МИНОБРНАУКИ РОССИИ

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

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Программа производственной практики

QUALITY CONTROL OF MEDICINES

Код УМК 93098

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

Пермь, 2020

1. Вид практики, способ и форма проведения практики

Вид практики **производственная**
Тип практики **практика по контролю качества лекарственных средств**
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 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 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))

ПК.1 Способен к обеспечению и проведению контроля качества лекарственных средств в условиях фармацевтических организаций

Индикаторы

ПК.1.2 Проводит анализ фармацевтических субстанций и лекарственных препаратов в соответствии с установленными требованиями, проводит оценку лекарственных средств по внешнему виду, упаковке, маркировке, выявляет фальсифицированные и контрафактные лекарственные средства

ПК.1.3 Оформляет документацию установленного образца по приемочному контролю лекарственных средств, медицинских изделий, биологически активных добавок и других товаров аптечного ассортимента, а также по изъятию продукции из обращения

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

Индикаторы

ПК.2.2 Контролирует качество изготовленных лекарственных препаратов

УК.8 Знает правовые и этические нормы, способен оценивать последствия нарушения этих норм

Индикаторы

УК.8.2 Ориентируется в этических нормах поведения в разных видах профессиональной деятельности и последствиях их нарушения

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, выделенных для прохождения практики	14
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
Study of the regulatory framework		
116	Discipline provides a systematic view of the regulatory framework that ensures proper quality control of drugs	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Federal law on medicines		
10	The role of the Federal law on the quality of medicines for the work of the pharmacist	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Typical professional and job requirements for the pharmacist engaged in quality control of medicines manufactured in pharmacies (Appendix 2 to the order of the Ministry of health of the Russian Federation № 214 from 16.07.1997 g.)		
10	The role of standard professional and job requirements for the pharmacist engaged in quality control of medicines manufactured in pharmacies, for its practical activities	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Regulations on control and analytical laboratory (Center for quality control of medicines)		
10	Knowledge of the structure and function of the control and analytical laboratory for the control and quality of medicines	Pharmaceutical company "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		

Количество часов	Содержание работ	Место проведения
medicines manufactured 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
Regulatory documentation for quality control and storage of drugs and dosage forms and sanitary regime for the manufacture of pharmacies liquid, sterile and other dosage forms		
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
Regulatory documentation for quality control and storage of medicines and dosage forms and sanitary regime: on the standards of deviations allowed in the manufacture of medicines and packaging of industrial products in pharmacies		
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
Regulatory documentation 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		
8	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 "Medisorb", Department of chemistry, Perm state University
Regulatory documentation quality control and storage of drugs and dosage forms and health mode health mode pharmacies		
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
Normative 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		
8	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
Normative documentation on quality control and storage of medicines and dosage forms and sanitary regime: on lists, 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
Regulatory documentation for 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		
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 "Medisorb", Department of chemistry, Perm state University
Regulatory documentation for quality control and storage of medicines and dosage forms and sanitary regime: safety and fire safety instructions, recommendations for rational organization		
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
The study of the General structure of the analytical office(analytical table), its location, a set of reagents, indicators, chemical utensils, the connection of the analytical office with all departments of the pharmacy		
100	The device of the analytical office.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Development of acceptance control of drugs coming to the pharmacy for compliance with the requirements of ND in terms of "Description", "Packaging", "Marking", as well as control of the correctness of issuing and issuing certificates		
10	Control of drug acceptance in the pharmacy Department.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Familiarization with the storage conditions and compliance with the shelf life of medicines		
10	Storage of drugs in the pharmacy Department.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
The development responsibilities of the pharmacist-analyst to check the status of bureocracy system and pipettes (correct Assembly, cleanliness of ponds and pipettes) and the quality of washing dishes		
10	Requirements for the cleanliness of dishes in the practical activities of the pharmacist.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Study of the analytical office documentation (logs of analyses, reports, protocols, etc.)		
10	Documentation of the analytical office.	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Development of all types of intra-pharmacy control and keeping logs of control results provided for the pharmacist-analyst in the pharmacy		

Количество часов	Содержание работ	Место проведения
10	The condition monitoring of in-store preparing of journals	Pharmaceutical company "Medisorb", Department of chemistry, Perm state University
Pharmacopoeia analysis of purified water, chemical and pharmaceutical preparations of inorganic and organic nature, finished dosage forms (tablets, solutions for injections, eye drops, 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 solutions, 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. Every day one hour of the student's working time is allotted for the registration of the diary.

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
ПК.2.2 Контролирует качество изготовленных лекарственных препаратов	Know: the basics of analysis and evaluation of the quality of medicines, regulations governing the circulation of medicines. To be able: to carry out quality control of medicines in the conditions of pharmaceutical companies, to issue normative documents of conformity of quality. Own: methods of analysis and evaluation of the quality of medicines, methods and methods of organization of quality control of medicines at the level of production, distribution, storage.	**Неудовлетворительно** The student is not able to perform quality control of medicines. Fragmentary skills to work with Pharmacopoeia and regulatory documentation. Errors and inaccuracies of representation about methods and methods of the organization of quality control of medicines at the level of production, distribution, storage. **Удовлетворительно** The student is able to control the quality of medicines, but has little knowledge of the methods of analysis and evaluation of the quality of medicines. In General, successful, but not systematic use of the ability to work with Pharmacopoeia and regulatory documentation. Incomplete understanding of methods and methods of organization of quality control of medicines at the level of production, distribution, storage. **Хорошо** The student is able to control the quality of medicines, does not fully know the methods of analysis and evaluation of the quality of medicines. Knowledge contains some gaps in the ability to work with Pharmacopoeia and regulatory documentation, some gaps in the understanding of methods and methods of organization of quality control of medicines at the level of production, distribution, storage. **Отлично** The student is able to perform quality control of medicines. Formed systematic skills to work with Pharmacopoeia and regulatory documentation. Full understanding of methods and methods of organization of quality control of medicines at the level of production, distribution, storage.

