immunobiological Products" is provided with learning and teaching documentation, as well as materials in all disciplines (modules) and practices, including electronic educational-methodical complexes posted in electronic information and educational environment of the University.

The University has facilities and resources that are in compliance with applicable fire safety rules and regulations and ensure all types of the disciplinary and interdisciplinary preparation, practical and scientific research works of students, provided for by the curriculum.

The list of facilities and resources, learning and teaching support, required for implementation of the degree program, includes the following: special rooms in the form of classrooms for conducting lecture-type activities, seminar-type activities, course work development (course work execution), group and individual tutorials, current control and midterm assessment. There are also rooms for independent work and rooms for storage and preventative maintenance of training equipment. Special rooms are equipped with designated furniture and teaching aids intended for presentation of teaching information to a large audience. Laboratories are equipped with laboratory equipment depending on the degree of complexity. Sets of demonstration equipment and illustrative study guides providing for topic-based illustrations and corresponding to discipline (module) programs, working educational programs of disciplines (modules), are offered for lecture-type activities.

Rooms for students' independent work are equipped with computer hardware with the possibility of connecting to the Internet network and access to electronic information and educational environment of the organization. Furthermore, students' independent work is arranged with the use of electronic resources of the University.

The library fund is provided with the required number of printed publications, moreover, there is an access to electronic library systems.

The University has the necessary licensed software package the composition of which is given in working programs of disciplines (modules) and is subject to annual update.

The students are provided with an access (remote access), including in the event of doing electronic learning, applying distance learning technology, to today's professional databases and inquiry and communications systems the composition of which is determined in working programs of disciplines (modules) and is subject to annual update.

During the whole period of studying every student and a teacher are provided for with an unlimited access (including the remote one) to electronic library systems and to electronic information and educational environment of the University from any place with the available Internet connection.

Electronic information and educational environment of the University provides for:

- the access to curricula, working programs of disciplines (modules), practices, editions of electronic library systems and electronic learning resources specified in working programs;
- recording of progress of the educational process, results of midterm assessment and results of the degree program completion;
- the formation of electronic portfolio of the student, including the preservation of student's works and grades for these works by any participants of the educational process;
- interaction between participants of the educational process, as well as synchronous and (or) asynchronous communication via Internet.

Functioning of electronic information and educational environment complies with the requirements of the legislation of the Russian Federation in the field of education and is provided for with the relevant means of information and communication technologies and qualification of the University employees who use and maintain it.

### Staffing of the Degree Program

Implementation of the master's degree program "Production of Immunobiological Products" is ensured by the senior academic staff of the organization, as well as by persons engaged in the implementation of the master's degree program under the terms of the civil contract in accordance with the requirements of the Federal State Educational Standard for this field of education.

The percentage of the employed academic staff (reduced to integer rates) is at least 60 % of the total number of the University academic staff. The percentage of the academic staff (reduced to integer rates) having education and (or) a degree that correspond to the profile of the discipline (module) taught in the total number of the academic staff implementing the master's degree program is at least 80 %. The percentage of the academic staff (reduced to integer rates) having a degree and (or) an academic rank in the total number of the academic staff implementing the master's degree program is at least 70 %. The percentage of staff (reduced to integer rates) among the heads and employees of organizations whose activities are related to the specialization (profile) of the master's degree program (having at least 3 years of work experience in this professional field) in the total number of staff implementing the master's degree program is at least 10%.

General management of the science based content of the master's degree program is responsibility of an employed academic of the University having the Doctor of Sciences degree, carrying out independent scientific research projects (involved in implementation of such projects) in the field of education, having annual publications of the results of the scientific research activities in leading domestic and (or) foreign peer reviewed scientific journals and editions, as well as taking part in annual evaluation of the results of the scientific research activities at national (departmental, industrial) and international conferences.

The list of the academic staff engaged in the implementation of the master's degree program is included in the certificate of staffing of the educational process.

## Uniqueness and Competitive Advantages of the Master's Degree Program "Production of Immunobiological Products"

The relevance of this degree program is associated with the need of today's society for immunobiological products – vaccines and serums intended for specific prophylaxis, diagnostics and treatment of dangerous infectious diseases. In current conditions when the humanity continues struggling with epidemic spread of dangerous viral and bacterial infections, the need of the society to create reliable and safe immunobiological products is extremely high. In order to ensure safety and effectiveness of finished products in the course of developing, producing and scaling-up of immunobiological products, it is necessary to take into account a plenty of factors, peculiarities and risks. The master's graduate, who has completed full comprehensive and practical training and who has a set of necessary competences, is able to cope with such wide variety of tasks. To educate and train high-skilled specialists required for the industry related to the production of immunobiological products, degree programs with a high level of consolidation of educational and industrial organizations, which are, in fact, employers for future specialists, are of great importance.

The master's degree program "Production of Immunobiological Products" has been created in cooperation with employers, the main one of which is FSUE Saint Petersburg Scientific Research Institute of Vaccines and Serums, and the Manufacturer of Bacterial Products of the FMBA of Russia. Moreover, the education is conducted in cooperation with M.P. Chumakov Federal Scientific Center for Research and Development of Immunobiological Products of Russian Academy of Sciences, Moscow, LLC Institute for Preclinical Studies, St. Petersburg, and other enterprises and organizations of the industry.

The master's degree program "Production of Immunobiological Products" takes into account the current scientific trends, teaching staff and master's students annually participate in international and all-Russian scientific conferences, take part in the publication of articles, as well as are engaged in a patent work. The recent developments of new process lines, new methods of quality control, techniques for scaling technologies, ensuring the safety of immunobiological products and other aspects of the program are included not only in the educational process, but also are integrated into the production process. On the basis of Saint Petersburg Scientific Research Institute of Vaccines and Serums, vaccines against influenza, pneumococcal disease, hemolytic infection, tubercular allergen are produced; new shops of finished medicinal products, recombinant preparations, conjugated vaccines have been built; vaccines to prevent COVID-19, meningococcal disease and HPV virus are developed. Technology aspects are reflected in the learning process.

The master's degree program "Production of Immunobiological Products" contains the needs of today's labor market which requires high-skilled specialists in the production of immunobiological products, search of new solutions and technologies in this industry, in the field of scientific researches and implementation of their results in the production process. The employer needs personnel who will be able to create high-yielding producer strains using genetic engineering methods, develop schemes of fermentation and cultivation of producers, develop and implement schemes for purification and folding of recombinant products, control methods, including to confirm specific activity of vaccine formulations, lead and provide many other job tasks of the production.

Active career guidance counseling involving employers is carried out with students within the educational process, open webinars, meetings with applicants, production facility tours are conducted each year. Saint Petersburg Scientific Research Institute of Vaccines and Serums has started career guidance counseling project Bionica on popularization of professions, which is developed both in Russia and in the territory of the Republic of Nicaragua. Saint Petersburg Scientific Research Institute of Vaccines and Serums has "Mentoring Laboratory", a unique project which combines best practices in transferring knowledge and competences not only for new employees, but also career guidance counseling with the young people.