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QUALIFICATION WORK

on the topic: «**ANALYSIS OF KEY PROBLEMS AND WAYS TO IMPROVE THE QUALITY MANAGEMENT SYSTEM IN A PHARMACEUTICAL ORGANIZATION»**

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АНОТАЦІЯ

У дослідженні проаналізовано ключові проблеми і шляхи удосконалення системи управління якістю у фармацевтичній організації. Розроблено рекомендації щодо оптимізації процесів системи управління якістю. Кваліфікаційна робота містить 44 сторінки, включає 19 рисунків і 2 таблиці. Представлено список літератури з 30 джерел.

Ключові слова: ключові проблеми, шляхи удосконалення, система управління якістю, фармацевтична організація.

ANNOTATION

The study analyzed key problems and ways to improve the quality management system in a pharmaceutical organization. Recommendations were developed for optimizing the processes of the quality management system. The qualification work contains 44 pages, includes 19 figures and 2 tables. A list of literature from 30 sources is presented.

Keywords: key problems, ways to improve, quality management system, pharmaceutical organization.

CONTENT

INTRODUCTION

Relevance of the research topic. A quality management system (QMS) is a key element of the successful operation of any business, especially in the pharmaceutical industry, on which people's health and lives directly depend. In addition to modern market requirements, increased competition and compliance with international standards such as ISO 9001, GMP (Good Manufacturing Practice) and ICH Q10, the development of a quality management system is a strategic task for pharmaceutical companies. One of the leading representatives of the pharmaceutical industry in Ukraine is corporation "ARTERIUM", which has significant potential for improving production processes and strengthening competitive positions in domestic and foreign markets [11].

The pharmaceutical industry is one of the most regulated, as its products directly affect the safety and effectiveness of patient treatment. In the context of modern globalization and constant updating of the regulatory framework, companies need to adapt their quality management systems to new challenges, such as digitalization, process automation, strengthening internal control and risk management. For corporation "ARTERIUM" this issue is extremely relevant, since the company strives to ensure high product quality, compliance with international standards, and meet the growing needs of consumers [5].

The importance of developing a QMS is also justified by the minimization of production costs, increasing resource efficiency and optimizing logistics processes. The development and implementation of innovative approaches to quality management allows the enterprise not only to reduce costs, but also to ensure stable product quality, which is critically important for the pharmaceutical industry [13].

The relevance of the topic is also due to the increasing role of digital technologies in quality management processes. The use of modern tools, such as data management systems, analytical platforms and automated control modules, opens up new opportunities in monitoring, analysis and development of production processes. For corporation "ARTERIUM" the introduction of such technologies can

become a significant factor in increasing competitiveness in the international market [3]. It is also important to consider the increased requirements of regulatory authorities, which entails increased quality control at all stages of production. In this regard, the development of a quality management system is a necessary condition for the licensing ability and long-term success of the company [5].

Therefore, improving the quality management system is an important direction that will contribute not only to strengthening the market positions of the enterprise, but also to ensuring a high level of consumer trust in its products [20].

The purpose of the qualification work is to analyze of key problems and ways to improve the quality management system in a pharmaceutical organization.

To achieve the goal of the qualification work, it is necessary to solve the following **tasks**:

- to reveal the essence of the concept of quality management and its importance for the pharmaceutical industry;
- to analyze approaches to quality management in leading pharmaceutical companies;
- to analyze the current integrated pharmaceutical quality system;
- to assess the main problems and areas for improving the quality management system;
- to develop recommendations for improving the quality management system;
- to implement innovative methods of product quality control;
- to explore the implementation of digital technologies to improve the efficiency of quality management.

The object of the study is the quality management system at the corporation "ARTERIUM".

The subject of the study is the processes and methods of improving the quality management system of a corporation "ARTERIUM", including quality control tools, optimization of production and management processes, as well as

improving interaction between the company's divisions to achieve a high level of product quality.

Methods were used for the research within the framework of the qualification work: document analysis – study of the enterprise's internal documentation on the quality management system, ISO standards, regulations, as well as instructions and regulations governing production processes and quality control; system approach – assessment of the quality management system as an integral process; method of monitoring and analysis of quality indicators – study of existing product quality indicators and their comparison with industry standards to identify weaknesses in production processes; method of expert assessments – involvement of enterprise specialists to assess the effectiveness of existing quality management methods and identify ways to improve; modeling method – creation of models to predict the results of the implementation of new quality management methods, as well as to analyze the impact of changes in production processes; comparison method – comparison of the quality management system of corporation "ARTERIUM" with similar systems at other enterprises in the pharmaceutical industry to identify opportunities for improvement; method of questionnaires and surveys – data collection using questionnaires and questionnaires among enterprise employees to identify problematic aspects in the quality management system; statistical method – processing and analysis of statistical data on product quality, the effectiveness of implemented measures and assessment of the effectiveness of the quality management system.

Practical significance of the obtained results. The practical significance of the results obtained is that they allow to improve the quality of the enterprise's products, reducing the number of defects and ensuring that the products comply with international standards. The proposed methods for optimizing production processes contribute to reducing costs, increasing the efficiency of resource use and reducing the production cycle time. The implementation of recommendations for improving the quality management system will strengthen the competitiveness of corporation "ARTERIUM" in the market, and will also increase consumer confidence due to

stable product quality. The implementation of the proposed changes will also contribute to the development of corporate culture, raising employee awareness of the importance of quality management and involving them in improvement processes. In addition, the results of the study will become the basis for integrating the enterprise's quality management system with international standards, which will increase the efficiency and stability of its activities. They can also become the basis for further scientific research in the field of quality management, which will contribute to the development of new approaches to solving current problems in the pharmaceutical industry.

Approbation of research results and publication. Qualification work is approved on X international scientific and practical distance conference «Social pharmacy: status, problems and prospects». Article has been published: Bondarieva I.V., Malyi V.V., Essakhi D. Analysis of approaches to quality management in leading pharmaceutical companies. Social pharmacy: status, problems and prospects: materials of the X International Scientific-Practical Distance Conference (24th April of 2025, Kharkiv) / ed. col.: A. A. Kotvitska and others. – Kh.: National University of Pharmacy, 2025. – P. 416-417.

Structure and scope of the qualification work. The qualification work consists of an introduction, a literature review, an experimental part, generalized conclusions, a list of sources used and appendices. The total volume of the work is 44 pages, including 19 figures and 2 tables. 30 sources of literature were used and analyzed within the framework of the study.

CHAPTER I
THEORETICAL BASIS OF QUALITY MANAGEMENT IN PHARMACEUTICAL PRODUCTION

1.1. The essence of the concept of quality management and its importance for the pharmaceutical industry

The concept of quality management involves a systematic approach to ensuring that products and services meet requirements, standards and consumer expectations. It covers all stages of a pharmaceutical company's activities – from product design and development to production, quality control and after-sales service. The main components of this concept are quality planning, control, continuous process improvement and ensuring the improvement of the management system [19]. Fig. 1.1. presents a quality system [4].

Fig. 1.1. Quality system of a pharmaceutical organization

ISO 9001 is a quality management system (QMS) standard from the international organization for standardization. It is a globally recognized framework applicable to virtually any industry, and it allows for voluntary third-party certification. According to ISO, more than 1.2 million organizations are certified in

more than 170 countries. This standard focuses on general quality management principles such as top management commitment, customer focus, a process approach, and continual improvement [14].

GMP regulations are mandatory in the EU for cosmetic products and are strongly recommended by many other countries, such as the United States. In the United States, GMP is enforced by the US Food and Drug Administration (FDA) through Current Good Manufacturing Practices (CGMP), which cover a wider range of industries such as cosmetics, food products, medical devices, and prescription drugs. Similarly, the FDA has established CGMP for food and dietary supplements to ensure the safety of these products. Thus, although GMP regulations are applied in many countries, they may be mandatory in some and strongly recommended in others [11].

GMP regulations ensure that products consistently meet high quality standards, are fit for their intended use, and comply with a marketing or clinical trial license. Unlike ISO standards, which are voluntary, GMP is legally binding, and compliance is enforced by national or regulatory authorities. GMP is essential for ensuring the safety, consistency, and efficacy of products, as it helps maintain strict quality control and manufacturing standards in the pharmaceutical, medical, food, and cosmetic industries [12].