ПК.1

Способен к обеспечению и проведению контроля качества лекарственных средств в условиях фармацевтических организаций

Компетенция	Планируемые результаты обучения	Критерии оценивания результатов обучения
ПК.1.3 Оформляет документацию установленного образца по приемочному контролю лекарственных средств, медицинских изделий, биологически активных добавок и других товаров аптечного ассортимента, а также по изъятию продукции из обращения	To know: normative and legal base of registration of documents of primary accounting at production and quality control of dosage forms, intra-apical preparation and packing of medicines; rules of registration of documentation at withdrawal of production from the address. Be able to: form a conclusion about the quality of medicines, comply with the rules of registration of documents of primary accounting, the rules of documentation for the withdrawal of products from circulation. Own: methods necessary to assess the quality of medicines, medical products, dietary supplements and other products of the pharmacy range; rules of documentation for the withdrawal of products from circulation.	**Неудовлетворительно** Knowledge is unsystematic, fragmentary. The answers made gross, fundamental mistakes. The student is not able to assess the quality of medicines, medical products, dietary supplements and other products of the pharmacy range. There is no knowledge of the legal framework for registration of documents of primary accounting and withdrawal of products from circulation. Difficulties and mistakes are not eliminated after leading questions of the teacher. **Удовлетворительно** Knowledge of the main provisions of the program. The answer is not complete, without justification and explanation. The student is able to assess the quality of medicines, medical products, dietary supplements and other products of the pharmacy range, but the assessment is not complete enough. Significant difficulties in the description of the legal framework for registration of documents of primary accounting and withdrawal of products from circulation. Errors are eliminated by additional questions of the teacher. **Хорошо** 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. The student is able to assess the quality of medicines, medical devices, dietary supplements and other products of the pharmacy range, but the assessment is not fully complete. Minor errors, inaccuracies, which are corrected after the comments of the teacher. **Отлично** Comprehensive in-depth knowledge on registration of documentation of the established sample on acceptance control of medicines,

		Отлично medical devices, biologically active additives and other goods of the pharmaceutical range, and also on withdrawal of production from the address. The student is able to assess the quality of medicines. The answer is justified, reasoned.
ПК.1.2 Проводит анализ фармацевтических субстанций и лекарственных препаратов в соответствии с установленными требованиями, проводит оценку лекарственных средств по внешнему виду, упаковке, маркировке, выявляет фальсифицированные и контрафактные лекарственные средства	Know: fundamentals of chemical, biological, physico-chemical and other methods necessary for the examination of medicines. To be able: to carry out examination of medicines by means of chemical, biological, physico-chemical and other methods. Own: chemical, biological, physico-chemical and other methods necessary for the examination of medicines.	**Неудовлетворительно** Knowledge is unsystematic, fragmentary. The answers made gross, fundamental mistakes. The student is not able to carry out the examination of medicines. Difficulties and mistakes are not eliminated after leading questions of the teacher. **Удовлетворительно** Knowledge of the main provisions of the program. The answer is not complete, without justification and explanation. The student is able to analyze pharmaceutical substances and drugs, but has little knowledge of methods of analysis and evaluation of the quality of drugs. Errors are eliminated by additional questions of the teacher. **Хорошо** 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. The student is able to make the analysis of pharmaceutical substances and drugs, but does not fully know the chemical, biological, physico-chemical and other methods. Minor errors, inaccuracies, which are corrected after the comments of the teacher. **Отлично** Comprehensive in-depth knowledge of reception of recipes (requirements) and release of dosage forms on them. The answer is justified, reasoned. The student is able to analyze pharmaceutical substances and drugs in accordance with the established requirements.

УК.8

Знает правовые и этические нормы, способен оценивать последствия нарушения этих норм

Компетенция	Планируемые результаты обучения	Критерии оценивания результатов обучения
УК.8.2 Ориентируется в этических нормах	To know: strategies and tactics of professional speech behavior in	**Неудовлетворительно** The student is not guided in ethical standards of behavior in different types of professional

поведения в разных видах профессиональной деятельности и последствиях их нарушения	business and medical discourses; laws of selection of speech means in professional communication of the pharmacist; the main phonetic, lexical, word-forming laws of the studied language, to know and correctly use the basic vocabulary, terminology of the specialty. Be able to: select speech means for effective communication with colleagues; competently conduct business documentation accompanying professional activities; conduct dialogue and monologue on topics of everyday and professional nature, read and translate specialized literature. Own: skills of perception and generation of oral and written genres of professional speech of the pharmacist; grammatical and lexical minimum providing understanding at written and oral communication, skills of oral and written speech in the conditions of professional communication.	**Неудовлетворительно** activity, can not critically assess the consequences of their violation. **Удовлетворительно** The student is guided in ethical standards of behavior in different types of professional activity, but can not critically assess the consequences of their violation. **Хорошо** The student is guided in ethical norms of behavior in different types of professional activity, but does not fully assess the consequences of their violation. **Отлично** The student is fully oriented in ethical standards of behavior in different types of professional activities and is able to critically assess the consequences of their violation.

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