



Pharmaceutical quality assurance methods comparison in Ukraine and the world: A literature review

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Abstract. The study of quality assurance methods for medicinal products in Ukraine and other countries is relevant to the improvement and development of the pharmaceutical industry. The study aimed to compare the quality systems for the supply of medicines in Ukraine and abroad. The structural and logical analysis methods, as well as bibliosemantic and analytical-synthetic methods, were used in the study. The comparison was conducted by analysing documents issued in foreign countries by regulatory authorities, such as the Food and Drug Administration in the United States of America or the European Medicines Agency in Europe, which is substantial in ensuring the quality of medicines. In Ukraine, the State Service of Ukraine on Medicines and Drugs Control is a regulatory body. The analysis revealed several differences in the quality control systems for medicines in Ukraine and abroad. Good Manufacturing Practice standards are universally recognised for quality assurance in pharmaceutical production. Compliance with the standards is mandatory in Ukraine and abroad. Regular testing of medicines in authorised laboratories is crucial to ensure their safety and effectiveness. Ukraine, similarly to other countries, conducts quality control testing. Monitoring and reporting of adverse drug reactions after the sale is essential to identify and address safety issues. Although pharmacovigilance systems exist in Ukraine and abroad, there may be differences in terms of reporting requirements, infrastructure and resources allocated to pharmacovigilance activities. Scheduled inspections of production facilities and distribution channels are carried out to verify compliance with the rules. Educating healthcare professionals and the public about the importance of ensuring the quality of medicines contributes to informed decision-making. The analysis of the quality control of medicinal products suggests that the fundamental methods of quality assurance are similar around the world, while differences in the regulatory framework, resources, infrastructure and implementation may affect the efficiency and effectiveness of quality assurance measures between Ukraine and other countries. Collaboration, compliance with international standards and continuous improvement are essential to promote quality assurance practices in Ukraine and abroad

Keywords: regulatory authorities in medicine; medicinal products; good manufacturing practice; pharmacovigilance; side effects

Introduction

Ensuring the quality of medicines is an important component of Ukraine's healthcare policy. Modern approaches to quality assurance are based on a concept that ensures the proper circulation of medicines. The provision of information to physicians and patients about medicinal products begins at the stage of their pharmaceutical development and is based on laboratory and clinical trials, control of

medicinal product production, quality, appropriate storage and sales conditions. In other words, a concept has been developed according to which quality and safety guarantees are provided at all stages of the life cycle of a medicinal product. All measures aimed at implementing the concept of ensuring the proper quality of medicines, following the recommendations of the World Health Organization

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(WHO), are aimed at meeting the needs of patients [1]. According to the concept of development of the pharmaceutical industry in Ukraine for 2011-2023, the main task is to ensure the quality, safety and efficacy of medicines, thereby achieving the goal of improving public health and increasing life expectancy [2].

At the present stage, the Ukrainian pharmaceutical market is actively developing, raising questions about the proper quality assurance of medicines and the prevention of drug fraud. To improve the Ukrainian quality system for medicines, a thorough analysis of the experience of different countries is needed. Analysis and comparison of the experience of other countries will also help to provide the population with quality medicines and improve the existing system of regulation and control of the country's pharmaceutical market. In terms of drug quality standards, Ukraine is still trying to achieve a quality of medicines comparable to many developed countries, which affects the ability to provide the population with quality and safe medicines [3]. Despite the constant development of the pharmaceutical industry in Ukraine, there have been few studies comparing the structure of the pharmaceutical industry in Ukraine with other countries. Such studies would help to improve and enhance the efficiency of pharmacy professionals and help to achieve the main goal of providing patients with the highest quality, most effective and safe medicines.