In the pharmaceutical industry, the importance of this concept is extremely important, since the quality of pharmaceutical products directly affects the health and safety of consumers. In an industry where products are highly sensitive to changes and require strict control at all stages of production, the concept of quality management plays a key role in ensuring the safety, efficacy and reliability of medicines [14].

Quality control at all stages of development, manufacturing and testing ensures the safety and efficacy of products for consumers, which is the main task of pharmaceutical companies. The implementation of this concept allows companies to comply with international standards, such as GMP (Good Manufacturing Practices) and ISO 9001, which opens up opportunities for entering international markets and

increases competitiveness [20].

Quality management system is presented on Fig.1.2.

Fig. 1.2. Quality management system

Emphasis on defect prevention during the development and production stages minimizes the risks associated with product recalls or legal issues, and also helps to strengthen consumer confidence. In addition, continuous improvement of production processes, optimization of resources and reduction of costs allows not only to maintain high product quality, but also to increase the productivity of the enterprise [11].

The quality management system ensures compliance with all regulatory requirements and standards, which allows avoiding legal and financial sanctions, in particular in the event of non-compliance of pharmaceutical products with state or international requirements [13].Thus, the concept of quality management is the basis for the successful operation of pharmaceutical enterprises, as it guarantees the safety and effectiveness of products, meets consumer requirements and state standards, and contributes to increasing competitiveness in the market [12].

1.2. Analysis of approaches to quality management in leading pharmaceutical companies

Quality management is one of the most important components of the success

of the pharmaceutical industry, as it directly affects the safety, efficacy and compliance of products with international standards. Leading pharmaceutical manufacturers use different approaches to quality management, focusing on the highest standards and innovative practices that ensure the safety and efficacy of drugs [12].

Table 1.1 presents an analysis of quality management aspects in leading foreign pharmaceutical companies [6].

Table 1.1

Analysis of quality management aspects in leading foreign pharmaceutical companies

Company	Key approaches to quality management	Tools and methods	Features
Pfizer	Systematic approach to risk management, patient focus, data-driven decision-making	ISO 9001, Six Sigma, Lean, risk analysis	Global production and supply network, wide product range
Novartis	Strategic quality planning, innovation, cooperation with regulatory authorities	Balanced Scorecard, Six Sigma, Lean, artificial intelligence technologies	Focus on biotechnology, personalized medicine
Roche	Focus on scientific research, high ethical standards, partnership with patients	ISO 9001, Good Clinical Practice (GCP), Good Manufacturing Practice (GMP)	Leader in oncology, diagnostics
Sanofi	Systematic approach to quality management, focus on patient safety, sustainable development	ISO 9001, Six Sigma, Lean, environmental standards	Wide range of products, global presence

A key component of quality management for leading pharmaceutical companies is strict adherence to GMP standards, which regulate all aspects of pharmaceutical production. These standards cover requirements for production facilities, equipment, manufacturing processes, quality control, storage conditions, and transportation. All stages of production must be documented and controlled to avoid deviations from established standards. The implementation of GMP guarantees consistent product quality and minimizes risks associated with the safety and efficacy of drugs [6].

Many leading pharmaceutical companies integrate their quality management systems with international standards such as ISO 9001 (General Requirements for Quality Management Systems) and ISO 13485 (Quality Management Systems for Medical Devices). These standards allow pharmaceutical companies to create a holistic quality control system that extends not only to drug production but also to all other processes, from development to sales [10].

Leading companies are actively implementing the concept of total quality management (TQM), which involves integrating quality management at all levels of the organization, from management to production workers. This approach includes not only quality control processes, but also aims to continuously improve productivity, reduce costs and increase customer satisfaction. Thanks to TQM, pharmaceutical manufacturers focus on preventing errors, rather than correcting them, which contributes to improving product quality [5].

To ensure consistent quality at all stages of production, pharmaceutical companies actively use statistical methods such as control charts, variance analysis, and design of experiments. This allows not only to monitor production processes in real time, but also to predict possible errors at the development stage and make decisions to improve production conditions [11].

Leading pharmaceutical companies are actively using modern technologies to automate quality control processes. This includes the introduction of automated product monitoring and testing systems, the use of modern data analysis tools, and the application of real-time monitoring technologies for production processes.

Digitalization allows for the reduction of human errors, acceleration of verification processes, and more accurate tracking of results [5].

An important aspect of quality management is training and development of personnel. Leading companies invest significant resources in the development of their employees, conducting regular training, seminars and certifications to maintain high quality standards. This allows companies to ensure that all employees understand the importance of quality control and are prepared to apply best practices in their work processes [1].

Thus, the approaches to quality management of leading pharmaceutical companies include the integration of international standards, continuous process improvement, the use of the latest technologies and systems, and a focus on the professional development of employees. All these approaches ensure high product quality, which is important for the pharmaceutical industry, where the safety and effectiveness of drugs are in the first place [7].

Conclusions to chapter I

1. The essence of the concept of quality management and its significance for the pharmaceutical industry are described.
2. The approaches to quality management in leading pharmaceutical companies are analyzed.

CHAPTER II
ANALYSIS OF THE QUALITY MANAGEMENT SYSTEM OF CORPORATION "ARTERIUM"

2.1. Analysis of the current integrated pharmaceutical quality system of corporation "ARTERIUM"

CORPORATION "ARTERIUM" is one of the leading pharmaceutical companies in Ukraine, combining the development, production and sale of high-quality effective medicines. The company's main mission is to create products that promote a healthy, long and productive life. The company's vision is focused on long-term leadership and sustainable development through the expansion of business geography, the search for new opportunities to meet healthcare needs, achieving the highest quality standards and building consumer trust in products.

The company was founded in 2005 and unites two pharmaceutical enterprises: KYIVMEDPREPARAT and GALICHPHARM, which produce products under the ARTERIUM brand. KYIVMEDPREPARAT is a national leader in the production of antibacterial drugs. Its history dates back to 1847, and today the company produces both generic and original medicines in various forms: injections in vials, tablets, capsules, ointments, gels and suspensions. Since 2006, the company has expanded its activities by starting the production of veterinary medicines. GALICHPHARM, which has been operating since 1911, specializes in the production of herbal medicines. Its range includes injections in ampoules, tablets, tinctures, extracts, syrups and drops.

The quality management system of both companies complies with the international environmental management standard DSTU ISO 14001:2006, and the production facilities are certified in accordance with the requirements of Good Manufacturing Practice (GMP). In addition to the manufacturing enterprises, the corporation includes LLC ARTERIUM LTD, founded in 2008. Since 2016, the company has been providing a wide range of services in the field of interaction with regulatory authorities, including registration and maintenance of registration

dossiers, pharmacovigilance and consulting. The company operates in 16 countries, covering six product categories: active pharmaceutical ingredients, human medicines, veterinary medicines, herbal medicines, medical devices and dietary supplements. The quality management system of LLC "ARTERIUM LTD" meets the requirements of the international standard ISO 9001 [5]. Screenshot of the website at corporation "ARTERIUM" is presented in Fig. 2.1.

