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## FEATURES OF THE FOREIGN STUDENTS TRAINING IN THE ELECTIVE DISCIPLINE "QUALITY SYSTEMS IN PHARMACY"

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**Abstract.** The pharmaceutical industry is rapidly developing and implementing new innovative approaches and legal regulation of the drugs quality management system, which includes a set of process methods and resources that are necessary for quality management. Therefore, the mastery by students of the specialty 226 "Pharmacy, Industrial Pharmacy" of the elective discipline "Quality Systems in Pharmacy" is an important issue of their professional training which will help them to master the methodology of quality management, normative-legislative and organizational-economic aspects of quality control of medicinal products at pharmaceutical enterprises. The elective discipline "Quality Systems in Pharmacy" is closely connected to some other disciplines, such as "Pharmacy and Industrial Technology of Drugs", and "Technology of Cosmetic Drugs". Training takes place according to the credit-module system in accordance with the basic requirements of the Bologna Convention.

The main tasks of the elective discipline "Quality Systems in Pharmacy" are: providing the students with general knowledge about the quality indicators of medicines depending on the stage of their life cycle by fulfilling the requirements of good pharmaceutical practices and developing documentation in accordance with their requirements; formation of practical skills related to the rules and requirements for the creation, manufacture, research, distribution, sale, and storage of medicines in accordance with the requirements of good pharmaceutical practices operating in the European Union; improvement of the level of general and scientific development of students, formation of their outlook and perspective as modern qualified specialists in the field of pharmacy.

**The aim of the research** is to study the peculiarities of the training of foreign students of the specialty 226 "Pharmacy, Industrial Pharmacy" in the Ivano-Frankivsk National Medical University (IFNMU) in the elective discipline "Quality Systems in Pharmacy". The subject of study of the discipline "Quality Systems in Pharmacy" is the methodology of pharmaceutical development, the components of the quality assurance system of medicines, including the requirements of the Guidelines of good practices in pharmacy for each stage of the life cycle of a medicinal product. The discipline is usually chosen by the well formed specialists.

Teaching the elective discipline "Quality Systems in Pharmacy" at the specialty 226 "Pharmacy, Industrial Pharmacy" of IFNMU is necessary for students to thoroughly master the quality management system of medicines, it contributes to the optimization of the educational process and the improvement of the new principle of problem-oriented education of students and its control. This discipline orients students to the importance of the following issues: ensuring the quality of medicines at all stages of their life cycle; regulatory activities in the field of quality control of medicines; implementation of medicines; optimization and monitoring of pharmaceutical quality systems processes. This discipline forms the important competencies, knowledge, skills, abilities, and aspirations of students for self-development, while their teacher also develops and improves in the professional field together with students. Taking into account the trend of the European development of the pharmaceutical industry, the quality management system of medicines also should be harmonized with European standards.

**Keywords:** quality of medicines, elective discipline, foreign students, training, quality systems in pharmacy, competence, Ivano-Frankivsk National Medical University, pharmacists, higher education, good pharmaceutical practice, distance learning, educational and professional program.

**Introduction.** The study of academic disciplines at the pharmaceutical faculties in higher education institutions of Ukraine in the field of knowledge 22 Health Care, specialty 226 "Pharmacy, Industrial Pharmacy" of the second (master's) level of education, lays the foundations of professional training, which contributes to the formation in students of general knowledge, special competences and professional skills on ensuring the quality of medicines according to the good pharmaceutical practices [1].

The study of the complex of pharmaceutical sciences and social disciplines plays an important role in

shaping the worldview of pharmacists, providing them with special training and forming program results for further professional activities [2, 3].

The pharmaceutical industry is rapidly developing and implementing new innovative approaches and legal regulation of the drugs quality management system, which includes a set of process methods and resources that are necessary for quality management. Therefore, the mastery by students of the specialty 226 "Pharmacy, Industrial Pharmacy" of the elective discipline "Quality Systems in Pharmacy" is an important issue of their professional

training which will help them to master the methodology of quality management, normative-legislative and organizational-economic aspects of quality control of medicinal products at pharmaceutical enterprises [4, 5].

