Federal State Autonomous Educational Institution of Higher Education
«Peoples ' Friendship University of Russia »

the Shared Research and Educational Center

The working program of the discipline

Name of the discipline:

Good pharmaceutical practice / Надлежащая фармацевтическая практика

Recommended for the field of / specialty:

33.06.01 Pharmacy

Direction of the program:

Pharmaceutical technology (in collaboration with the University of Basel)

2020

1. Goals and objectives of the discipline:

The purpose of studying the discipline is the formation and development of professional competencies in the field of industrial technology of medicines, which is good pharmaceutical practice.

To achieve this goal in the course, the following tasks are solved

Tasks:

1. Teaching postgraduate students, the principles "good pharmaceutical practice".
2. obtaining knowledge, skills and practical abilities in the field of good pharmaceutical practice among postgraduate students.

2. The position of the discipline in the structure of "the educational program of higher education":

The discipline "Good Pharmaceutical Practice" is an optional discipline studied in graduate school in the field of "Pharmacy" in the direction of Pharmaceutical technology (in conjunction with the University of Basel).

To study this discipline, a graduate student must have a higher pharmaceutical education or relevant specialized retraining, have knowledge, skills and abilities in the field of pharmacology, pharmaceutical technology, pharmaceutical chemistry and pharmacognosy.

The study of the discipline is necessary to expand the knowledge of postgraduate students in the field of good pharmaceutical practice and prepare it for the delivery of the state final certification and defense of the dissertation work.

Table № 1

Предшествующие и последующие дисциплины, направленные на формирование компетенций

№ п/п	Code and name of competence	Previous discipline	Subsequent disciplines (disciplines unit)
General professional competencies			
1	GEPC-3: the ability and preparation to analyze, summarize and publicly present the results of scientific research.	Methodology of scientific research	Research practice, Scientific research, State final certification
2	GEPC-4: preparation to implement the developed methods and techniques aimed at the rational, effective, and safe use of medicines.	Methodology of scientific research	Research practice, Scientific research, State final certification
3	GEPC-5: ability and preparation to use laboratory and instrumental equipment for obtaining scientific data.	Methodology of scientific research	Research practice, Scientific research, State final certification
Professional competence			

4	PC-1: ability to do scientific research on the development and creation of innovative drugs, including the ones which are derived from medicinal plant materials	Methodology of scientific research	Research practice, Scientific research, State final certification
5	PC-2: ability for scientific research on obtaining more advanced forms of drugs with predictable pharmacokinetic characteristics based on modern technologies	Methodology of scientific research	Research practice, Scientific research, State final certification

3. Requirements for mastering the discipline:

The discipline study process aims to develop the following competencies:

- GEPC-3: The ability and willingness to analyze, summary and publicly display the results of scientific research
- GEPC -4: The ability to implement developed methods and techniques aimed at rational, effective and safe use of medicines
- GEPC -5: The ability and willingness to use a laboratory equipment and tools to obtain scientific data
- PC-1: ability to do scientific research on the development and creation of innovative drugs, including those which are derived medicinal plant materials
- PC-2: ability for scientific research on obtaining more advanced forms of drugs with predictable pharmacokinetic characteristics based on modern technologies

As a result of studying the discipline, a graduate student must:

Know: 1 - he basics of general theoretical disciplines in the amount necessary to solve professional tasks;
2 - The current status of drug development. Factors affecting the development of new drugs. The main stages of drug development.;
3 – Concept of Good Practice in Pharmacy - GXP.
4 Good Laboratory Practices - GLP.
5 Good Clinical Practice - GCP.
6 Good Storage Practices - GSP.
7 Good Manufacturing Practices - GMP.
8 Good Pharmacy Practice - GPP.

Be able to: 1 - operate the obtained theoretical knowledge in the process of development and validation of technological methods;
2 - organize experiments and tests;
3 - interpret and evaluate the results of drug development;
4 - use normative documentation regulating the processes of development, production, regulation and storage of drugs.

Have: 1- methods of processing and analysis of the results obtained;
2 - skills for optimizing the formulations of dosage forms;
3 - skills in optimization of technological processes.

4. Scope of discipline and types of educational work

The total workload of the discipline is 4 credit units

Type of study	Total hours	Courses
		2 courses
Classes (total)	144	144
Including:		
Lectures	40	40
Practical lessons (PL)	40	40

Seminars (C)	-	-
Laboratory work (LW)	-	-
Independent work (IW) (total)	46	46
Including	-	-
Course projects	-	-
Presentatios graphic works	-	-
abstract	46	46
Other types of independent work		
Intermediate validation (test, exam)	18, credit	18, credit
Total study time – hours/credits	144/4	144/4

