

МИНОБРНАУКИ РОССИИ

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

Кафедра фармакологии и фармации

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Программа учебной практики

**GROUP PROJECT WORK (PRACTICE IN GENERAL PHARMACEUTICAL
TECHNOLOGY)**

Код УМК 94563

Утверждено
Протокол №1
от «10» сентября 2021 г.

Пермь, 2021

1. Вид практики, способ и форма проведения практики

Вид практики **учебная**

Тип практики **практика по общей фармацевтической технологии**

Способ проведения практики **стационарная, выездная**

Форма (формы) проведения практики **дискретная**

2. Место практики в структуре образовательной программы

Учебная практика « Group project work (Practice in general pharmaceutical technology) » входит в обязательную часть Блока « С.2 » образовательной программы по направлениям подготовки (специальностям):

Специальность: **33.05.01** Фармация

направленность Программа широкого профиля (для иностранных граждан)

Цель практики :

The purpose of Practice in general pharmaceutical technology is to develop and consolidate the professional competencies necessary for the practical work of a pharmacist in the field of production and quality control of finished dosage forms (FDF). Consolidation of theoretical knowledge and practical skills obtained in the study of pharmaceutical technology of pharmaceutical products in industrial production.

Задачи практики :

Tasks of practice:

- 1) get an idea about the work of the main and auxiliary shops of the pharmaceutical enterprise;
- 2) get acquainted with the order of input control of raw materials, auxiliary materials, reagents;
- 3) to study the technological instructions for the production of medicines;
- 4) get acquainted with the main processes and devices of pharmaceutical technology of industrial drugs;
- 5) to study the technology, processes and equipment used in the production of finished dosage forms and master the main sections of the industrial regulations for the production of medical products;
- 6) to study normative documents on system of preparation of water for the production purposes, air preparation and certification of clean rooms, on preparation of the personnel for work in rooms of classes of purity D, C and B.
- 7) learn to justify the rational technology of dosage forms of industrial production, to study the requirements for packaging of finished products, storage conditions of FDF.

3. Перечень планируемых результатов обучения

В результате прохождения практики **Group project work (Practice in general pharmaceutical technology)** у обучающегося должны быть сформированы следующие компетенции:

33.05.01 Фармация (направленность : Программа широкого профиля (для иностранных граждан))

ПК.2 Способен к осуществлению технологических процессов при изготовлении лекарственных препаратов в условиях аптечных организаций

Индикаторы

ПК.2.1 Готовит лекарственные препараты по рецептам и требованиям в условиях аптечных организаций

УК.2 Способен управлять проектом, организовывать и руководить работой команды

Индикаторы

УК.2.3 Разрабатывает мероприятия по реализации проекта на разных этапах его жизненного цикла, вносит корректировки в ходе реализации проекта

УК.4 Способен анализировать и учитывать разнообразие культур в их социально-историческом и философском аспектах в процессе социального взаимодействия

Индикаторы

УК.4.3 Воспринимает социальные, этические, конфессиональные и культурные различия

УК.4.4 Выстраивает социальное взаимодействие с учетом культурных различий

УК.9 Способен использовать базовые дефектологические знания в социальной и профессиональной сферах

Индикаторы

УК.9.3 Выстраивает профессиональное взаимодействие с лицами, имеющими психофизиологические особенности, с учетом нозологии

4. Содержание и объем практики, формы отчетности

Discipline gives systemic ideas about working methods and principles of pharmaceutical business organization at its various stages

Направления подготовки	33.05.01 Фармация (направленность: Программа широкого профиля (для иностранных граждан))
форма обучения	очная
№№ триместров, выделенных для прохождения практики	12
Объем практики (з.е.)	3
Объем практики (ак.час.)	108
Форма отчетности	Экзамен (12 триместр)

Примерный график прохождения практики

Количество часов	Содержание работ	Место проведения
Organizational and methodological briefing		
12	A detailed acquaintance with the regulatory documentation for the design and validation of pharmaceutical production (GMP, GLP, GCP). Acquaintance with industry standards (OST) for the compilation of quality indicators of drugs and the development of skills in the examination of FA and FAE projects. Acquisition of skills in the preparation and examination of draft production regulations (LR, PIR, IR)	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Industrial production of drugs. Regulatory documentation for the pharmaceutical industry		
28	Organization of industrial production of medicines in accordance with the requirements of GMP. Environmental aspects of the organization of pharmaceutical production. Normative documentation regulating the production and quality control of finished medicines. Quality standards for drugs (RP monograph, Manufacturer's monograph, Technical conditions), laboratory, pilot, industrial regulations, technological instructions. Drawing up technological and apparatus production schemes.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
The structure of the pharmaceutical company. The technological process of production. Validation Quality control		
28	Pharmaceutical manufacturing enterprise. The structure of enterprises, the workshop principle of the organization of production of drugs. The technological process and its components. Stages and operations of the technological process. Production control. Validation (certification). Quality Control Department and Quality Assurance Department. Functions Material balance. Technological output, waste, expense ratio and expense rates. The decision of settlement problems.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Development of normative documents at a pharmaceutical enterprise		

