# МИНОБРНАУКИ РОССИИ

Федеральное государственное бюджетное образовательное учреждение высшего образования "Пермский государственный национальный исследовательский университет"

# Кафедра фармакологии и фармации

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Программа производственной практики

**QUALITY CONTROL OF MEDICINES** 

Код УМК 93098

Утверждено Протокол №6 от «23» марта 2020 г.

# 1. Вид практики, способ и форма проведения практики

Вид практики производственная

Тип практики профессиональная – практика, направленная на приобретение профессиональных умений и опыта профессиональной деятельности

Способ проведения практики стационарная, выездная

Форма (формы) проведения практики дискретная

# 2. Место практики в структуре образовательной программы

Производственная практика « Quality control of medicines » входит в Блок « С.2 » образовательной программы по направлениям подготовки (специальностям):

Специальность: 33.05.01 Фармация

направленность Программа широкого профиля (для иностранных граждан)

# Цель практики:

The practice is aimed at expanding the theoretical knowledge gained in the educational process, expanding and consolidating practical skills and competencies for solving specific problems of the practical activity of a pharmacist-analyst in the conditions of pharmacies, control and analytical laboratories, laboratories of the quality control department of pharmaceutical production, to acquire and consolidate the experience of independent work.

# Задачи практики:

The objectives of the discipline "quality control of medicines" are:

- familiarization with the organization and technical equipment of the workplace pharmacist-analyst;
- carrying out quality control of pharmaceutical forms of manufacture and factory production under the direction of the pharmacist analyst and registration of the relevant documentation.

# 3. Перечень планируемых результатов обучения

В результате прохождения практики **Quality control of medicines** у обучающегося должны быть сформированы следующие компетенции:

- 33.05.01 Фармация (направленность : Программа широкого профиля (для иностранных граждан))
- **ОПК.17** способность действовать в нестандартных ситуациях, нести социальную и этическую ответственность за принятые решения
- **ПК.1** способность к обеспечению контроля качества лекарственных средств в условиях фармацевтических организаций
- **ПК.10** способность к проведению экспертизы лекарственных средств с помощью химических, биологических, физико-химических и иных методов
- **ПК.12** способность к проведению контроля качества лекарственных средств в условиях фармацевтических организаций
- **ПК.17** способность к организации контроля качества лекарственных средств в условиях фармацевтических организаций
- **ПК.2** способность к проведению экспертиз, предусмотренных при государственной регистрации лекарственных препаратов
- **ПК.8** готовность к своевременному выявлению фальсифицированных, недоброкачественных и контрафактных лекарственных средств

# 4. Содержание и объем практики, формы отчетности

This type of practice strengthens knowledge and skills in the field of research of physical and chemical properties of drugs, methods of their analysis. In production pharmacies, a specialist in the field of pharmaceutical chemistry carries out intra-pharmacy quality control of drugs, and in pharmaceutical enterprises controls the quality of pharmaceutical forms of factory production, pharmacists-analysts work in the centers of certification and quality control of drugs, in testing laboratories, research institutes dealing with the quality control of drugs and the search for new drugs. Compliance of medicines to the required level of quality is established using the methods of analysis prescribed in state standards (state Pharmacopoeia).

Направления подготовки	33.05.01 Фармация (направленность: Программа широкого		
	профиля (для иностранных граждан))		
форма обучения	очная		
№№ триместров,	14		
выделенных для			
прохождения практики			
Объем практики (з.е.)	6		
Объем практики (ак.час.)	216		
Форма отчетности	Экзамен (14 триместр)		