5. Content of the discipline

5.1. Contents of discipline sections

№ п/п	Name of the section, topic of the academic discipline (module)	Section content, topic (module)
1	Good Practice in Pharmacy - GXP	Quality assurance in the field of drug regulation. GXP concept. Stages of the life cycle of a medicinal product. Features of drugs as a consumer product. Various approaches to the issues of quality assurance of a medicinal product. The concept of drug quality, proclaimed by the WHO. Approaches to the implementation of GMP rules in Russia. WHO Policy on regulation of drugs. Pharmacological supervision
2	Good Laboratory Practice - GLP	Good Laboratory Practice. Scope of application. Preclinical study. Stages and types of preclinical studies. Categories of preclinical studies of drugs. Objectives of preclinical research. GLP requirements. Documentation of preclinical studies. SOP of the research laboratory. Final report of preclinical trials. GLP in Russia. Experimental biological clinic (vivarium). the concept of replacement. GLP requirements on using lab animals. Alternatives in Experimental Pharmacology. Bioethics Committee. Quality control service at the bases of preclinical research of drugs. The main directions of inspection.
3	Good Clinical Practice - GCP	Клинические испытания. История создания GCP. Надлежащая клиническая практика. Цели, основные принципы и требования GCP. Внедрение GCP в России. Файл клинических испытаний. Брошюра исследователя. Индивидуальная регистрационная форма (CRF). Клинические базы. Фазы и виды клинических испытаний. Рандомизация. Стратификация. Дизайн (схема) клинических испытаний. Значение клинических испытаний. Обязанности исследователя. Защита прав пациента. Контроль качества клинических испытаний (мониторинг, аудит, инспекция). Этапы проведения инспекции клинического испытания. Этические и правовые аспекты GCP
4	Good Storage Practice - GSP	Good Storage Practice for Pharmaceutical Products. GSP Guide. GSP in Russia. Types of storage facilities. Monitoring storage conditions. General requirements for the storage of drugs. Documentation: written instructions and reports. Marking. Dispatch and transport.

5	Good Manufacturing Practice - GMP	The role of international standards for the pharmaceutical industry in Russia. Requirements for pharmaceutical production. The history of the development of GMP. Official GMP guidelines. Main provisions and requirements of GMP. Basic principles of GMP. Pharmaceutical company documentation. Specification for raw materials, packaging material, finished product. Basic GMP requirements for the production of drugs. Validation of drug production for compliance with GMP. Complaints and product recalls. Claims and Complaints. Complaint type. Internal inspection (self-inspection). The main factors influencing the conduct of internal audits. The procedure for conducting audits. GMP and drug production licensing system
6	Good Pharmacy Practice - GPP	History of the establishment of pharmacies. drug financing system. Guide to Good Pharmaceutical Practice. GPP requirements and elements. Advertising of medicines. GPP in Russia. drug classes. Specialized pharmacies. Internet pharmacies

5.2. Sections of the discipline and types of classes

№ п/п	The name of the discipline section	lecture	Prac. Les..	Lab. classes.	seminars	IW	Total hours
1.	Good Practice in Pharmacy - GXP	2	2	-	-	-	4
2.	Good Laboratory Practice - GLP	8	8	-	-	12	28
3.	Good Clinical Practice - GCP	4	-	-	-	6	10
4.	Good Storage Practice - GSP	8	10			8	26
5.	Good Manufacturing Practice - GMP	14	20			14	48
6.	Good Pharmacy Practice - GPP	4	-			6	10
Total:		40	40			46	
Total hours - 126							

6. Laboratory workshop

№ п/п	Name of the section of the academic discipline (module)	Name of laboratory (practical) work	Total hours
1.	Good Practice in Pharmacy - GXP	Investment and social aspects of the industry's transition to international standards for the regulations of medicines. Ways to implement GMP rules. The main differences between the new original medicinal product and the protected trade mark. The path of a drug from the manufacture to consumer	2
2.	Good Laboratory Practice - GLP	The concept and principles of good laboratory practice. Good Laboratory Practice. Basic principles of GLP	8

3.	Good Storage Practice - GSP	Good Storage Practice for Pharmaceutical Products. GSP Guide. The link between GSP and other Good Practices	10
4	Good Manufacturing Practice - GMP	The role of international standards for the pharmaceutical industry in Russia. Requirements for pharmaceutical production. The history of the development of GMP. Official GMP Guides	20
Total hours			40

MATERIAL AND TECHNICAL SUPPORT OF THE DISCIPLINE

During the program, the following equipment are used: a personal computer, multimedia equipment, laboratory equipment, products and samples for testing.