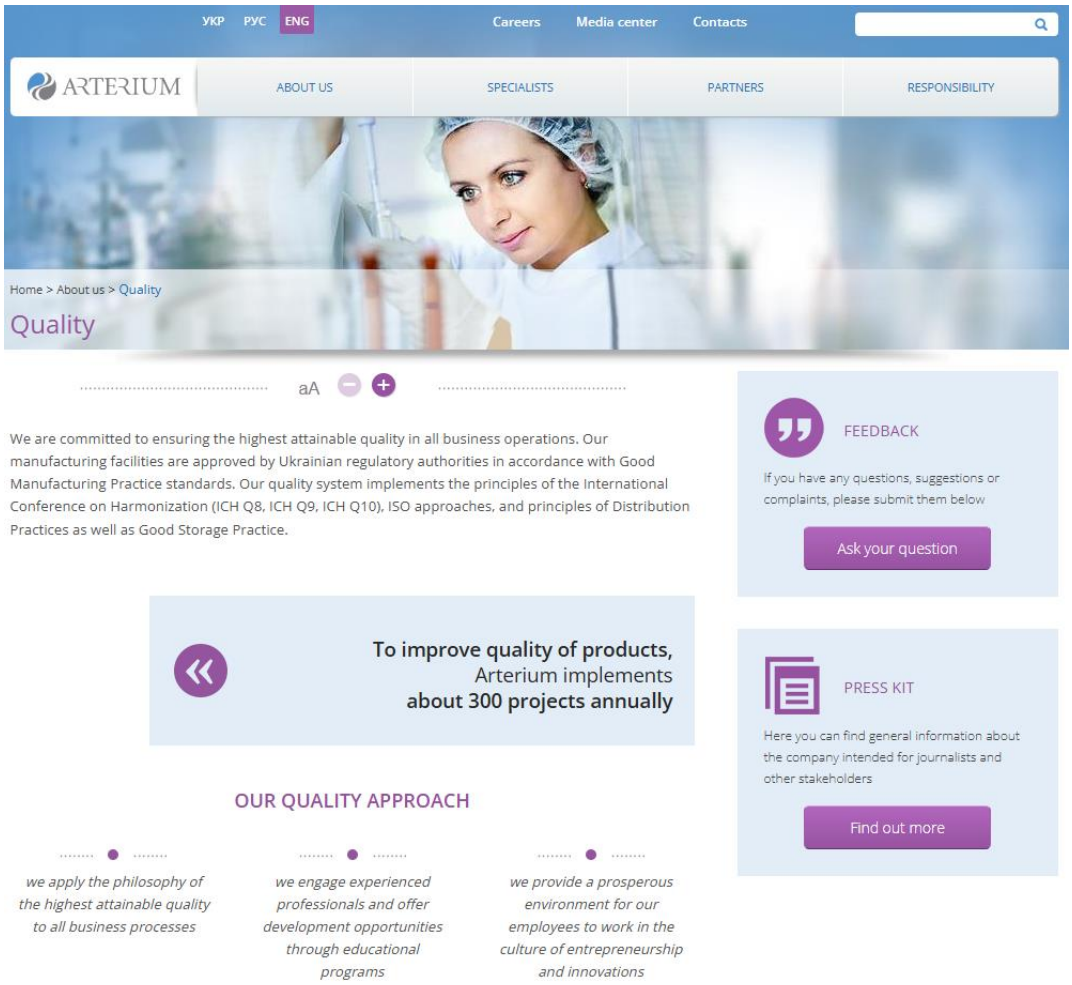

Fig. 2.1. Screenshot of the website at corporation "ARTERIUM"

The corporation's product range includes more than 140 medicines belonging to 11 out of 14 pharmacotherapeutic groups. A special place in the portfolio is occupied by original drugs, including THIOTRIAZOLIN, L-lysine ESCINATE®, THIOCETAM and UROLESAN. The corporation strictly adheres to international quality standards, including the principles of Good Manufacturing Practice (GMP), the International Conference on Harmonization (ICH Q8, ICH Q9, ICH Q10), as

well as Good Distribution and Warehouse Practices. Every year, "ARTERIUM" implements about 300 projects aimed at improving product quality [9]. The company adheres to the principle of the highest achievable quality in all business processes, attracting experienced specialists and providing opportunities for their professional development through educational programs. An important aspect of corporate policy is creating a favorable environment for employees that promotes the development of a culture of entrepreneurship and innovation [11].

2.2. Assessment of the main problems and areas for improving the quality management system of corporation "ARTERIUM"

To improve the quality management system of corporation "ARTERIUM" a survey was conducted among 55 companys employees (Appendix A). We analyzed the distribution of employees of corporation "ARTERIUM" by their positions in accordance with the data obtained. According to the results of the analysis, 7% of respondents hold senior management positions, which indicates a limited number of people who make strategic management decisions. The largest percentage, namely 39%, is made up of middle managers who are responsible for coordinating and implementing operational tasks (Fig. 2.2).

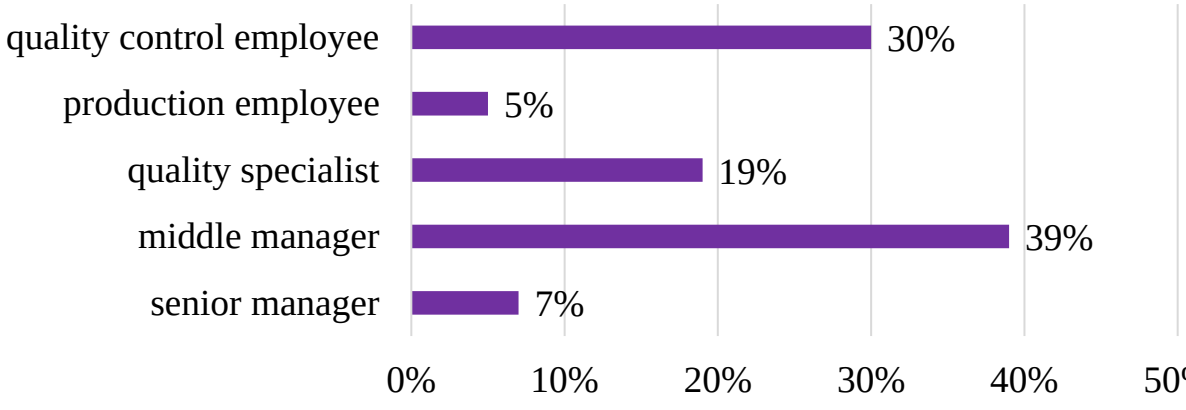

Fig. 2.2. Distribution of employees of corporation "ARTERIUM" by positions held

Quality specialists, who play a key role in ensuring that products meet standards, make up 19% of the total number of respondents. In turn, production

department employees make up the smallest group among the survey participants – only 5%. At the same time, a significant share, 30%, is occupied by quality control department employees, which emphasizes the importance of the inspection and monitoring function in the overall quality management system. Thus, the resulting distribution reflects the structure of management and production processes at the enterprise, where significant attention is paid to middle management and quality control.

Next, an analysis of the work experience of employees of corporation "ARTERIUM" was conducted (Fig. 2.3).

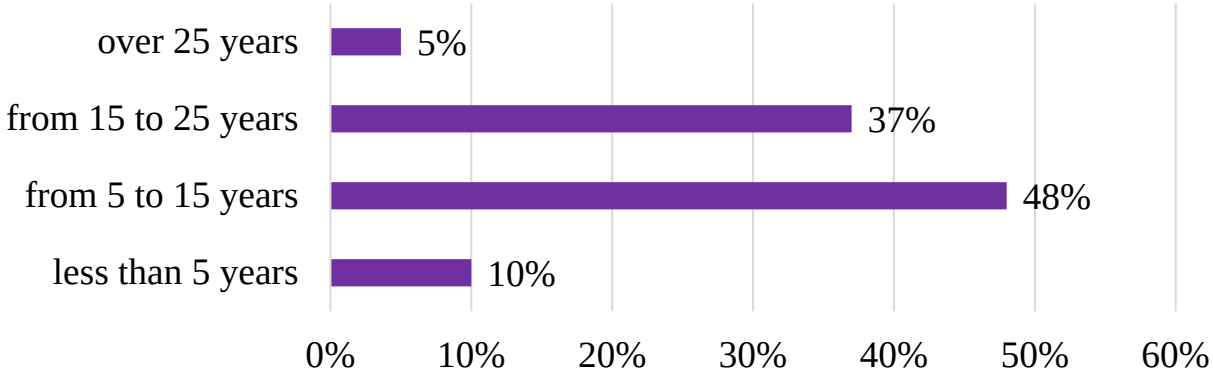

Fig. 2.3. Distribution of respondents of corporation "ARTERIUM" by length of service

According to the results obtained, only 10% of respondents have less than 5 years of experience in the company. This may indicate a certain level of stability in the company's personnel policy. The largest share, namely 48%, is made up of employees with 5 to 15 years of experience. This indicator demonstrates that a significant part of the staff has sufficient experience in the organization, which is important for ensuring its effective operation. Employees with 15 to 25 years of experience make up 37%, which indicates a high level of loyalty to the company and accumulated professional experience that contributes to the stability of processes. At the same time, the smallest share, namely 5%, is made up of employees with over 25 years of experience. This may be due to the general trend towards staff renewal or the specifics of work in the pharmaceutical industry. The data obtained reflect

both the stability of the staff and a certain orientation towards attracting new specialists, which contributes to the dynamic development of the enterprise.