Примерный график прохождения практики

Количество часов	Содержание работ	Место проведения	
	• •	<u> </u>	
Study of the	regulatory framework		
116	Discipline provides a systematic view of the regulatory framework	Pharmaceutical company	
	that ensures proper quality control of drugs	"Medisorb", Department of	
		chemistry, Perm state	
		University	
Federal l	aw on medicines		
10	The role of the Federal law on the quality of medicines for the	Pharmaceutical company	
	work of the pharmacist	"Medisorb", Department of	
		chemistry, Perm state	
		University	
Typical 1	professional and job requirements for the pharmacist engaged in qua	ality control of medicines	
manufactured in pharmacies (Appendix 2 to the order of the Ministry of health of the Russian Federation №			
214 from 16.	1		
10	The role of standard professional and job requirements for the	Pharmaceutical company	
	pharmacist engaged in quality control of medicines manufactured	"Medisorb", Department of	
	in pharmacies, for its practical activities	chemistry, Perm state	
		University	
Regulation	ons on control and analytical laboratory (Center for quality control	· · · · · · · · · · · · · · · · · · ·	
10	Knowledge of the structure and function of the control and	Pharmaceutical company	
	analytical laboratory for the control and quality of medicines	"Medisorb", Department of	
		chemistry, Perm state	
		University	
Order No. 214 and instructions of the Ministry of health of the Russian Federation on quality control of			
order 1.0. 21 , and insurations of the filmony of health of the reasonal federation on quarty control of			

Количество часов	Содержание работ	Место проведения
medicines ma	nufactured in pharmacies	
10	Knowledge of the order No. 214 and the instruction of MOH of the Russian Federation about quality control of the medicines made in drugstores for practical activity of the pharmacist.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
_	ry documentation for quality control and storage of drugs and dosag facture of pharmacies liquid, sterile and other dosage forms	ge forms and sanitary regime
8	Knowledge of regulatory documentation for quality control and storage of medicines and dosage forms and sanitary regime for the manufacture of pharmacies liquid, sterile and other dosage forms for the practical activities of the pharmacist.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
	ry documentation for quality control and storage of medicines and ce standards of deviations allowed in the manufacture of medicines a	
8	Knowledge of regulatory documents on quality control and storage of medicines and dosage forms and sanitary regime: on the norms of deviations allowed in the manufacture of medicines and packaging of industrial products in pharmacies for the practical activities of the pharmacist.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
	ry documentation on quality control and storage of medicines and d	
regime: on th	e organization of storage in pharmacies of various groups of medici Knowledge of regulatory documents on quality control and storage of medicines and dosage forms and sanitary regime: on the organization of storage in pharmacies of various groups of medicines and medical products for the practical activities of the pharmacist.	Pharmaceutical company
Regulato mode pharma	ry documentation quality control and storage of drugs and dosage for acies	orms and health mode health
8	Knowledge of normative documentation on quality control and storage of medicines and dosage forms and sanitary regime: on sanitary regime of pharmacy institutions for practical activity of pharmacist.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
	ve documentation on quality control and storage of medicines and d	<del>-</del>
regime: on sh	Knowledge of regulatory documentation on quality control and storage of medicines and dosage forms and sanitary regime: on shelf life, storage conditions, sterilization regimes of medicines produced in pharmacies; type for the practical activities of the pharmacist.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Normativ	ye documentation on quality control and storage of medicines and d	osage forms and sanitary
	ets, accounting and storage of narcotic and psychotropic drugs	
8	Knowledge of regulatory documents on quality control and storage of medicines and dosage forms and sanitary regime: on lists, accounting and storage of narcotic and psychotropic drugs for the practical activities of the pharmacist.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University

Количество часов	Содержание работ	Место проведения
	ry documentation for quality control and storage of medicines and of e rules of prescribing and registration for release of medicines manual	
8	Knowledge of regulatory documentation on quality control and storage of medicines and dosage forms and sanitary regime: on the rules of prescribing and registration for release of medicines manufactured in pharmacies, etc.for the practical activities of the pharmacist.	Pharmaceutical company
	ry documentation for quality control and storage of medicines and of and fire safety instructions, recommendations for rational organizations.	
20	Knowledge of regulatory documentation for quality control and storage of medicines and dosage forms and sanitary regime: safety and fire safety instructions, recommendations for the rational organization of a group of Prov for the practical activities of the pharmacist.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
	f the General structure of the analytical office (analytical table), its	
100	emical utensils, the connection of the analytical office with all department of the analytical office.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
issuing certif 10	ns of "Description", "Packaging", "Marking", as well as control of the icates  Control of drug acceptance in the pharmacy Department.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Familiari	zation with the storage conditions and compliance with the shelf lif	· ·
10	Storage of drugs in the pharmacy Department.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
	elopment responsibilities of the pharmacist-analyst to check the state	
10	ect Assembly, cleanliness of ponds and pipettes) and the quality of Requirements for the cleanliness of dishes in the practical activities of the pharmacist.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
	the analytical office documentation (logs of analyses, reports, proto	ocols, etc.)
10	Documentation of the analytical office.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
_	ment of all types of intra-pharmacy control and keeping logs of contact and the pharmacy	trol results provided for the