S.H. Ubohov *et al.* [4] noted that the safety of medicines is a priority for healthcare systems in all developed countries, and Ukraine is no exception. No medicine in the world is 100% safe for the human body. S. Sarana & P. Noha [5] demonstrated that the main goal of all structures of the pharmaceutical industry in Ukraine is to ensure public access to quality and safe medicines. H. Buschmann *et al.* [6] emphasise that global information exchange between countries on adverse events enhances the safety of medicines in countries and can lead to timely policy decisions to protect patients in the event of adverse drug events. N. Zarivna [7] highlighted the main issues related to the development of draft quality control methods for finished medicines depending on the type of dosage form when studying the discipline "Standardisation of Medicines" by higher education students. The article analyses the main issues that students may have when developing appropriate specifications for medicinal products. This study concludes that knowing its requirements for quality indicators of medicinal products, analysis methods, a higher education student will learn not only to develop drafts of appropriate methods for quality control of medicinal products but will also be able to apply them in their practical activities to confirm the quality assessment of medicinal products. The legislation of Ukraine and the EU in the field of quality assurance of medicinal products was compared by L. Yurkovska *et al.* [8]. Ukrainian scientists have found that the EU and Ukrainian pharmaceutical legislation on quality assurance of medicinal products have common features, including the number and diversity of existing regulations, which create contradictions between them and the possibility of regulatory gaps.

The main trend in the development of this legislation in the EU and Ukraine is the inconsistency of legislative acts and the lack of significant legislative efforts to codify them.

In other words, all the analysed studies were aimed at studying the methods of quality assurance of medicinal products and ways to improve them, but the works of other authors almost do not compare the structures of quality assurance of medicinal products with similar methods and structures in other countries. Given the above, the study aims: to compare the current state and trends in the development of quality assurance of medicinal products in Ukraine and abroad by analysing regulatory sources for pharmaceutical products, and EU and Ukrainian legislation that defines the basis for quality assurance of medicinal products. The study analysed literature sources for 2018-2024 related to the methods of ensuring the quality of medicines in Ukraine, the EU and the USA, and examined the main documents and laws that ensure the quality of medicines in these countries. The literature search was conducted in scientometric databases (Scopus, Web of Science, PubMed, EMBASE) and on the website of the Ministry of Health of Ukraine. The following keywords were used to search the literature: "regulatory authorities in medicine", "medicinal products", "good manufacturing practice", "pharmacovigilance", "adverse events".

The methods of structural and logical analysis were used to identify scientific data from the analysed literature sources according to a certain system, classify them, and establish interconnections and relationships between them. The bibliosemantic method was used to determine the state of the art of studying the safety and quality of medicines and ways to improve them by analysing the results and conclusions of previous studies based on scientific sources and modern electronic resources. The analytical and synthetic methods provided a comparison of various elementary theoretical and causal relationships as a result of treatment and also met the requirements for studying the processes of side effects as a holistic research object interconnected with a complex of influencing factors and as a fragmentary element requiring a detailed analysis of each of the individual characteristics.

Key Aspects of Drug Quality Control in Ukraine

Quality assurance of medicinal products in Ukraine includes the following methods. One of the key links in ensuring the quality of medicinal products is regulatory supervision, which ensures the implementation and control of compliance with the requirements of the legislation by state authorities, such as the State Service of Ukraine on Medicines and Drugs Control (SMDC). The State Administration on Medicines is the main body responsible for regulating the circulation of medicines in Ukraine. This includes registration of medicinal products, issuance of licences for their manufacture and distribution, as well as control over their quality and safety, including inspections of production facilities and warehouses, sampling and analysis, and verification of compliance with the

requirements of Good Manufacturing Practice (GMP). The State Administration on Medicinal Products (hereinafter SAMP) monitors and analyses adverse reactions to medicinal products and maintains a pharmacovigilance system to ensure the safety and efficacy of medicinal products and is responsible for controlling the circulation of narcotic drugs, psychotropic substances and precursors in Ukraine, including licensing, registration, inspections and control over the legalisation of revenues from their circulation [9]. In general, the SAMP aims to ensure the safety, efficacy and availability of medicines and control drug trafficking in Ukraine following the requirements of national and international legislation [10].