When assessing the current state of the quality management system in the organization, respondents provided answers that allow us to understand the overall level of satisfaction with the functioning of this system. According to the data obtained, the majority of survey participants (64%) consider the quality management system to be "very effective". This indicates a high level of trust in existing processes, their compliance with international standards and the ability to ensure stable quality of products or services. This indicator is evidence that the system not only performs its functions, but also exceeds the expectations of employees in many aspects. 29% of respondents assessed the system as "sufficiently effective". This category corresponds to the level when the main functions of the quality management system are performed properly, but there are aspects that require some improvement. This indicates that the organization has the potential to further improve processes and introduce innovations in the field of quality management.

A small proportion of respondents (5%) consider the system to be "ineffective", which may indicate the presence of problems or limitations that negatively affect its work. Such an assessment may signal the need for a more thorough analysis of individual elements of the system and the identification of critical areas for improvement (Fig. 2.4).

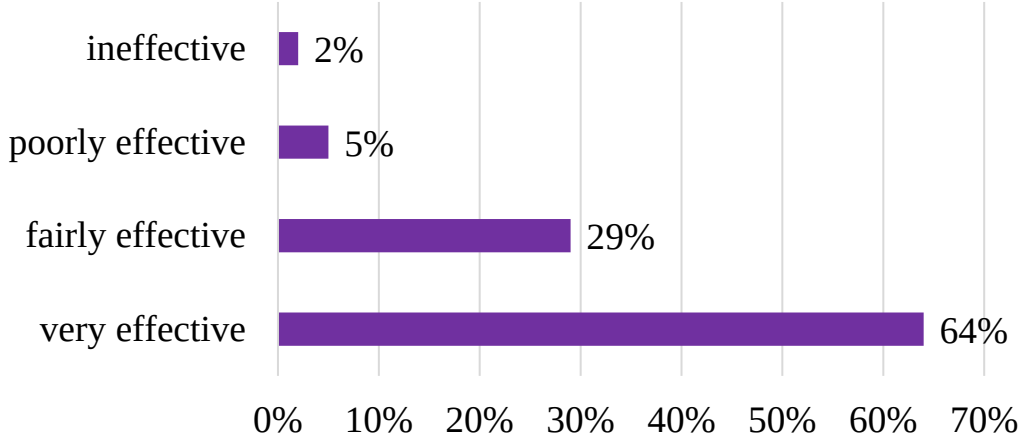

Fig. 2.4. Assessment of the current state of the quality management system corporation "ARTERIUM"

Only 2% of respondents rated the system as "ineffective". This indicates the presence of serious problems in some departments or processes that require immediate review and correction. Such a low percentage suggests that critical shortcomings are isolated cases and do not affect the overall state of the system.

Therefore, most respondents positively assess the current state of the quality management system, indicating its stability and effectiveness, while maintaining room for further improvement (Fig. 2.4).

Analyzing the problems that most affect the quality management system, the main factors that hinder its effective functioning were identified. The leader among the problems is the "imperfect regulatory framework", which was noted by 59% of respondents. This indicates that the existing legislation and regulatory requirements do not fully meet the needs of modern production or do not provide proper support in the implementation of effective quality management practices. This situation creates difficulties for an enterprise that seeks to meet international standards and remain competitive. In second place was the problem of "low employee motivation", which was noted by 28% of respondents. It indicates the need to revise the personnel management policy, in particular, the implementation of measures to increase employee interest in achieving high results, stimulate professional development and create a favorable working environment. The lack of qualified personnel was identified as a significant barrier to effective quality management by 7% of respondents. This factor indicates that the organization may face a shortage of specialists who have the necessary knowledge and skills to ensure that products meet high quality standards. The lack of modern equipment was noted by 6% of respondents. This shows that for a small part of employees, the problem of technical support is an important limitation. It may be necessary to consider updating or upgrading individual technological processes to ensure their compliance with modern requirements. Thus, the greatest impact on the quality management system is exerted by regulatory aspects, followed by issues of staff motivation, the availability of qualified specialists and technical support. These results help to

outline the key areas that should be paid attention to in order to improve the effectiveness of quality management in the organization (Fig. 2.5).

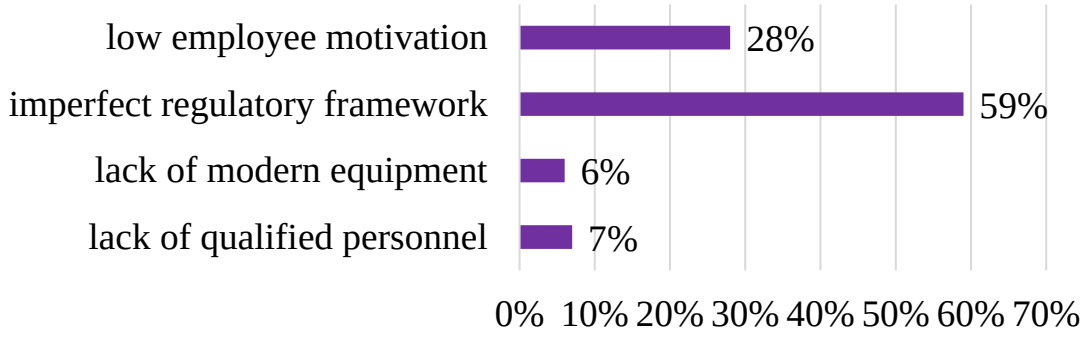

Fig. 2.5. Assessment of the problems that most affect the quality management system

At the next stage of the work, the level of personnel training in the field of quality management was assessed. It was found that the vast majority of employees (72%) assess the level of training as high. This indicates that the company has qualified specialists who have the necessary knowledge, skills and experience to effectively perform tasks in the field of quality management. This result indicates the successful work of the organization in the direction of training and development of personnel, which allows ensuring that products or services comply with international quality standards. 20% of respondents assessed the level of training as average. This indicates that the organization has employees who have basic knowledge in the field of quality management, but they may lack deeper specialization or practical experience to solve complex tasks. This result may indicate the need for additional educational events, trainings or seminars to improve the professional level of such employees. 8% of respondents consider the level of training to be low. This indicates that the organization has a small proportion of personnel who are not sufficiently familiar with quality management methods or do not have proper training to perform their duties. This situation may be the result of insufficient attention to the training and development of this group of employees, and also requires an immediate review of approaches to professional development. Thus, the results indicate that the majority of staff have a high level of training,

which ensures the effectiveness of the quality management system. However, there is a certain proportion of employees with medium and low levels of training, which indicates the potential for improving training programs and supporting staff in mastering new knowledge and skills (Fig. 2.6).

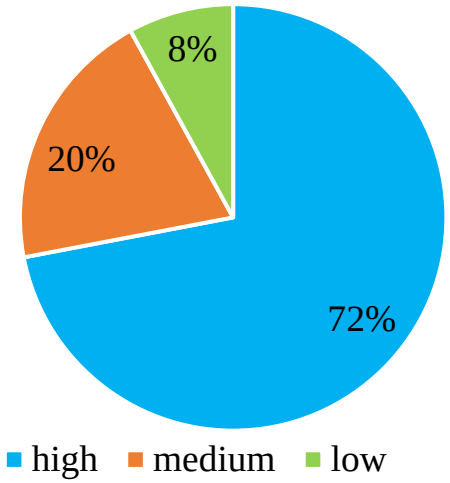

Fig. 2.6. Analysis of the level of personnel training in the field of quality management

Next, we analyzed the level of funding for quality improvement activities (Fig. 2.7).