Количество	Содержание работ	Место проведения	
часов	Содержиние риссі	тисето проведения	
10	The condition monitoring of in-store preparing of journals	Pharmaceutical company	
		"Medisorb", Department of	
		chemistry, Perm state	
		University	
Pharmac	opoeia analysis of purified water, chemical and pharmaceutical pre	parations of inorganic and	
organic natu	re, finished dosage forms (tablets, solutions for injections, eye drops	s, ointments, etc.) according to	
the methods	of GF, FS, VF		
10	Water quality control in pharmacy departments.	Pharmaceutical company	
		"Medisorb", Department of	
		chemistry, Perm state	
		University	
Express analysis of dosage forms withdrawn from pharmacies (powders, mixtures, ointments, eye drops,			
injection solu	utions, alcohol solutions, etc.).)		
20	Quality control of dosage forms.	Pharmaceutical company	
		"Medisorb", Department of	
		chemistry, Perm state	
		University	
Analysis of medicinal plant raw materials, extraction preparations (tinctures, extracts, etc.)			
20	Quality control of dosage forms obtained by extraction.	Pharmaceutical company	
		"Medisorb", Department of	
		chemistry, Perm state	
		University	

# 5. Перечень учебной литературы, необходимой для проведения практики

# Основная

1. Ali R. Rajabi-Siahboomi Multiparticulate Drug Delivery. Formulation, Processing and Manufacturing. Controlled Release Society, 2017. Online ISBN 978-1-4939-7012-4. Текст электронный //: https://link.springer.com/book/10.1007/978-1-4939-7012-4#toc https://link.springer.com/book/10.1007/978-1-4939-7012-4

# Дополнительная

1. Yvonne Bouwman-Boer, V'Iain Fenton-May, Paul Le Brun Practical Pharmaceutics. An International Guideline for the Preparation, Care and Use of Medicinal Products. KNMP and Springer International Publishing Switzerland 2015. Online ISBN 978-3-319-15814-3. Текст электронный // : https://link.springer.com/book/10.1007/978-3-319-15814-3 https://link.springer.com/book/10.1007/978-3-319-15814-3

# 6. Перечень ресурсов сети «Интернет», требуемых для проведения практики

Для проведения практики использование ресурсов сети «Интернет» не предусмотрено.

# 7. Перечень информационных технологий, используемых при проведении практики

Образовательный процесс по практике **Quality control of medicines** предполагает использование следующего программного обеспечения и информационных справочных систем:

On-line access to the Electronic library system (EBS)

access to the electronic information and educational environment of the University;

Internet services and electronic resources (search engines, e-mail, professional thematic chats and forums, audio and video conferencing systems, online encyclopedias, etc.).

The list of necessary licensed and (or) freely distributed software:

- 1. The application allows you to view and play media content PDF-files "Adobe Acrobat Reader DC".
- 2. Programs, video demonstrations (player) "Windows Media Player".
- 3. The program of browsing Internet content (a browser) "Google Chrome".
- 4.Office Suite of applications "LibreOffice".

При освоении материала и выполнения заданий по дисциплине рекомендуется использование материалов, размещенных в Личных кабинетах обучающихся ЕТИС ПГНИУ (**student.psu.ru**).

При организации дистанционной работы и проведении занятий в режиме онлайн могут использоваться:

система видеоконференцсвязи на основе платформы BigBlueButton (https://bigbluebutton.org/). система LMS Moodle (http://e-learn.psu.ru/), которая поддерживает возможность использования текстовых материалов и презентаций, аудио- и видеоконтент, а так же тесты, проверяемые задания, задания для совместной работы.