The purpose of studying the elective discipline "Quality Systems in Pharmacy" at the second (master's) level of higher education of Ukraine, specialty 226 "Pharmacy, Industrial Pharmacy" at the Ivano-Frankivsk National Medical University (IFNMU) is the mastering by students of systemic theoretical knowledge and practical skills to ensure and manage the quality of medicines at all stages of their life cycle: beginning from the development, research, standardization, registration, production, storage and sale of medicines, to the formation of students' general knowledge of quality management methodology, requirements of regulatory and legislative documents, organizational and economic issues regarding the quality of medicines, which is necessary for a specialist to perform his duties [4].

The subject of study of the discipline "Quality Systems in Pharmacy" is the methodology of pharmaceutical development, the components of the quality assurance system of medicines, including the requirements of the Guidelines of good practices in pharmacy for each stage of the life cycle of a medicinal product [5, 6].

The main tasks of the elective discipline "Quality Systems in Pharmacy" are: providing the students with general knowledge about the quality indicators of medicines depending on the stage of their life cycle by fulfilling the requirements of good pharmaceutical practices and developing documentation in accordance with their requirements; formation of practical skills related to the rules and requirements for the creation, manufacture, research, distribution, sale, and storage of medicines in accordance with the requirements of good pharmaceutical practices operating in the European Union; improvement of the level of general and scientific development of students, formation of their outlook and perspective as modern qualified specialists in the field of pharmacy [7].

**Rationale for the research.** The professional training of a qualified specialist who is master of pharmacy in specialty 226 "Pharmacy, Industrial Pharmacy" should correspond to the European vector of development of the pharmaceutical industry. Therefore the medicines quality management system must be fully harmonized with European standards. Leading scientists of Ukraine developed pharmaceutical quality systems in pharmacy: V.F. Koniev, V.P. Heorhievskiy, O.I. Hryzodub, M.O. Liapunov, A.H. Kotov, M.H. Levin, O.V. Stefanov, L.O. Chaika, L.G. Almakaieva, V.S. Danylenko, V.I. Maltsev, M.S. Ponomarenko, V.O. Shapovalova, V.V. Shapovalov and many others [8].

International cooperation in the field of harmonization and quality assurance of medicines is carried out according to the system of certification and quality of medicines for international trade, which is functioning on the basis of WHO [9].

An important role in the training of a qualified Master of Pharmacy belongs to the elective discipline "Quality Systems in Pharmacy", the educational program of which uses the most current data, in accordance with the current legislation in the field of pharmacy.

Attention is paid to the study of guidelines for ensuring the quality control of medicines, such as GMP

(Good Manufacturing Practice); GCP (Good Clinical Practice); GDP (Good Distribution Practice); GLP (Good Laboratory Practice); GSP (Good Storage Practice) and the ISO 9001 standard, which includes a set of procedures, protocols, plans, reports, methods and other processes that provide the improvement and continuous quality control of medicines. The main issues of these guidelines are actively discussed at lectures and practical classes [10 - 12].

The development of medicines in compliance with the requirements of the above-mentioned regulatory guidelines and standards will ensure their quality and improve risk control at pharmaceutical enterprises. The study of the discipline "Quality Systems in Pharmacy" gives the student basic knowledge of modern concepts and legal documents of medicines quality management and knowledge of the functions and structure of regulatory and supervisory bodies operating in the state system of ensuring the medicines quality, their registration and re-registration, licensing of the pharmaceutical industry enterprises, certification and accreditation, as well as the main aspects of ensuring the quality of circulation of medicines.

**The purpose of the research** is to study the peculiarities of the training of foreign students of the specialty 226 "Pharmacy, Industrial Pharmacy" in the Ivano-Frankivsk National Medical University (IFNMU) in the elective discipline "Quality Systems in Pharmacy".