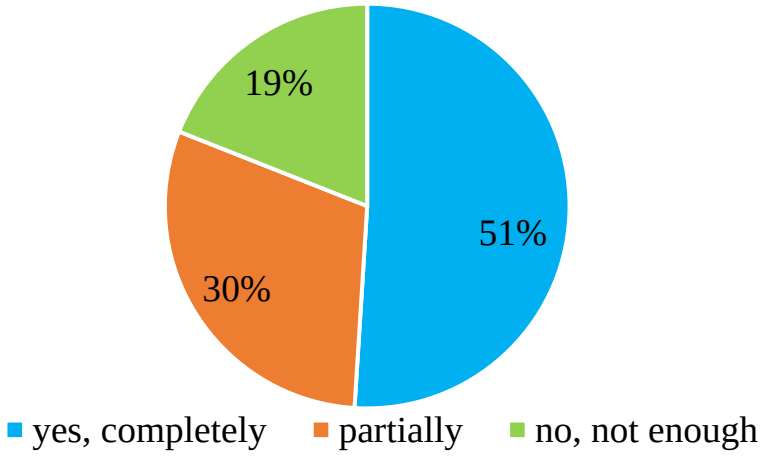

Fig. 2.7. Analysis of the level of funding for quality improvement activities

It was found that 51% of respondents consider the level of funding for quality improvement activities to be fully sufficient. This indicates that for most employees,

the organization provides the necessary resources to implement initiatives and projects related to improving the quality management system. This result indicates effective management of financial resources and strategic attention of management to quality issues. At the same time, 30% of respondents assessed the funding as partially sufficient. This means that in some cases there are resources for implementing quality improvement activities, but they may not be enough for large-scale or innovative projects. This result emphasizes the need to optimize budgets or prioritize the most important initiatives. 19% of respondents indicated an insufficient level of funding. This indicates that almost a fifth of employees believe that the resources allocated to ensuring and improving quality are limited, which may hinder the implementation of necessary changes or innovations. Such a situation may indicate certain financial constraints that prevent achieving maximum efficiency in this area. Overall, the survey results show that most employees are positive about the level of funding for quality improvement activities, but there is a significant proportion of respondents who indicate a partial or complete lack of resources. This indicates the possibility of reviewing financial strategies and finding additional sources of funding to fully meet the needs of quality management (Fig. 2.7).

At the next stage of our work, we analyzed the responses of employees of corporation "ARTERIUM" regarding the quality control methods used at the enterprise. This made it possible to determine which approaches to quality assurance are dominant in the company and how they contribute to achieving high standards. The absolute majority of respondents (81%) indicated that the main method of quality control in the organization is the use of automated control systems.

This result emphasizes the importance of technological support for quality management processes. Automation allows you to achieve high accuracy of inspections, quickly detect deviations, reduce the human factor and increase the efficiency of processes. This indicates the implementation of modern solutions that meet international standards and allow the enterprise to remain competitive. 10% of respondents noted constant monitoring of processes as the main method of quality control. This approach provides systematic supervision of all stages of production,

which allows you to identify and eliminate possible problems in a timely manner (Fig. 2.8).

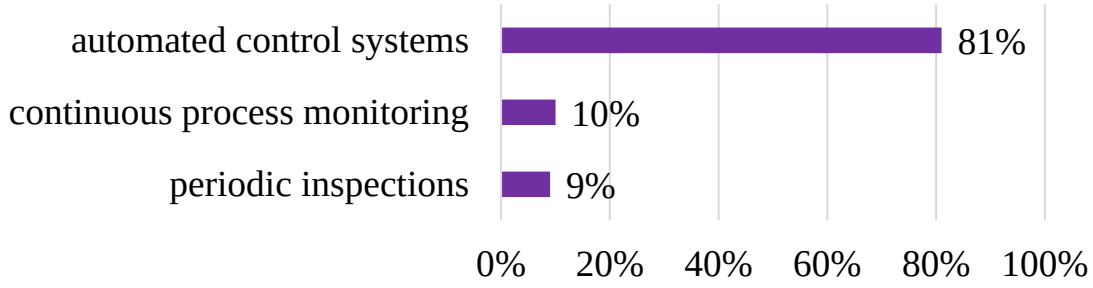

Fig. 2.8. Analysis of quality control methods used at the enterprise

Constant monitoring helps maintain stable product quality and increases consumer confidence. Periodic inspections were cited as a quality control method by 9% of respondents. Although this approach is less popular, it also plays an important role in quality assurance, allowing for thorough inspections at specific stages of production or after the completion of individual processes.

Thus, the results of the analysis demonstrate that corporation "ARTERIUM" is focused on the implementation of modern automated control systems that ensure the efficiency and reliability of quality management processes.

At the same time, the use of constant monitoring and periodic inspections complements the overall control system, providing a comprehensive approach to maintaining high quality standards (Fig. 2.8).

Next, we analyzed the responses on the effectiveness of the feedback system for identifying quality problems. The majority of respondents (97%) noted that corporation "ARTERIUM" has a feedback system for identifying quality problems. This indicates that the company pays significant attention to creating communication channels that allow for quick receipt of information about possible shortcomings or deviations in processes. Feedback systems may include regular surveys, analysis of customer feedback, collection of proposals from personnel and other mechanisms. Their implementation ensures a quick response to identified problems, contributes to process improvement and product quality improvement. However, 3% of

respondents indicated that the pharmaceutical organization does not have a feedback system for identifying quality problems. This may indicate certain shortcomings in communication processes at the level of individual departments or divisions. The absence of such a system may slow down the identification and elimination of problems, which negatively affects the overall quality of products or services.

Thus, the results of the study indicate that the majority of employees recognize the existence of an effective feedback system in the enterprise, which is an important element of quality management. However, the presence of a certain proportion of respondents who indicated its absence emphasizes the need for further improvement of communication processes to ensure the involvement of all participants in the system for identifying and solving quality problems.

At the next stage of our work, the effectiveness of the feedback system was analyzed (Fig. 2.9).

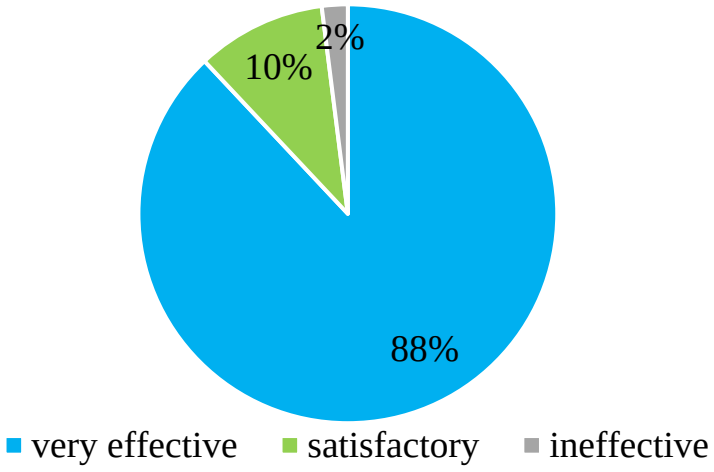

Fig. 2.9. Analysis of the effectiveness of the feedback system

The feedback system was found to be very effective, as evidenced by the high percentage of positive ratings. 88% of respondents indicated that the system provides effective interaction and allows for timely information about emerging problems or needs. It is a convenient tool for receiving and providing feedback, which contributes to a quick response to requests and resolving emerging issues.

Only 10% of respondents rate the system satisfactorily. This indicates that certain aspects of the system's operation can be improved. For example, there may

be delays in processing requests or the need to improve the communication channel, which affects the speed and accuracy of receiving feedback.

Only 2% of respondents consider the feedback system ineffective, which indicates a small percentage of dissatisfied users. This may be due to specific cases or shortcomings in the work of individual elements of the system that need improvement. In the general context, the feedback system demonstrates high efficiency, which has a positive impact on the overall process of communication and problem solving.

Next, we analyzed the importance of areas for improving the quality management system. The most important areas for improving the quality management system, according to the survey, are process automation, staff training, implementation of new standards and increasing employee motivation. Each of these areas plays an important role in improving overall efficiency and quality of work. Process automation occupies the highest position, receiving 30% support (Fig. 2.10).

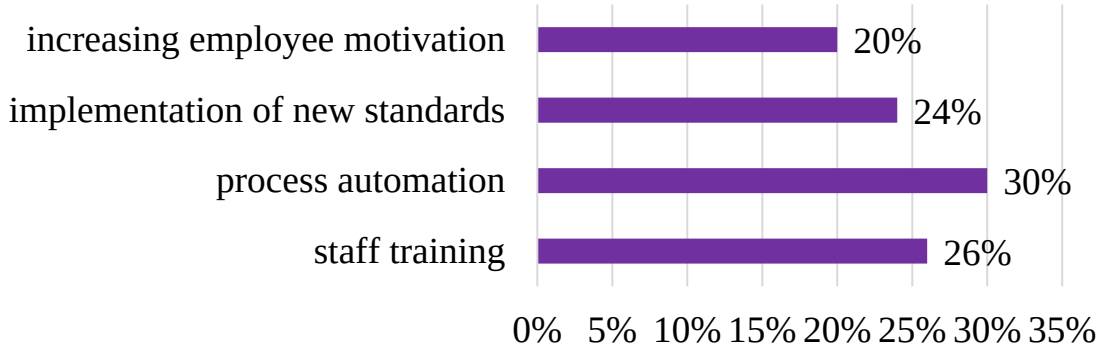

Fig. 2.10. Analysis of the importance of areas for improving the quality management system

This indicates the need to introduce modern technologies to reduce the human factor, increase the accuracy of task performance and optimize work processes. Automation allows you to significantly reduce the likelihood of errors and simplify monitoring and quality control at various stages of production. Staff training, which was supported by 26% of respondents, is another important area for improving quality management. Qualified employees are able to ensure a high level of task

performance, considering the latest requirements and standards. Regular training and development ensure compliance with modern market requirements and technical standards. The introduction of new standards, supported by 24% of respondents, is a key area, since compliance with international quality standards allows not only to improve products, but also to increase the company's competitiveness in the market. Constant updating of standards and requirements allows to meet the requirements of consumers and regulators. Increasing employee motivation, which was supported by 20%, is also an important aspect for ensuring high quality of work. Motivation can include both material and non-material incentives that contribute to employee involvement, increasing their interest in achieving high results and supporting corporate values. Thus, each of these areas requires attention and development to achieve maximum efficiency and stable quality in all aspects of work (Fig. 2.10).