Количество часов	Содержание работ	Место проведения
28	Development of regulatory documentation for the drug. Development of a draft industrial production regulation.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Certification on the basis of practice		
12	The structure and nature of filling the diary of a practice report.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University

5. Перечень учебной литературы, необходимой для проведения практики

Основная

1. Marianthi G. Ierapetritou, Rohit Ramachandran Process Simulation and Data Modeling in Solid Oral Drug Development and Manufacture. Springer Science+Business Media, New York, 2016. Online ISBN 978-1-4939-2996-2. Текст электронный // : <https://link.springer.com/book/10.1007/978-1-4939-2996-2#toc>
<https://link.springer.com/book/10.1007/978-1-4939-2996-2>

2. Yvonne Bouwman-Boer, V'lain 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>

Дополнительная

1. Richard S. Larson Bioinformatics and Drug Discovery. Humana Press, 2006. Online ISBN 978-1-59259-964-6. Текст электронный // : <https://link.springer.com/book/10.1385/1592599648#toc>
<https://link.springer.com/book/10.1385/1592599648>

2. Ali R. Rajabi-Siahboomi. Multiparticulate Drug Delivery. Formulation, Processing and Manufacturing. Controlled Release Society / Ali R. Rajabi-Siahboomi // Publisher Name: Springer, New York, NY. — 2017. — 396 p. — ISBN 978-1-4939-7012-4. — Текст : электронный // Электронно-библиотечная система SpringerLink : [сайт]. <https://link.springer.com/book/10.1007/978-1-4939-7012-4>

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

При прохождении практики требуется использование следующих ресурсов сети «Интернет» :

www.iprbookshop.ru Электронно-библиотечная система

www.roszdravnadzor.ru Федеральная служба по надзору в сфере здравоохранения

www.iprbookshop.ru Электронно-библиотечная система IPRbooks

7. Перечень информационных технологий, используемых при проведении практики

Образовательный процесс по практике **Group project work (Practice in general pharmaceutical technology)** предполагает использование следующего программного обеспечения и информационных справочных систем:

Presentation materials (slides on the topics of lecture and practical classes).

On-line access to the Electronic Library System (EDS).

Access to the electronic informational and educational environment of the university;

Testing.

The list of necessary licensed and (or) free software:

1. Office suite of applications "LibreOffice".

2. An application that allows you to view and play media content of PDF files "Adobe Acrobat Reader DC".

3. Programs, demonstrations of video materials (player) "WindowsMediaPlayer".

4. The program for viewing Internet content (browser) "Google Chrome".

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

1. Lectures - an Audience equipped with presentation equipment (projector, screen, computer / laptop) with the appropriate software.

2. Seminar type classes (seminars, practical classes) - an Audience equipped with presentation equipment (projector, screen, computer/laptop) with appropriate software, chalk (s) or marker Board.

3. Laboratory classes - laboratory "Pharmaceutical technology", equipped with specialized equipment. The composition of the equipment is defined in the Passport of the laboratory.

4. Independent work-the Audience for independent work, equipped with computer equipment with the ability to connect to the Internet, provided with access to the electronic information and educational environment of the University.

Premises of the Scientific library PSU.

Помещения научной библиотеки ПГНИУ для обеспечения самостоятельной работы обучающихся:

1. Научно-библиографический отдел, корп.1, ауд. 142. Оборудован 3 персональными компьютерами 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

Educational practice is carried out in accordance with the contract, which is concluded between the University and the enterprise.

Students must perform the tasks provided by the program of practice; study and strictly observe the rules of labor protection and safety during the tour to the basic enterprises

The reporting document is a diary of practice, which the student makes together with the head of the base, guided by the program of practice.

Current control of students is carried out in the following forms:

recording of visits; interview on individual tasks / practical (course) works, including problem solving, calculations.

Intermediate certification at the end of practice is made in the following form:

the credit in the form of individual interview on questions to offset is handed over, the reporting document – diary is checked.