**Materials and methods.** We used an empirical research method (survey). Survey was a key research method, as it allows to get answers from the student audience regarding the organization of the educational process. With the help of a survey, you can respond to problems during training in a timely manner. A survey was conducted to assess the specifics of the training of the 5<sup>th</sup> year foreign students of the specialty 226 "Pharmacy, Industrial Pharmacy" in IFNMU, who completed their studies in the elective discipline "Quality Systems in Pharmacy". A properly developed questionnaire consisted of 30 questions related to the organization of the educational process at the Department of Pharmaceutical Management, Technology of Drugs and Pharmacognosy. The survey was attended by 4 Ukrainian-speaking and 2 English-speaking foreigners who studied remotely on a contract form of education.

The results of the survey of the foreign students were processed by the method of variational statistics with the calculation of the average value and its standard error.

**Research results.** According to the curriculum, the elective discipline "Quality System in Pharmacy" is studied by the 5<sup>th</sup> year students of the specialty 226 "Pharmacy, Industrial Pharmacy" in the 9<sup>th</sup> semester, at the stage when students have already acquired basic knowledge of pharmaceutical disciplines. The discipline is usually chosen by the well formed specialists who possess a large stock of theoretical knowledge and practical skills and are motivated to study a new subject, so it is important for the teacher to systematize information for the proper conduction of the discipline study. The curriculum of the discipline includes total 90 hours, of which 20 hours are lectures, 30 hours are practical classes, and 78 hours are devoted to the independent extracurricular work. Lecture and practical material is taught at the level of modern scientific and practical data with the aim of forming students' program results.

Today, because of the full-scale armed aggression of the Russian Federation against Ukraine, students of the Faculty of Foreign Citizens Training of IFNMU have the opportunity to study remotely in order to be safe. We conducted an analysis of problems in the organization of the educational process during distance education. A group of distance learning students took part in the survey: 6 students, 3 of which are female and 3 are male. The average age of the respondents was 24 years (the youngest was 21 and the oldest – 26). 83.3 % of the respondents stated that they became students of the university after graduating from a lyceum or gymnasium, and 16.7 % had already worked in a medical institution and studied at the different profile institutions before entering IFNMU.

66.7 % of respondents consider the oral survey to be the most objective type of knowledge control during the classes, 33.3 % consider written answers to control questions of the topic of the class to be the most objective knowledge control. Considering the type of training, the majority of the students (50 %) preferred practical classes, 33.3 % – traditional lectures, and only 16.7 % of respondents chose distance learning. To the question "How can you describe your overall interest in the educational process at the faculty?" 83.3 % of students noted that they have great ambitions for new knowledge and like the educational process the same way as they did at the beginning of their journey in the university, and 16.7 % of students responded that they have sufficient interest in the educational process.

All respondents noted a sufficiently high level of the general benefit of the received education – 66.7 % of respondents rated the general benefit of education at 9 points out of 10 and 33.3 % rated the importance of the received education at 10 points. The process of studying the discipline "Quality Systems in Pharmacy" was interesting for 100 % of respondents. Students noted the connection of this discipline with the future profession, they considered the educational material to be understandable, relevant and interesting. 50 % of respondents had experience of practical work in a pharmacy during their studies, that is why the elective discipline "Quality Systems in Pharmacy" was very interesting and necessary for them.

100 % of respondents noted that they felt supported and respected by the teacher in classes and were satisfied with the teaching methodology of the elective discipline "Quality Systems in Pharmacy". All students noted that the teacher's communication with them in classes met the requirements of pedagogical ethics, the teacher objectively assessed the students' knowledge of the selected discipline, the educational material was accessible, the educational, methodological and information support in the discipline "Quality Systems in Pharmacy" was sufficient.

When evaluating the lecture material, 83.3 % of the respondents noted that the lectures were prepared at a sufficient level, different approaches were used to explain theoretical concepts, and 16.7 % gave their own answer that the lectures were excellent.

The elective discipline "Quality Systems in Pharmacy" is based on the foundations of interdisciplinary study of social and special disciplines, such as "Biopharmacy", "Drug Technology", "Standardization of Medicines", "Organization and Economy of Pharmacy" and "Management and Marketing in Pharmacy".