We determined the frequency of training for personnel on quality issues. It was found that 60% of respondents noted that training for personnel on quality issues is conducted regularly (Fig. 2.11). This indicates the importance of continuous training and advanced training of employees on standards and requirements related to the quality of work. Regular training allows employees to stay abreast of the latest trends, changes in industry requirements, and also helps to strengthen the corporate culture of quality, contributing to its integration into everyday activities.

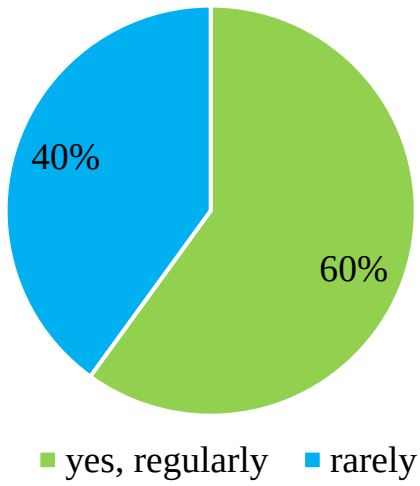

Fig. 2.11. Analysis of the frequency of training for quality personnel

On the other hand, 40% of respondents noted that quality training is rarely conducted, which may indicate the need to improve the training system at corporation "ARTERIUM". Irregular training may limit employees' opportunities to acquire relevant knowledge, which in turn may negatively affect the quality of work. In such cases, there may be a need to improve the training process and provide more frequent and diverse training that would cover different aspects of quality management.

Irregular training may also be due to limited resources, lack of management attention to the issue, or other internal factors. The lack of systematic training can affect work efficiency and the ability of personnel to adapt to changes that are constantly occurring in the field of quality standards (Figure 2.11).

Also, of interest was information on the assessment of the impact of employee motivation on the quality of products/services at corporation "ARTERIUM" (Fig. 2.12).

The impact of employee motivation on the quality of products and services at corporation "ARTERIUM" is assessed as very significant, which is confirmed by the results of the survey, where 75% of respondents indicated exactly such an assessment. This indicates that motivation is an important factor in achieving high quality standards at the enterprise. Interested and motivated employees are ready to make more efforts to improve results, perform tasks at the highest level and maintain high standards of product and service quality. Motivation helps not only to increase work efficiency, but also to strengthen team spirit, create a favorable atmosphere for achieving common goals.

In comparison, 20% of respondents indicated that the impact of motivation on quality is moderate. This may indicate that motivation has some effect on the quality of work, but is not the only factor that determines the final result. In such cases, it is necessary to strengthen the link between motivation and quality through the development of additional incentives, improved training systems and a clearer understanding of how specific motivational factors can be applied to the quality control process.

Only 5% of respondents believe that the impact of motivation on quality is insignificant. This may indicate the existence of other important factors that, in their opinion, play a more significant role in ensuring quality. However, this percentage is quite small, which means that most employees are aware of the importance of motivation for achieving high results in production and service.

Thus, for most employees of corporation "ARTERIUM", motivation has a direct and very significant impact on the quality of products and services, which emphasizes the importance of effective motivation strategies to ensure high standards at a pharmaceutical enterprise (Fig. 2.12).

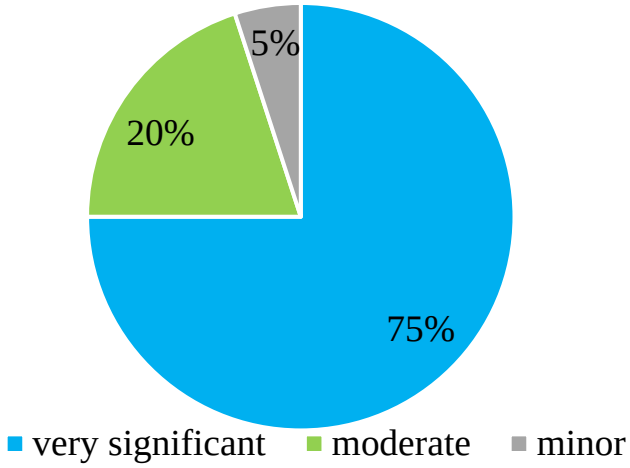

Fig. 2.12. Assessment of the impact of employee motivation on the quality of products/services at corporation "ARTERIUM"

Next, the availability of modern equipment to ensure high quality of medicines was analyzed (Fig. 2.13).

At corporation "ARTERIUM", the availability of modern equipment to ensure high product quality is assessed very positively. 89% of respondents noted that the equipment fully meets the needs of the organization. This indicates that the company invests in technologies that allow maintaining high quality standards at all stages of production. The use of modern equipment allows ensuring accuracy, efficiency and stability of production processes, which, in turn, has a positive effect on the final product and consumer satisfaction.

At the same time, 8% of respondents indicated that the equipment partially meets the needs. This may indicate the presence of certain technical limitations or the need to update individual elements of the equipment to fully achieve the required level of quality. Partial non-compliance may be associated with certain aspects of the production processes or the need for modernization to ensure continuous compliance with high quality standards.

Only 3% of respondents indicated that equipment needs to be updated, which is a fairly low percentage. This may indicate that the enterprise has already made significant steps towards updating its technological base, but some old equipment may still need to be replaced or upgraded to improve efficiency and product quality. In such cases, it is important to constantly monitor technological developments and implement the necessary updates in a timely manner.

Overall, most respondents confirm the availability of modern equipment that meets the requirements for ensuring high quality, with a minimal number of comments regarding the need for updating or partial non-compliance. This indicates a stable technical base of the enterprise, which is an important factor in achieving high product quality standards.

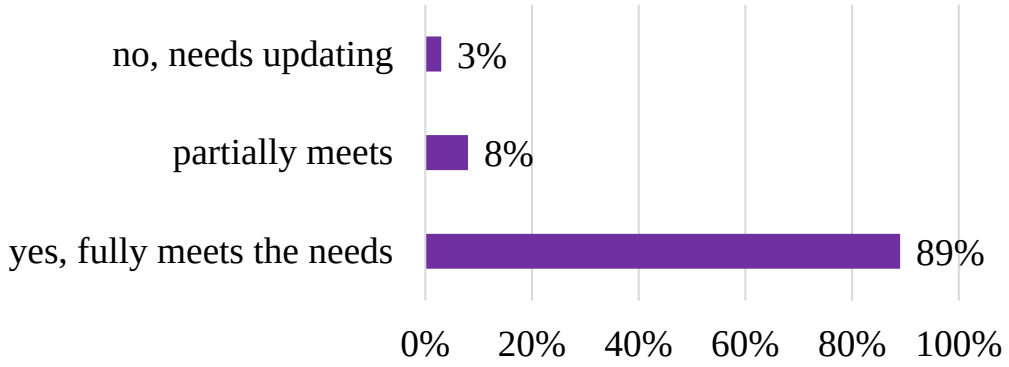

Fig. 2.13. Analysis of the availability of modern equipment to ensure high quality of medicines