система тестирования Indigo (https://indigotech.ru/).

# 8. Описание материально-технической базы, необходимой для проведения практики

Independent work-laboratory "Pharmaceutical and industrial technology" PSU and laboratory of pharmaceutical company "Medisorb", equipped with specialized equipment, premises of pharmaceutical organizations on the basis of agreements concluded between the university and these organizations. The composition of the equipment is defined in the Passport of the laboratory.

Помещения научной библиотеки ПГНИУ для обеспечения самостоятельной работы обучающихся:

- 1. Научно-библиографический отдел, корп.1, ауд. 142. Оборудован 3 персональными компьютера с доступом к локальной и глобальной компьютерным сетям.
- 2. Читальный зал гуманитарной литературы, корп. 2, ауд. 418. Оборудован 7 персональными компьютерами с доступом к локальной и глобальной компьютерным сетям.
- 3. Читальный зал естественной литературы, корп.6, ауд. 107а. Оборудован 5 персональными компьютерами с доступом к локальной и глобальной компьютерным сетям.
- 4. Отдел иностранной литературы, корп.2 ауд. 207. Оборудован 1 персональным компьютером с доступом к локальной и глобальной компьютерным сетям.
- 5. Библиотека юридического факультета, корп.9, ауд. 4. Оборудована 11 персональными компьютерами с доступом к локальной и глобальной компьютерным сетям.
  - 6. Читальный зал географического факультета, корп. 8, ауд. 419. Оборудован 6 персональными

компьютерами с доступом к локальной и глобальной компьютерным сетям.

Все компьютеры, установленные в помещениях научной библиотеки, оснащены следующим программным обеспечением:

Операционная система ALT Linux;

Офисный пакет Libreoffice.

Справочно-правовая система «КонсультантПлюс»

# 9. Методические указания для обучающихся по освоению дисциплины

Students are required to complete the internship:

- 1) observe the established work schedule and follow the instructions of the practice leaders;
- 2) daily record the results of work in the diary, certifying them with the signature of the responsible person;
- 3) in the last entry in the diary to make a summary in which to highlight the main results of the practice. In the process of practical training the student is trained:
- implementation of all types of quality control of substances and dosage forms in accordance with regulatory documents;
- the use of chromatographic, photometric and other physical and chemical methods of analysis to assess the quality of medicines (tests for authenticity, purity and quantification).

For students with disabilities and persons with disabilities on the basis of their written application the organization of practice is realized taking into account features of psychophysical development, individual opportunities and health status of students. This ensures compliance with the following General requirements: use of special technical means of training collective and individual use, provision of services of the assistant rendering such learner needs technical assistance, convenient access to buildings and premises where practices are held, other conditions without which it is impossible or difficult passing practice.

Choice of places of practice for disabled people and persons with disabilities it is made taking into account the requirements of accessibility for students and recommendations medical and social expertise reflected in the individual rehabilitation program invalid's. At the direction of the disabled person or the person with HIA in the organization, on the enterprise for the head agrees with the enterprise on passing of industrial practice conditions of its passing and types of activity taking into account recommendations medico-social examination and individual rehabilitation program of the disabled person.

For the development of the theoretical part of the practice of the disabled and persons with disabilities health opportunities are provided the opportunity to use electronic technologies, remote mastering of material by providing tasks and their control through the Internet, as well as individual consultations with the application of both e-mail, and visual communication using "Skype".

When performing the experimental part of the practice as needed additional means of protection are provided, individual assistance is provided training and support personnel, as well as other activities taking into account nosologies diseases of students.

Format of protection of practice reports for persons with disabilities and persons with disabilities it is established taking into account their individual psychophysical features (orally, in writing, using electronic or other technical means). In the process of protection the student with HIA has the right to use the necessary technical means.