To the question "Whether the educational objectives of the discipline "Quality Systems in Pharmacy" correspond to the content of the disciplines you studied before?" 66.7 % of students answered that the content of some educational questions was repeated; 16.7 % of students noted that they are not sure but are satisfied with the educational goals of the discipline; and 16.7 % of students answered that a lot of educational issues were the subject of study in other disciplines.

To the question "Which topics of the discipline "Quality Systems in Pharmacy" were the most interesting to you?" 66.7 % of respondents noted that all topics of the elective discipline are interesting and instructive; 16.7 % noted the topic "Production and clinical research of medicines" to be the most interesting; and 16.7 % considered the topic "Preclinical research of medicines" the most interesting. During the survey, it turned out that the informative videos shown to the students during the classes were also very helpful and instructive for them.

Respondents also assessed the value of research work for them. 83.3 % of students answered that the value of research work gives impetus to their independent work and development, but they have not yet tried themselves in writing scientific articles. 16.7 % of students noted that scientific research increases interest in learning and they have already taken part in writing scientific theses and reports.

Regarding the distance learning, 50 % of students responded that it was difficult for them to answer this question; 33.3 % had a positive attitude and only 16.7 % noted that they are completely satisfied with distance learning.

To the question "Has your attitude towards education changed compared to the initial period?" 83.3 % of respondents noted that their attitude to learning has not changed and they still like to study very much, and 16.7 % of respondents became interested in learning already in senior years.

All respondents indicated that the teacher devoted some time during the class to the issue of preparation for the integrated test exam Step-2, and also worked on some oral questions that are necessary for preparation for the state graduation exam. 100 % of the surveyed students rated the implementation of the elective discipline "Quality Systems in Pharmacy" as "excellent" and noted that nothing needs to be changed or improved.

After completing the course of studying the discipline "Quality Systems in Pharmacy", students passed final modular control. The results did not show a high level of knowledge: 2 students received from 163 to 168 points, 2 students received from 141 to 147 points and 2 students received from 120 to 131 points, which is the minimum result, with the maximum possible result of 200 points. The success of students' studies is affected by various factors, in particular distance learning, because there is no direct communication with the teacher and a decrease in the student's mental activity.

**Discussion of results.** Definitely, distance learning cannot replace live communication between the teacher and students. Recent years have become a period of challenges for educational transformations in universities: the COVID-19 pandemic has necessitated a rapid transition to the implementation of the educational process in distance mode. The full-scale armed aggression of the

russian federation against Ukraine caused the need to organize safe education for students.

The basic structural division of the higher education institution is the Department, the main purpose of which is to ensure the continuity and effectiveness of the training of future specialists and their support in personal and professional development. The tasks of every department are the implementation of educational programs, organization and implementation of the educational process at the appropriate scientific and methodical levels and others. The computer cannot replace the teacher, but it can increase the level and degree of grades objectivity, makes materials more available to every student, taking into account their characteristics, individual style, learning rate etc.

The form of assignments should satisfy the following conditions: be clear, provide unambiguous answers and short solutions. At the Department of Pharmaceutical Management, Technology of Drugs and Pharmacognosy we implemented two types of assignments: tests – to control the level of students' knowledge, and situational tasks – to assess the development of thinking. These allows to give an objective assessment of the extent to which students understand the connection between theoretical material and practical actions, whether students are able to analyze, summarize the material and predict the ways of situations development. Considering the features of educational diagnostics, it is necessary to emphasize once again how important it is for students to understand whether there are objective benchmarks for evaluating the results of their educational activities and what they are.

According to the educational and professional program (EPP) "Pharmacy, Industrial Pharmacy" for the second (master's) level of higher education one of the forms of attestation of students in specialty 226 "Pharmacy, Industrial Pharmacy" is the Integrated test exam Step-2, which is carried out in accordance with the Procedure for conducting a unified state qualification exam for the applicants of a master's degree in the field of knowledge "Health care". It consists of the following components: the integrated test exam "STEP", which evaluates the compliance of the quality of training of specialists with the standards of higher education and is carried out by the Testing Center of the Ministry of Health of Ukraine; an objective structured practical exam or a comprehensive practical-oriented qualification exam, which assesses the readiness of the graduate to carry out professional activities by demonstrating the practical components of professional competence and is carried out by the examination board of the University.