At the next stage, we analyzed the quality standards applied at corporation "ARTERIUM". The enterprise applies a number of international quality standards that ensure high efficiency, environmental friendliness and safety of production

processes. 100% of respondents noted that the organization adheres to the following basic standards: ISO 9001 (standard that defines the requirements for a quality management system. Its application in an organization ensures the effective operation of all processes, focusing on continuous improvement of products and services, as well as on meeting consumer requirements. Compliance with this standard helps to create a systematic structure for quality control at all stages of production); ISO 14001 (standard that regulates the environmental management system. Its application in an organization allows to effectively control the impact of production on the environment, reduce the level of pollution and resource consumption, which contributes to the sustainable development of the enterprise and increases its environmental responsibility); OHSAS 18001 (standard for occupational safety and health management. It provides a high level of protection of employees from occupational risks, helps to create a safe working environment and reduce the number of industrial injuries, which is an important aspect for any enterprise focused on efficient work and social responsibility); GMP (Good Manufacturing Practices) (a standard that regulates good manufacturing practice. The implementation of GMP allows you to control the quality of products at all stages of their production, from raw materials to finished products, which is especially important for the pharmaceutical and chemical industries, where product quality directly affects the health of consumers); SA8000 (an international standard for social responsibility. This standard is aimed at improving working conditions, protecting workers' rights and ensuring ethical norms in relations between employers and employees. SA8000 supports the observance of human rights, the fight against child labor and discrimination); ISO 50001 (a standard that defines requirements for an energy management system. Its application helps an organization effectively manage energy resources, reduce energy costs and contribute to reducing the environmental footprint, which is an important aspect for increasing the energy efficiency of an enterprise).

Thus, the application of these standards in corporation "ARTERIUM”, allows to ensure high quality indicators of products and services, effective resource

management, environmental protection and occupational safety, as well as a responsible attitude to social aspects. These standards are the basis for achieving stability, competitiveness and sustainable development of the enterprise in the market (Fig. 2.14).

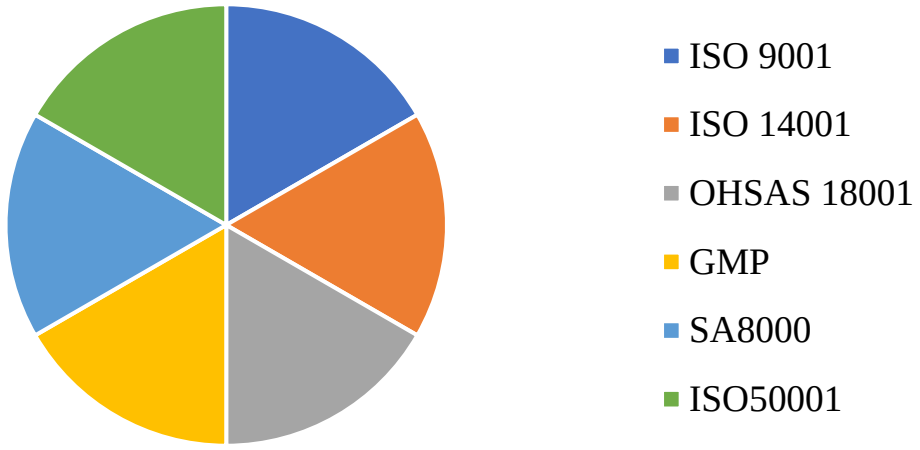

Fig. 2.14. Analysis of quality standards applied at corporation "ARTERIUM"

It was found that corporation "ARTERIUM" conducts quality management system audits regularly, with 99% of respondents indicating that they are conducted annually or more often. This means that the organization pays significant attention to continuous monitoring and improvement of its quality management system, which is an important element for maintaining high standards in production and service provision. Regular audits allow for timely identification of shortcomings in processes, assessment of the effectiveness of existing measures and taking corrective actions to improve product quality and compliance with international standards.

Audits are conducted in accordance with established procedures, which allows for a detailed examination of all aspects of the company's operations, including compliance with ISO, GMP and other requirements. Regular audits also help strengthen the corporate culture of quality by ensuring constant attention to processes and results at all levels of the organization. This allows not only to detect violations or non-conformities in a timely manner, but also to systematically improve operational efficiency and reduce risks associated with quality management.

Only 1% of respondents indicated that audits are conducted irregularly, indicating a small portion of the organization where there may be some issues with the frequency or regularity of such audits. In such cases, there may be a need to strengthen control over audit schedules or optimize the process to ensure a more consistent assessment of the effectiveness of the quality management system.

In general, regular audits are one of the important factors that maintain a stable level of quality and contribute to continuous improvement of processes at the enterprise.

It was found that corporation "ARTERIUM" actively uses innovative technologies to improve quality, as evidenced by 80% of positive responses from respondents. This indicates that the organization is focused on implementing modern technological solutions to improve its production processes, improve the quality of products and services, and optimize resource costs. The use of innovative technologies allows the enterprise not only to meet market requirements, but also to stay ahead of the competition, introducing the latest achievements in the industry that ensure increased accuracy, efficiency and stability of results. Innovative technologies may include automation of production lines, the use of the latest equipment for quality control, the use of modern software solutions for monitoring and managing processes, as well as the use of new methods of data processing and feedback. These technologies allow to significantly reduce the number of errors, increase production speed and ensure more accurate compliance with quality standards at all stages of production. However, 20% of respondents noted that innovative technologies are not used in their organization. This may indicate certain limitations associated with the resources required to implement new technologies, or with insufficient attention to this aspect by management. In such cases, the enterprise may need to reconsider its development strategy and invest in the latest technologies to ensure competitiveness and compliance with the requirements of the modern market. In general, most enterprises of corporation "ARTERIUM" actively use innovative technologies to improve product quality, which is an important aspect of their competitiveness and long-term success in the market.

We further established that corporation "ARTERIUM" has a quality management system development strategy, which has different levels of certainty among respondents. 65% of respondents noted that the quality management system development strategy is clearly developed. This indicates that the organization has a well-structured and understandable strategy that covers all the main aspects of ensuring high quality standards at all stages of the production process. A clearly defined strategy allows management to effectively plan actions, allocate resources and monitor results, ensuring continuous improvement of the quality management system. 30% of respondents indicated that the quality management system development strategy in the organization is partially defined. This means that there are certain areas of quality development, but they may not be fully formulated or may not cover all aspects that must be taken into account to achieve and maintain high standards. Partial definition of the strategy may indicate that the organization is working on its improvement or is looking for new ways to manage quality more effectively. 5% of respondents indicated that there is no strategy for developing a quality management system. This may indicate the need to develop or refine a strategy to define the main goals and objectives in the field of quality management, as well as to contribute to the sustainable development of the organization.

At the next stage of our work, the sources of information on quality were analyzed (Fig. 2.15). Corporation "ARTERIUM" uses various sources of information to assess and monitor the quality of products and services, among which the largest share is occupied by internal inspection reports. 60% of respondents indicated that the organization actively uses these reports for quality analysis and control. Internal inspections are an important tool for identifying problems at different stages of production, as well as for detecting possible deviations from established quality standards. Internal inspection reports allow for timely detection of shortcomings in processes and implementation of corrective actions, which contributes to improving product quality. Customer feedback data is a less significant source of information, as only 12% of respondents indicated it as an important factor in the quality management system. However, this type of feedback

is important for understanding consumer needs and identifying shortcomings that may affect the perception of quality. Customer feedback allows you to consider their requirements and expectations, which allows you to adjust products or services in accordance with market changes. The results of external audits are also used to assess quality, as noted by 28% of respondents. External audits are an important source of independent assessment of an organization's compliance with international quality standards, such as ISO or GMP. They provide an external perspective on the company's processes and allow you to identify potential problems that internal audits may have missed. The results of external audits can help the organization receive recommendations for further improvements to the quality management system. Thus, the main source of information for quality monitoring is internal audit reports, which emphasizes the importance of continuous self-control in the organization. At the same time, external audits and customer feedback also play their role, helping to complement and refine the quality picture (Fig. 2.15).