For students with disabilities and persons with disabilities on the basis of their written application, the organization of practice is implemented taking into account the peculiarities of psychophysical development, individual capabilities and health of students. This ensures compliance with the following General requirements:

the use of special technical means of training

collective and individual use, providing the services of an assistant, providing such a student with the necessary technical assistance, providing convenient access to the buildings and premises where practices are held, other conditions without which it is impossible or difficult to pass the practice. The choice of places of practice for the disabled and persons with disabilities is made taking into account the requirements of accessibility for students and recommendations of medical and social expertise reflected in the individual rehabilitation program of the disabled person. At the direction of the disabled person or person with disabilities in the organization, to the enterprise industry internship supervisor negotiates with the company the terms of its passage and activities taking into account the recommendations of the medico-social assessment and individual program of rehabilitation of the disabled. To master the theoretical part of the practice, disabled people and persons with disabilities are given the opportunity to use electronic technologies, remote mastering of the material by providing tasks and their control over the Internet, as well as individual consultations using both e-mail and visual communication using "Skype". When performing the experimental part of the practice, additional means

of protection are provided as necessary, individual assistance of educational and support personnel is provided, as well as other measures taking into account the nosologies of the disease of students. The format of the protection of practice reports for persons with disabilities and persons with disabilities is established taking into account their individual psychophysical characteristics (orally, in writing, using electronic or other technical means). In the course of protection of the report on practice the student with disabilities has the right to use technical means necessary for it. For the visually impaired, a portable video magnifier can be provided, it is possible to use your own devices. For deaf and hard of hearing students can be presented sound amplifying equipment, it is possible to use equipment for individual use. At the request of a student with disabilities in the process of protection of the report on practice, the presence of an assistant can be provided, providing the student with the necessary technical assistance, taking into account his individual characteristics. If necessary, persons with disabilities and persons with disabilities may be given additional time to prepare responses when defending practice reports.

Фонды оценочных средств для проведения промежуточной аттестации

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

ПК.2

Способен к осуществлению технологических процессов при изготовлении лекарственных препаратов в условиях аптечных организаций

Компетенция	Планируемые результаты обучения	Критерии оценивания результатов обучения
<p>ПК.2.1 Готовит лекарственные препараты по рецептам и требованиям в условиях аптечных организаций</p>	<p>Know: technology, theoretical and regulatory framework for the manufacture of medicines according to prescriptions and requirements in the conditions of pharmacy organizations. Be able to: produce all kinds of dosage forms in the pharmacy. Own: skills of manufacturing and control of dosage forms in the pharmacy.</p>	<p style="text-align: center;">Неудовлетворительно</p> <p>Knowledge is unsystematic, fragmentary. The answers made gross, fundamental mistakes. Difficulties in understanding the technology of manufacturing drugs according to prescriptions and requirements in the conditions of pharmacy organizations. Difficulties and mistakes are not eliminated after leading questions of the teacher.</p> <p style="text-align: center;">Удовлетворительно</p> <p>Knowledge of the main provisions of the program. The answer is not complete, without justification and explanation. Poor knowledge of manufacturing technology of medicines according to prescriptions and requirements in the conditions of pharmacy organizations. Errors are eliminated by additional questions of the teacher.</p> <p style="text-align: center;">Хорошо</p> <p>Full knowledge of the training material provided by the program, successful completion of all tasks provided by the forms of current control. The answer is justified, reasoned. Minor errors, inaccuracies, which are corrected after the comments of the teacher.</p> <p style="text-align: center;">Отлично</p> <p>Comprehensive in-depth knowledge of manufacturing technology of medicines according to prescriptions and requirements in the conditions of pharmacy organizations. The answer is justified, reasoned.</p>

УК.4

Способен анализировать и учитывать разнообразие культур в их социально-историческом и философском аспектах в процессе социального взаимодействия

<p>УК.4.3 Компетенция Воспринимает социальные, этические, конфессиональные и культурные различия</p>	<p>Планируемые результаты обучения Know: the main characteristics of the team, its features, ethical standards and principles of business communication; features of interaction with other people to solve professional problems, taking into account their social, ethical, religious and cultural differences. Be able to: build and maintain working relationships with team members; to tolerate diversity and social, cultural, ethical, confessional differences. Own: psychological methods of professional communication.</p>	<p>Критерии оценивания результатов обучения Неудовлетворительно The student is not able to effectively interact and communicate with colleagues, management and consumers. The student is not able to tolerate representatives of social, cultural and religious communities. Удовлетворительно The student is able to interact and communicate with colleagues, management and consumers, but has little knowledge of psychological methods of professional communication with representatives of social, cultural and religious communities. Хорошо The student is able to build and maintain working relationships with team members; to perceive diversity and social, cultural, ethical, confessional differences, does not fully understand the concepts of peculiarities, ethical norms and principles of business communication. Отлично The student is fully able to perceive social, ethical, confessional and cultural differences when interacting with other people to solve professional problems.</p>
<p>УК.4.4 Выстраивает социальное взаимодействие с учетом культурных различий</p>	<p>Know: the rules of business conversation, public speaking, the ability to find compromises taking into account cultural differences, the rules of respect for the historical heritage and cultural traditions of the people. Be able to: analyze logically and argumentatively, conduct a discussion among colleagues, conduct trainings, conferences, presentations taking into account cultural differences; take care of the historical heritage and cultural traditions of the people; Own: skills of conflict resolution, establishing a microclimate in the team; experience of interaction in the team and the team; skills of building social interaction taking into account cultural differences.</p>	<p>Неудовлетворительно The student is not able to build social interaction taking into account cultural differences. The student does not know the rules of business conversation, public speaking, is not able to find compromises taking into account cultural differences, does not know the rules of respect for the historical heritage and cultural traditions of the people. Удовлетворительно The student is able to interact and communicate with colleagues, management and consumers, but does not take into account the historical heritage and cultural traditions of the interlocutors. Хорошо The student is able to build and maintain working relationships with team members; conduct discussions among colleagues, conduct trainings, conferences, presentations, does not fully possess the skills of building social interaction taking into account cultural</p>