The elective discipline "Quality Systems in Pharmacy" is designed to form educational program results in accordance with the EPP of specialty 226 "Pharmacy, Industrial Pharmacy".

**Conclusion.** Thus, the teaching of the elective discipline "Quality Systems in Pharmacy" at the specialty 226 "Pharmacy, Industrial Pharmacy" in IFNMU is necessary for students to thoroughly master the quality management system of medicines, it contributes to the optimization of the educational process and the improvement of the new principle of problem-oriented education of students and its control. This discipline orients students to the importance of the following issues: ensuring the quality of medicines at all stages of their life cycle; regulatory

activities in the field of quality control of medicines; implementation of medicines; optimization and monitoring of pharmaceutical quality systems processes. This discipline forms the important competencies, knowledge, skills, abilities, and aspirations of students for self-development, while their teacher also develops and improves in the professional field together with students. Taking into account the trend of the European development of the pharmaceutical industry, the quality management system of medicines also should be harmonized with European standards.

Foreign students of the 5th year of the Faculty of Pharmacy of IFNMU, who study distance, not completely satisfied with the form of education, only 16.7% were satisfied with the distance form of education. Students gave an assessment of "excellent" implementation of the selective discipline "Quality systems in pharmacy", but the results of their success were low.

The success of students' studies is affected by various factors, in particular distance learning, because there is no direct communication with the teacher and a decrease in the student's mental activity.

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### ОСОБЛИВОСТІ ПІДГОТОВКИ ІНОЗЕМНИХ СТУДЕНТІВ З ВИБІРКОВОЇ ДИСЦИПЛІНИ «СИСТЕМИ ЯКОСТІ У ФАРМАЦІЇ» НА ФАРМАЦЕВТИЧНОМУ ФАКУЛЬТЕТІ

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**Резюме.** Вивчення студентами спеціальності 226 «Фармація, промислова фармація» вибіркової дисципліни «Системи якості у фармації» є важливим

напрямок фахової підготовки кваліфікованого спеціаліста, який освоїть методологію управління якістю, нормативно-законодавчих та організаційно-економічних аспектів контролю якості лікарських засобів на фармацевтичних підприємствах. Вибіркова дисципліна «Системи якості у фармації» є продовженням ряду дисциплін, а саме: аптечної та промислової технології ліків, технології косметичних лікарських засобів та інших. Навчання відбувається за кредитно-модульною системою згідно до основних вимог Болонської конвенції.

Основними завданнями вивчення вибіркової дисципліни «Системи якості у фармації» є: формування у здобувачів вищої освіти загальних знань щодо показників якості лікарських засобів відповідно до етапу їх життєвого циклу шляхом виконання вимог належних фармацевтичних практик та розробки документації у відповідності до їх вимог; формування практичних навичок, що стосуються правил і вимог створення, виготовлення, дослідження, дистрибуції, реалізації, зберігання лікарських засобів; підвищення рівня загального та наукового розвитку у здобувачів вищої освіти.

**Метою роботи** є дослідження особливостей підготовки іноземних студентів на фармацевтичному факультеті Івано-Франківського національного медичного університету з вибіркової дисципліни «Системи якості у фармації».

Викладання вибіркової дисципліни «Системи якості у фармації» на фармацевтичному факультеті ІФНМУ необхідне для досконалого вивчення студентами системи управління якістю лікарських засобів, сприяє оптимізації навчального процесу та удосконаленню нового принципу проблемно орієнтованого навчання студентів та його контролю. Дисципліна орієнтує студентів на важливість питань забезпечення якості лікарських засобів на всіх етапах життєвого циклу, регуляторної діяльності у сфері контролю за якістю, реалізації лікарських засобів, моніторингу процесів фармацевтичних систем якості.

**Ключові слова:** якість лікарських засобів, вибіркова дисципліна, іноземні студенти, навчання, системи якості у фармації, компетентність, Івано-Франківський національний медичний університет, фармацевти, вища освіта, належна фармацевтична практика, дистанційне навчання, освітньо-професійна програма.

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