Similar to European countries, drug manufacturers in Ukraine must comply with GMP standards to ensure product quality. The main provisions of the GMP were adopted as the basis for the licensing conditions for the manufacture of medicines in 2011 [11]. At that time, not all drug manufacturers in Ukraine were able to ensure that their products met the requirements of the GMP. The introduction of new licensing conditions resulted in a 20% reduction in the number of drug manufacturers [12]. In 2014, 110 companies in the Ukrainian pharmaceutical market had a production licence, which did not take a wait-and-see attitude but actively implemented innovative technologies, new drugs, quality assurance systems, principles and rules of the GMP [13]. Pharmaceutical companies that met GMP requirements were certified for compliance with GMP requirements at the national level and by inspectors from other countries. The pharmaceutical industry in Ukraine is constantly monitoring the quality of its products through regular quality checks in designated laboratories to verify compliance with standards and specifications.

Monitoring and reporting of adverse drug reactions to identify and resolve possible quality issues is one of the main functions of pharmacovigilance. The state pharmacovigilance system in Ukraine was established in 1996. Currently, the system is represented by the following links: central (the State Expert Centre of the Ministry of Health of Ukraine); regional (regional branches of the Centre in all regions of Ukraine); local (pharmacovigilance in healthcare facilities) [14]. In addition to the state pharmacovigilance system, everyone who applies for registration of a medicinal product in Ukraine must establish and maintain a pharmacovigilance system with an agreed quality system. If the above condition is not met, the medicinal product will be prohibited for use in Ukraine. After all, the main task of pharmacovigilance – improving patient treatment and safety during the use of medicines – is only possible if reliable and objective information on safety (the occurrence of adverse drug reactions) and efficacy of medicines has been previously provided. Pharmacovigilance departments receive the necessary information on the side effects of medicines and the achievement of treatment effects from the holders of marketing authorisations, doctors participating in clinical trials and doctors directly treating patients. Ukrainian specialists have extensive experience in using

passive and active methods of collecting information on adverse effects during the use of medicines [15].

Pharmacovigilance is of particular importance for the implementation of state healthcare programmes for the treatment of serious diseases, socially dangerous diseases and the prevention of controlled infections. Pharmacovigilance authorities ensure that manufacturing facilities and supply chains are regularly inspected to verify compliance with production standards and requirements [16]. Manufacturers that meet the quality standards are issued certificates to confirm their compliance. Cooperating with international organisations and regulatory bodies to share information and agree on best practices in quality assurance. These methods help ensure a high level of quality of medicines available in Ukraine and ensure their safety and efficacy for patients [17, 18].

According to WHO estimates, the prevalence of counterfeit medicines in developed countries is about 10%, and in third-world countries, it is almost half of all medicines [19]. In Ukraine, from 0.3% to 10% of counterfeit medicines are sold in different versions. In addition, while in 2013, 99 batches and 68 names were detected and banned in Ukraine, in 2014, in the first eight months alone, 309 batches and 69 names of substandard drugs were detected and banned. And this is a calculation of only the number of names and batches of drugs, without indicating the total number and cost of such counterfeit drugs, as it is almost impossible to calculate them [20]. Counterfeit medicines pose a high threat to the lives and health of Ukrainian citizens. Following the publication of such information about the increase in the number of counterfeit medicines, temporary control commissions were set up in many cities of Ukraine to study the situation around the circulation of counterfeit medicines [21].

The main task of the commissions is to check the distribution of medicines through the wholesale and retail network. In 2019-2024, due to the improvement of the regulatory framework responsible for the quality of medicines and the intensification of inspections by the State Administration of Ukraine on Medicines and Drugs Control, the likelihood of detecting counterfeit medicines has significantly decreased [22]. Due to the continuous improvement of pharmacological legislation, control over the counterfeiting of medicines in Ukraine has been strengthened. Thus, in August 2023, during a special operation in Kyiv and Kharkiv regions, law enforcement officers successfully identified and eliminated a channel for the illegal transportation of counterfeit oncology medicines to Ukraine. Most of the counterfeit medicines were manufactured in several countries in the Middle East [23].