		<p>Хорошо differences.</p> <p>Отлично The student is fully able to build social interaction taking into account cultural differences, takes care of the historical heritage and cultural traditions of the people.</p>
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УК.9

Способен использовать базовые дефектологические знания в социальной и профессиональной сферах

Компетенция	Планируемые результаты обучения	Критерии оценивания результатов обучения
<p>УК.9.3 Выстраивает профессиональное взаимодействие с лицами, имеющими психофизиологические особенности, с учетом нозологии</p>	<p>Knows the methods of organizing joint and individual activities with persons with psychophysiological characteristics, taking into account nosology.</p> <p>Able to apply methods of organizing joint and individual activities with persons with psychophysiological characteristics, taking into account nosology.</p> <p>Owms methods of organizing joint and individual activities with persons with psychophysiological characteristics, taking into account nosology.</p>	<p>Неудовлетворительно The student is not able to effectively interact and communicate with persons with psychophysiological characteristics. The student is not able to tolerate persons with psychophysiological characteristics, taking into account nosology.</p> <p>Удовлетворительно The student is able to interact and communicate with persons with psychophysiological characteristics, but has little command of the psychological methods of professional communication, methods of organizing joint and individual activities with them.</p> <p>Хорошо The student is able to build and maintain working relationships with persons with psychophysiological characteristics; does not fully own the psychological methods of professional communication, methods of organizing joint and individual activities with them.</p> <p>Отлично The student is fully able to build and maintain working relationships with persons with psychophysiological characteristics, taking into account nosology; fully owns the psychological methods of professional communication, methods of organizing joint and individual activities with them.</p>

УК.2

Способен управлять проектом, организовывать и руководить работой команды

<p>УК.2.3 Компетенция Разрабатывает мероприятия по</p>	<p>Планируемые результаты обучения To know: the main methods of project implementation at different stages of its life cycle;</p>	<p>Критерии оценивания результатов обучения Неудовлетворительно The student is not able to develop activities for the implementation of the project at different</p>
<p>реализации проекта на разных этапах его жизненного цикла, вносит корректировки в ходе реализации проекта</p>	<p>modern theoretical and experimental methods for the implementation of own and borrowed results of scientific research. Be able to: implement the project and make adjustments in the course of the project; identify the main patterns of the studied objects, predict new unknown patterns. Own: methods of project implementation at different stages of its life cycle.</p>	<p>stages of its life cycle, to make adjustments during the implementation of the project. The student is not able to carry out a quick and accurate search and use the necessary information on pharmaceutical activities, regulatory documents. Удовлетворительно The student is able to develop measures for the implementation of the project at different stages of its life cycle, but has little knowledge of the methods of its adjustment during implementation. Хорошо The student is able to develop measures for the implementation of the project at different stages of its life cycle, does not fully know the methods of its adjustment in the course of implementation. Отлично The student is fully able to develop activities for the implementation of the project at different stages of its life cycle, to make adjustments during the implementation of the project. The student is able to carry out a quick and accurate search and use the necessary information on pharmaceutical activities, regulatory documents.</p>

Оценочные средства

Вид мероприятия промежуточной аттестации : Экзамен

Способ проведения мероприятия промежуточной аттестации : Защищаемое контрольное мероприятие

Продолжительность проведения мероприятия промежуточной аттестации :
время отводимое на доклад 2

Показатели оценивания

<p>The student did not come to practice or did not draw up a practice diary and did not write a report.</p>	<p>Неудовлетворительно</p>
<p>The practice diary and the report on it are not drawn up in accordance with the criteria; when defending the work, the student does not answer asked questions or refuses oral protection.</p>	<p>Удовлетворительно</p>
<p>The practice diary and the report on it are not drawn up in accordance with the criteria; when defending the work, the student does not answer asked questions or refuses oral protection</p>	<p>Хорошо</p>

The practice diary and the report on it are designed in accordance with the criteria, while protecting the work, the student answers all questions asked.

Отлично