For the visually impaired, a portable video magnifier may be provided, possibly using your own devices. For deaf and hard of hearing students can be the sound amplifying equipment is presented, it is possible to use the equipment individual use. At the request of a student with HIA in the process of protecting the report on in practice, the presence of an assistant can be provided to assist the student the necessary technical assistance, taking into account its individual characteristics. By if necessary, persons with disabilities and persons with disabilities may be granted additional time preparation of replies in the reports of the practice.

The reporting document is the practice diary, which the student compiles together with the head from the base,

guided by the practice program of the diary.	. Every day one hour of the s	tudent's working time is allo	otted for the registration

# Фонды оценочных средств для проведения промежуточной аттестации

# Планируемые результаты обучения по дисциплине для формирования компетенции и критерии их оценивания

Компетенция	Планируемые результаты обучения	Критерии оценивания результатов обучения
ОПК.17 способность действовать в нестандартных ситуациях, нести социальную и этическую ответственность за принятые решения	To know: regulatory documents regulating the production and quality of medicines in pharmacies and pharmaceutical enterprises. To be able to: form a conclusion about the quality of drugs. To posses: b methods necessary for assessing the quality of medicines.	Неудовлетворительно The student is not able to assess the quality of medicines  Удовлетворительно The student is able to assess the quality of medicines, but the assessment is not complete enough  Хорошо The student is able to assess the quality of drugs, but the assessment is not fully complete  Отлично The student is able to assess the quality of
ПК.12 способность к проведению контроля качества лекарственных средств в условиях фармацевтических организаций	To know: fundamentals of analysis and evaluation of the quality of medicines. To be able to: produce quality control of drugs in pharmaceutical companies. To posses: methods of analysis and evaluation of the quality of medicines.	medicinesНеудовлетворительноThe student is not able to control the quality of medicines.УдовлетворительноThe student is able to control the quality of
ПК.10 способность к проведению экспертизы лекарственных средств с помощью химических, биологических, физикохимических и иных методов	To know: the basics of chemical, biological, physico-chemical and other methods necessary for the examination of medicines. To be able to: carry out the examination of medicines using chemical, biological, physico-chemical and other methods. To posses: chemical, biological, physico-	Неудовлетворительно The student is not able to conduct an examination of medicines Удовлетворительно The student is able to conduct an examination of medicines, but has little knowledge of chemical, biological, physico-chemical and other methods Хорошо The student is able to conduct an examination of

ПК.8 готовность к своевременному выявлению фальсифицированных, недоброкачественных и контрафактных лекарственных средств	chemical and other methods necessary for the examination of medicines.  To know: methods for assessing the quality of medicines, factors affecting the quality of medicines, conditions of treatment of medicines depending on their nature; To be able to: monitor compliance with the storage conditions of medicines, necessary excipients; in case of detection of substandard medicines, to register the results of the analysis, to identify the causes and take measures to eliminate deficiencies in the manufacture of medicines; To possess: methods for assessing the quality of medicines, the skills to establish the authenticity of the structure and purity using physical	Жорошо medicines, but does not fully know the chemical, biological, physico-chemical and other methods  Отлично The student is able to conduct an examination of medicines  Неудовлетворительно The student is not able to assess the quality of the drug.  Удовлетворительно The student is able to assess the quality of medicines, but there are difficulties with the interpretation of the data of physical and chemical analysis methods.  Хорошо The student is able to assess the quality of medicines, interpret the data of physical and chemical analysis methods, choose measures to eliminate deficiencies in the manufacture of medicines. Minor mistakes, inaccuracies, which are corrected after the comments of the teacher.  Отлично The student is able to assess the quality of medicines at a high level: owns the methods of quality assessment, knows the factors affecting
<b>ПК.1</b> способность к	To know: methods for assessing the quality of medicines, factors	nature, is able to interpret the data of physical and chemical analysis methods, choose measures to eliminate deficiencies in the manufacture of medicines. <b>Неудовлетворительно</b> The student is not able to analyze the quality of
обеспечению контроля качества лекарственных средств в условиях фармацевтических организаций	affecting the quality of medicines in the synthesis, preparation and storage of medicines.  To be able to: analyze solvents, excipients used for the preparation of dosage forms, pharmaceutical substances. In case of detection of substandard dosage forms to carry out registration of the analysis.	<b>Хорошо</b> The student is able to analyze the quality of medicines, but there are difficulties with the registration of substandard dosage forms.
	To possess: skills in assessing the quality of medicinal products, planning of analysis skills and complete the documentation on the quality control of medicines.	<b>Отлично</b> The student is able to analyze the quality of medicines, analyze solvents, excipients used for the preparation of dosage forms, pharmaceutical substances. The student reasonably plans the