The opening of a laboratory for quality analysis of medicines and drugs in the Kyiv region is a significant achievement. In this institution, specialists will conduct tests according to the highest European standards to identify low-quality medicines. According to the Ministry of Health of Ukraine, the laboratory is unique for Ukraine, and its qualifications have already been confirmed by the

World Health Organisation. The new institution will become a full member of the international network of official quality control laboratories in Europe. The latest laboratory equipment can perform complex analyses using a spectrometer, which can be used to determine the content of metals and elements in medicinal products; heavy metals and elements in medicinal plant materials; microbiological purity of medicinal products, quantification of antibiotics, vitamins, and preservatives. These changes will significantly reduce the likelihood of counterfeit medicines appearing on the pharmaceutical market [24].

To improve the pharmaceutical industry in Ukraine, the approach to professional development of pharmaceutical employees is constantly being improved. Thus, starting from 1 January 2024, all categories of specialists in the medical and pharmaceutical fields, without exception, must undergo continuing professional development (CPD). One of the main documents regulating CPD in the field of medicine is the Resolution of the Cabinet of Ministers of Ukraine No. 725 "On Approval of the Regulation on the System of Continuous Professional Development of Medical and Pharmaceutical Workers" [25]. According to the new rules, pharmaceutical employees must attend professional conferences and congresses annually, listen to webinars and take tests based on conference materials. Such an approach will significantly improve the knowledge of pharmaceutical workers and the level of patient care.

Order of the Ministry of Health of Ukraine No. 446 "Some Issues of Continuous Professional Development of Doctors" [26], Order of the Ministry of Health of Ukraine No. 742 "On the Certification of Junior Specialists with Medical Education" [27], Order of the Ministry of Health of Ukraine No. 2136 "On Approval of the List of Cycles of Specialisation and Thematic Improvement in Medical and Pharmaceutical (Pharmacy) Specialties" [28] are also in effect. However, the rules for calculating CPD points for pharmacists have not yet been finalised at the legislative level. Ukrainian scientists are guided by common goals with the EU in ensuring the quality of medicines, and regulatory infrastructure in the efficiency and effectiveness of quality assurance methods. Joint efforts, adherence to international standards and continuous improvement are necessary to improve the quality of medicines in both regions.

Comparison of Quality Assurance Methods for Medicines in Ukraine, the EU and the USA

When comparing the methods of quality assurance in Ukraine with those in Europe, in particular the EU, several differences and similarities are revealed. In Europe, drug quality control testing is governed by comprehensive rules and guidelines set by the European Medicines Agency (EMA) and the European Directorate for Quality in Medicines and Healthcare (EDQM). These rules set out specific requirements for test methods, specifications and quality control acceptance criteria. On the contrary, Ukraine has its regulatory framework controlled by the State Administration on Medicines and Drugs Control,

which may have different testing requirements and standards compared to Europe [29, 30].

The analysis showed that both Ukraine and Europe adhere to GMP standards to ensure the quality of pharmaceutical production. However, the implementation and enforcement of GMPs in Europe may be more stringent due to the developed pharmaceutical industry and regulatory infrastructure. GMP compliance in Ukraine and Europe differs in several key aspects. The differences in quality assurance between Ukraine and the EU start with the regulatory framework. For instance, in Europe, GMP compliance is regulated by EU directives and regulations, including the EU GMP Guidelines. On the contrary, Ukraine has a domestic set of GMP rules, which is controlled by the State Administration on Medicines. Although Ukraine strives to bring its rules in line with international standards, there are some differences in the interpretation and implementation of the rules compared to EU standards [31, 32]. The importance of GMP compliance is also confirmed by N.T. Do *et al.* [33].

When comparing the frequency of inspections, in Europe, the competent authorities conduct regular and thorough inspections of manufacturing facilities for compliance with GMP rules. These inspections are usually based on a risk assessment and may include both scheduled and unannounced visits [34]. According to the results of the study by S. Zhang & L. Zhu [35], in the context of different structures of distribution channels, quality control of medicines in the pharmaceutical sector is a common problem faced by all countries of the world, even very developed ones. There is a need to improve the reward and punishment mechanism to improve the pharmaceutical supply and to encourage state regulatory authorities to strictly control pharmaceutical enterprises and provide high-quality medicines to the population.