Name of the specialized laboratory	Type of class	Equipment name
Room number 123 the Shared Research and Educational Center	Lectures	Computer, multimedia projector, screen, board
The laboratories of the Shared Research and Educational Centre	Laboratory classes	Premises and equipment of the research and development center: • Capsule filling machine Harro Höfliger "Modu C L". • Laboratory rotary press for the production of BOSCH tablets (Oystar Manesty) "XSpress". • Laboratory installation for granulation BOSCH (Oystar Huttline) "Micromix". • Mini-Coater Glatt "GMPCI". • Semiautomatic filling machine "PRP-VIPS-MED E 456.00". • Semi-automatic roller for seaming aluminum caps "PZR-M-VIPS-MED. E418.00 ". • DOTT candle machine. BONAPACE. • Tester for testing tablets on abrasion SOTAX "F2". • Tester for determining the bulk density of Erweka "SVM 102" powders. • Tester for determining the strength of Erweka "SBT-2" suppositories. • Tester for determining the characteristics of Erweka "GT" granules. • Universal laboratory installation IKA "MagicLab". • Versatile Erweka drive with

		gearbox and coating nozzle. • Installation for granulation BOSCH (Oystar Huttline) "Mycrolab". • • Nano Spray Dryer Büchi "Nano Spray Dryer B-90". • Laboratory machine for obtaining transdermal patches and instant oral films Harro Hoefliger "PML-100". • Automatic blister machine for packing solid medicinal forms Uhlmann "B 1240".]

Main literature	
electronic journals of the American Chemical Society (ACS)	http://pubs.acs.org/
Cambridge Journals	https://www.cambridge.org/core
Electronic resources of the Springer	https://rd.springer.com/
additional literature	
PROQUEST DISSERTATIONS AND THESES GLOBAL	http://search.proquest.com/
Reaxys, Reaxys Medicinal Chemistry	https://www.reaxys.com/

Fund of assessment tools for intermediate certification

Passport of the fund of assessment tools for the discipline biotechnology 2020/2021 Direction / Specialty 06/33/01 "Pharmacy" postgraduate study in Pharmaceutical technology (in collaboration with the University of Basel) Discipline "Good Pharmaceutical Practice"

Controlled competence code	Controlled discipline topic	Forms of control of the level of development of basic educational programs			Topic scores
		Classroom work		Independent work	
		Working in the classroom	Attending lectures	Report	
GEPC-3, GEPC-4, GEPC-5, PC-1, PC-2	Good Practice in Pharmacy - GXP	4	1	-	5
GEPC-3, GEPC-4, GEPC-5, PC-1, PC-2	Good Laboratory Practice - GLP	15	1	4	20
GEPC-3, GEPC-4, GEPC-5, PC-1, PC-2	Good Clinical Practice - GCP	-	1	4	5
GEPC-3, GEPC-4, GEPC-5, PC-1, PC-2	Good Storage Practice - GSP	15	1	6	22
GEPC-3, GEPC-4, GEPC-5,	Good Manufacturing Practice - GMP	30	1	8	39

Questions to the post-graduate certification in the discipline "Good Pharmaceutical Practice"

1. The development history of GXP. GXP concept. Product life cycle stages (quality loop) in accordance with ISO 9000-1994. Medicines certification.
2. Factors influencing the development of new drugs. Requirements for new drugs. The main stages of drug creation.
3. Concept and principles of good laboratory practice. Good Laboratory Practice. Basic principles of GLP.
4. The history of the GCP creation. Clinical trials. Guidelines for clinical trials of drugs.
5. Licensing (registration) of medicines in the EU. WHO and EU registration requirements. Outline of the structure of a general technical document. Registration of drugs in the Republic of Kazakhstan.
6. The role of international standards for the pharmaceutical industry in Russia. Requirements for pharmaceutical production. The history of the development of GMP. Official GMP guidelines.
7. Good storage practices for pharmaceutical products. GSP Guide. Linking the GSP to Other Good Practices.
8. Distribution system in Russia. Distribution channels (distribution of pharmaceutical products). Economic incentives for distribution.
9. Guidelines for Good Pharmacy Practice. History of creation. Requirements and elements of the GPP.
10. State quality control of drugs. State control bodies. Basic principles of GPCL.
11. Investment and social aspects of the industry's transition to international drug circulation standards. Ways to implement GMP rules.
12. The main differences between the new original medicinal product and the protected trade mark. The path of drugs from developer to consumer.
13. Preclinical study of drugs. Basic principles of GLP. Objectives and categories of preclinical trials. Safety test.
14. Good (quality) clinical practice GCP. The purpose of the GCP. Quality assurance of clinical trials of medicinal products. GCP principle. Basic requirements of the GCP.
15. Types of applications for registration of a medicinal product. Registration materials (registration dossier). The structure of the registration dossier. Requirements for registration documents.
16. pharmacueticals guide. Good Manufacturing Practice "and its scope. Quality control. Quality system. GMP requirements.
17. Personnel requirements. Requirements for the premises. Types of storage facilities. Storage conditions for drugs.
18. Movement of drugs through a distribution company. Requirements for the transportation of medicines. List of standard working methods of the distribution company.
19.Categories of medicines. Standards for classifying prescription drugs. Factors preventing the development of the OTC drugs market.
20. Regulatory documentation. Factors affecting the correctness of the assessment of the quality of drug regulation. Administrative structure of the drug quality control laboratory

The developer:

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