### ПК.2

способность к проведению экспертиз, предусмотренных при государственной регистрации лекарственных препаратов To know: methods of qualitative and quantitative analysis of drugs, the chemical reactions underlying these methods, the list and principle of the equipment necessary for the examination, the requirements for reagents for testing for purity, authenticity and quantification.

To be able to: work on measuring instruments (pharmacy and analytical scales, photocolorimeter, Refractometer, spectrophotometer, etc.), plan and analyze drugs, interpret the results of the analysis of drugs to assess their quality.

To possess: skills of analysis of purified water and water for injection, components of dosage forms.

### Отлично

analysis, is able to maintain documentation on quality control of medicines.

# **Неудовлетворительно**

The student is not able to carry out the examination of medicines in accordance with the requirements of the state registration of medicines

# **Удовлетворительно**

The student is able to use the measuring equipment for the examination of medicines, owns the methods of qualitative and quantitative analysis. It is difficult to interpret the results of the analysis.

# Хорошо

The student is able to use the measuring equipment for the examination of medicines, owns the methods of qualitative and quantitative analysis. Able to interpret the results of the analysis, there are difficulties in preparing a report for state registration. Minor mistakes are made, which are eliminated with the help of additional questions of the teacher.

### Отлично

The student is able to carry out the examination of medicines in accordance with the requirements of the state registration of medicines.

### ПК.17

способность к организации контроля качества лекарственных средств в условиях фармацевтических организаций To know: the principles of working with laboratory equipment and utensils, methods of analysis of quality control of medicines.

To be able to: work on measuring instruments (pharmacy and analytical scales, photocolorimeter, Refractometer, spectrophotometer, etc.), plan and analyze drugs, interpret the results of the analysis of drugs to assess their quality.

To possess: the skills of the organization of analysis to assess the quality of medicines, reporting on the work of the pharmacy table, monitoring compliance with the conditions of storage and manufacture of medicines.

# Неудовлетворительно

The student is not able to organize quality control of medicines.

# Удовлетворительно

The student is able to carry out quality control of medicines, but there are difficulties with planning the analysis and reporting on the work of the pharmacy table.

### Хорошо

The student is able to carry out quality control of medicines, plan analysis and make a report on the work of the pharmacy table, prepare and evaluate the quality of auxiliary components for the manufacture of medicines. Minor errors were made in the interpretation of the results of the analysis of drugs, which are eliminated with the help of additional questions from the teacher.

### Отлично

The student is able to carry out quality control of

Отлично
medicines, to plan the analysis and make a
report on the work of the pharmacy table, to
prepare and evaluate the quality of auxiliary
components for the manufacture of medicines,
to interpret the results of the analysis of
medicines. All stages of planning, analysis and
reporting are justified and reasoned.

# Оценочные средства

Вид мероприятия промежуточной аттестации: Экзамен

Способ проведения мероприятия промежуточной аттестации: Защищаемое контрольное

мероприятие

Продолжительность проведения мероприятия промежуточной аттестации:

время отводимое на доклад .5

# Показатели оценивания

The student did not attend the practice or not issued internship journal and wrote	Неудовлетворительно
the report.	
The internship journal and its report are not issued according to the criteria, the	Удовлетворительно
student does not answer the questions or refuses oral defense during the defense of	
the work.	
the protection of In the internship journal and the report on it is issued in	Хорошо
accordance with the criteria, but the student does not answer all the questions.	
Practice diary and report on it is made in accordance with the criteria, the student	Отлично
answers all questions.	