The comparison shows some differences in the mechanisms for ensuring and complying with GMP rules. In Europe, failure to comply with GMP regulations can cause serious consequences, including regulatory measures such as suspension or revocation of manufacturing licences, product recalls or legal sanctions. The EU has established robust enforcement mechanisms. In Ukraine, despite the existence of regulatory consequences for non-compliance, enforcement may be less consistent or strict compared to Europe, potentially leading to different levels of compliance by producers [36]. European manufacturers have access to a wealth of training resources, guidance documents and industry best practices to support GMP compliance. In addition, European regulators provide support and guidance to manufacturers to help them meet GMP requirements. Despite limited resources and infrastructure issues that may affect the availability and quality of support for manufacturers, Ukraine has a high level of GMP compliance. It is worth noting that due to the efforts to provide training and consultancy, employees of Ukrainian pharmaceutical companies are constantly learning, not only in Ukraine but also abroad. Employees in the pharmaceutical industry are

trained to comply with GMP rules in their work and strictly adhere to them [37].

The above data is confirmed by the results of the study by L. Deshko *et al.* [38], which shows that Ukraine and Europe are striving to ensure GMP compliance to maintain the quality and safety of pharmaceutical products, differences in the regulatory framework, inspection methods, compliance mechanisms and access to resources may lead to differences in the level of compliance between the two regions. Europe usually has a wider network of quality control laboratories than Ukraine, which allows for more thorough and frequent testing of medicines. This can provide a higher level of confidence in the quality and safety of pharmaceutical products [39]. European countries generally have access to advanced testing methods and modern equipment for drug quality testing. This provides a wide range of analytical methods, including chromatography, spectroscopy and mass spectrometry, to be used to accurately assess drug quality [40]. In Ukraine, despite efforts to introduce modern testing methods, limited resources and infrastructure issues can affect the availability and sophistication of test equipment.

In the EU, quality control laboratories for medicinal products are often accredited or certified following international standards such as ISO/IEC 17025 [41]. Accreditation ensures that laboratories operate competently and produce reliable results. In Ukraine, despite efforts to improve the quality of testing laboratories, accreditation may not be as widespread or standardised as in Europe. European regulatory authorities established sampling and analysis protocols for pharmaceutical products to ensure that representative samples are tested, and accurate results are obtained. In Ukraine, although similar protocols may exist, differences in implementation and compliance with these protocols may arise due to limited resources and other factors [42, 43]. European countries actively cooperate with the EU to harmonise the methods and standards of drug quality control testing. This cooperation promotes consistency and compatibility of testing methods across Member States. In Ukraine, despite efforts to align with international standards and best practices, cooperation and harmonisation may be limited compared to Europe.

In Europe, there is a robust pharmacovigilance system in place to monitor and evaluate the safety of medicines after sale. The difference between pharmacovigilance in Ukraine and Europe lies primarily in the level of development, infrastructure and regulatory framework. Moreover, despite the constant improvement and development of new pharmacovigilance methods in Europe, according to F.S. Tonin *et al.* [44], the presence of impurities in finished products remains a serious problem for the pharmaceutical industry, as they can affect the efficacy and safety of medicines and lead to product withdrawal from the market. Several guidelines and pharmacopoeias guide the complex regulatory requirements; however, they are not always clear or cover specific topics in sufficient depth [45]. Medicinal products in the EU undergo a thorough assessment before

obtaining a marketing authorisation, including evaluation of quality, safety and efficacy data. The mutual recognition procedure facilitates the recognition of registration certificates issued by one EU Member State in other Member States, ensuring consistent quality standards across the EU. Cooperation between EU Member States, the EMA and other regulatory authorities to exchange information, harmonise rules and promote best practices in quality assurance. Using these methods, Europe maintains a high level of quality of medicines, guaranteeing the safety and efficacy of pharmaceutical products available to its citizens [46].

Quality assurance of medicines in the United States includes various methods controlled by the Food and Drug Administration (FDA) and other regulatory authorities [47]. Pharmaceutical companies must comply with the GMP regulations set by the FDA. These regulations ensure that medicines are consistently manufactured and controlled to meet quality standards suitable for their intended use. The FDA requires pharmaceutical companies to conduct rigorous testing of raw materials, intermediates and finished drugs to ensure that they meet specifications for identity, potency, purity and quality. This includes testing for impurities, efficacy, dissolution and stability. The FDA reviews and approves New Drug Applications and Abbreviated New Drug Applications before drugs can be marketed in the United States. This includes the evaluation of safety, efficacy and quality data provided by manufacturers. The FDA conducts inspections of manufacturing facilities in the US and other countries to ensure compliance with GMP and other quality standards. Inspections can be scheduled or triggered by specific problems or complaints. The FDA monitors the safety of medicines after sale through various surveillance systems, including the FDA Adverse Event Reporting System (FAERS) [48, 49]. Pharmaceutical companies are obliged to report adverse events, and the FDA investigates safety issues and takes regulatory action if necessary. For medical devices, the FDA applies the Quality System Regulations (QSR), which require manufacturers to establish and maintain quality management systems to ensure that their devices consistently meet quality requirements. The Drug Supply Chain Security Act (DSCSA) requires pharmaceutical manufacturers, distributors and pharmacists to implement systems to track prescription drugs as they move through the supply chain, increasing transparency and reducing the risk of counterfeit or falsified medicines. The FDA educates healthcare professionals and the public about the importance of drug safety and quality through various initiatives, including consumer advisories, educational materials, and outreach programmes. By using these methods, the FDA ensures that medicines available in the US meet strict quality standards, protecting public health and improving patient safety [50, 51].

Table 1 shows the main differences in the quality assurance of medicines in Ukraine, Europe and the USA. The comparison was based on the following parameters: regulatory supervision, production standards, pharmacovigilance, inspections, certification of medicines, quality, and safety (Table 1).

Table 1. Comparison of quality assurance of medicines in Ukraine, the USA and Europe

No.	Indicators	Region		
		Ukraine	Europe	USA
1	Regulatory oversight	State Service of Ukraine on Medicines and Drugs Control	EMA	FDA
2	Production standards	GMP	GMP	GMP
3	Pharmacovigilance	Monitoring and reporting of adverse drug reactions has been in place since 1996. Post-registration surveillance department within the State Enterprise "State Expert Centre of the Ministry of Health of Ukraine"	Monitoring and reporting of adverse drug reactions after sales	FAERS
4	Inspections	Inspections of production facilities by the State Administration on Medicinal Products	Inspections of production facilities and distribution channels by national competent authorities to verify compliance	FDA inspections of manufacturing facilities
5	Certification	Issuing certificates to manufacturers that meet quality standards	GMP certification	Certification FDA
6	Quality	Issuance of certificates to manufacturers that meet quality standards by the State Administration on Medicines	Quality control testing: constant testing of medicines in authorised laboratories	QSR
7	Security	Inspections of production facilities and supply chains to verify compliance with production standards	EDQM	DSCSA

Source: [2; 17; 47]

Overall, although both Ukraine and Europe are committed to ensuring the quality of pharmaceutical products through drug quality control testing, differences in regulatory frameworks, resources, infrastructure and cooperation may lead to differences in the level of complexity, accuracy and consistency of testing methods between countries.

Conclusions

Given the information analysed, it is possible to conclude that Ukrainian quality standards for medicines are in line with European standards and are constantly being improved. Ukraine's pharmaceutical industry is making efforts to align its regulations and standards with those of the EU as part of its integration goals. Legislation in Ukraine is constantly being developed to improve the regulatory framework for pharmaceuticals, including quality standards for medicines. These changes include updating existing rules and adopting new ones to align them with EU standards.

There is a tendency for the Ukrainian pharmaceutical industry to prefer to adopt European guidelines, such as those issued by the EMA and EDQM, to inform on internal standards for medicines, which helps to ensure compatibility with European practices. Together with international organisations, Ukraine's pharmaceutical industry has strengthened its regulatory infrastructure and improved the quality of medicines. Achieving full compliance requires ongoing effort and investment. Leading experts in the Ukrainian pharmaceutical industry are seeking to conclude mutual recognition agreements with the EU, under which both parties agree to recognise each other's systems

and standards for regulating medicines. This will facilitate trade and regulatory cooperation while promoting the convergence of standards.

European countries actively cooperate within the EU pharmacovigilance system, exchanging information and best practices to improve pharmacovigilance activities. In addition, Europe, given a robust regulatory framework, participates in international cooperation to ensure the quality of medicines around the world. Ukraine still has limited participation in such cooperation, which may affect its ability to access and share important pharmacovigilance information.

Overall, although Ukraine is working to bring its quality standards for medicines in line with the European ones, achieving full compliance may be a gradual process that requires comprehensive regulatory reforms, technical assistance and cooperation with European partners. Using the experience of the FDA and EMA, the Ukrainian pharmaceutical industry will be able to maintain a high level of quality of medicines, ensuring the safety and efficacy of pharmaceutical products for its citizens. Further research should monitor the development of the quality system for medicines in Ukraine and based on the results of the research, make the necessary changes to the country's pharmaceutical industry to improve the quality control of medicines.

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Conflict of Interest

The author declares no conflict of interest.

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Порівняння методів забезпечення якості лікарських засобів в Україні та за кордоном: огляд літератури

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Анотація. Вивчення методів забезпечення якості лікарських засобів в Україні та у інших країнах важливе для вдосконалення та розвитку фармацевтичної галузі. Метою роботи було порівняти системи якості забезпечення лікарських засобів в Україні та за кордоном. У роботі були використані методи структурно-логічного аналізу, бібліосемантичний та аналітико-синтетичний методи. Співставлення було проведено за допомогою аналізу документів, що видаються у іноземних країнах регулюючими органами, такими як Управління з контролю за продуктами та ліками у Сполучених Штатах Америки або Європейським агентством з лікарських засобів у Європі та відіграють важливу роль у забезпеченні якості ліків. В Україні за нормативний нагляд відповідає Державна служба України з лікарських засобів та контролю за наркотиками. Згідно результатів проведеного аналізу у системах контролю за якістю лікарських засобів в Україні та за кордоном виявлено ряд відмінностей. Стандарти Good Manufacturing Practice загальноновизнані для забезпечення якості у фармацевтичному виробництві. Дотримання стандартів є обов'язковим в Україні та за кордоном. Регулярні випробування ліків в уповноважених лабораторіях мають вирішальне значення для забезпечення їхньої безпеки та ефективності. Україна, як і інші країни, проводить тестування контролю якості. Моніторинг та звітність про побічні реакції на ліки після продажу мають важливе значення для виявлення та усунення проблем безпеки. Хоча системи фармаконагляду існують в Україні та за кордоном, можуть існувати відмінності з погляду вимог до звітності, інфраструктури та ресурсів, що виділяються на діяльність з фармаконагляду. Планові перевірки виробничих підприємств та каналів збуту проводяться для перевірки дотримання правил. Просвітництво медичних працівників та громадськості про важливість забезпечення якості лікарських засобів сприяє ухваленню обґрунтованих рішень. З проведеного аналізу контролю якості лікарських засобів можна зробити висновок, що фундаментальні методи забезпечення якості лікарських засобів у всьому світі схожі, відмінності у нормативній базі, ресурсах, інфраструктурі та реалізації можуть вплинути на ефективність та дієвість заходів забезпечення якості між Україною та іншими країнами. Співпраця, дотримання міжнародних стандартів та постійне вдосконалення необхідні для просування практики забезпечення якості в Україні та за кордоном.

Ключові слова: органи контролю у медицині; медичні препарати; належна виробнича практика; фармаконагляд; побічні дії