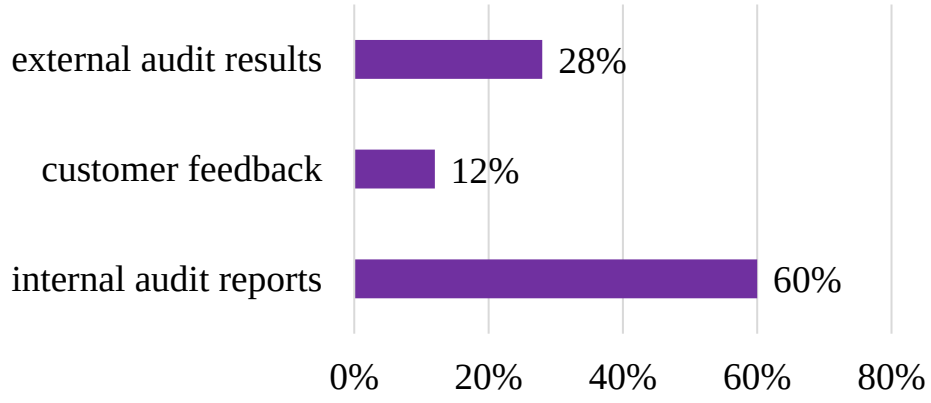

Fig. 2.15. Analysis of sources of information about quality

Next, we analyzed the involvement of employees in quality management processes (Fig. 2.16). At corporation "ARTERIUM", employees are sufficiently involved in quality management processes, which is confirmed by the responses of 86% of respondents who indicated that employees are fully involved. This indicates that the majority of employees actively participate in activities aimed at improving the quality of products and services. Involving employees at all stages of production, from quality control to the implementation of improvements, is an important factor

in achieving high standards. Active participation of personnel allows not only to ensure continuous improvement of processes, but also motivates employees to achieve common goals in quality assurance.

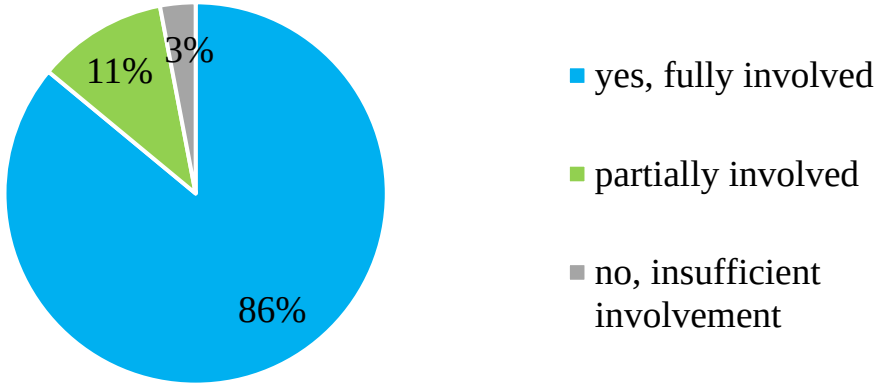

Fig. 2.16. Analysis employee involvement in quality management processes

However, 11% of respondents indicated that employees are partially involved in quality management processes. This may mean that not all employees are fully integrated into the quality control and improvement processes. Partial involvement may be associated with certain barriers, such as insufficient understanding of the importance of the quality management system or limited opportunities for employees to actively participate in these processes. In such cases, it is worth paying attention to the need for additional training or improved communication channels to involve all employees in this important area of activity. Only 3% of respondents indicated that employee involvement in quality management processes is insufficient. This may indicate that there are certain problems related to motivation, lack of a clear strategy or insufficient emphasis on the importance of quality management for the enterprise. In such cases, the organization should consider opportunities to improve staff involvement, for example, by strengthening internal communications, encouraging initiative and active participation in quality improvement processes. In general, the majority of employees in the enterprise are actively involved in quality management, which contributes to the effective achievement of high standards and stability of production processes.

Also, of interest was information on the analysis of the main obstacles to quality improvement (Fig. 2.17). It was found that the main obstacle to quality improvement at corporation "ARTERIUM" was considered by respondents to be the lack of management support, which received 40% of responses. This indicates that the key problem is insufficient attention from management to quality management issues or the lack of necessary solutions to implement effective changes. Management support is a critically important factor for the successful development of a quality management system, since it is the management that determines strategic priorities, allocates resources, and creates conditions for effective staff work. Insufficient support can slow down the process of implementing changes and reduce employee motivation to participate in quality improvement. In second place among the obstacles was the lack of modern equipment, which was noted by 32% of respondents. This emphasizes the importance of updating the technical base of the enterprise to ensure compliance with modern quality standards. Modern equipment allows to increase the accuracy and efficiency of production processes, and its lack can create significant difficulties in achieving the desired results, which affects the competitiveness of the organization. Low qualification of personnel, which was noted by 17% of respondents, is also an important obstacle to improving quality. This indicates the need to improve the qualifications of employees, organize trainings and education, which will allow employees to better understand their responsibilities, the latest standards and technologies. Highly qualified personnel is the basis for ensuring a stable level of quality of products and services.

Lack of resources received 11% of responses, indicating some limitations in financing or material support necessary to implement quality improvement measures. Although this factor ranks last among the indicated barriers, it can also affect the organization's ability to modernize equipment, implement new technologies or develop personnel. Thus, the main barriers to quality improvement in the organization are related to management decisions, technical support and personnel development. Overcoming these challenges requires a comprehensive

approach, including active support from management, investment in modern equipment and human resources.

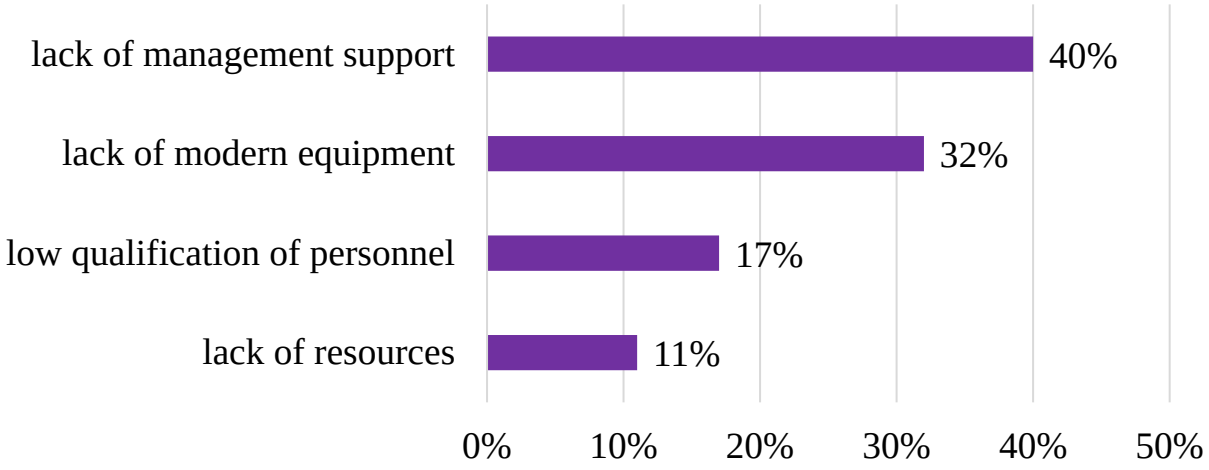

Fig. 2.17. Analysis of the main obstacles to improving quality in the company

Conclusions to chapter II

1. The current integrated pharmaceutical quality system of corporation "ARTERIUM" was analyzed. In order to improve the quality management system of corporation "ARTERIUM", a survey of 55 employees of the company was conducted. It was established that the company's quality management system demonstrates a high level of efficiency and responsibility for international standards. Most employees are satisfied with its functioning, which indicates trust in existing processes.

2. It was found that the company has a stable staff of experienced specialists. However, there is a need for further development of the competencies of middle and junior staff, particularly in the area of quality management. It has been established that the biggest problems affecting the system are the imperfect regulatory framework, insufficient employee motivation, and, in some cases, the lack of modern equipment. It was found that most employees have a high level of training, but there is potential for further development, especially for middle management. It was found that although most respondents are satisfied with the level

of funding for quality improvement measures, there is a need for additional investments, especially for the introduction of innovative technologies.

3. It was found that the company actively uses automated control systems, which indicates a modern approach to quality assurance. However, it is necessary to pay attention to the constant updating and improvement of these systems. It was found that the feedback system functions effectively, but requires further development for a faster response to changes and customer needs. It was found that the main areas for improving the system are automation of processes, staff training, implementation of new standards and increasing employee motivation.

4. It has been established that employee motivation has a significant impact on product quality. It is necessary to continue to develop the motivation system to increase employee engagement and efficiency. The company has modern equipment, but it is necessary to constantly monitor its condition and carry out timely modernization. The company adheres to international quality standards, which indicates a high level of responsibility. Regular audits of the quality management system allow for timely identification of shortcomings and implementation of improvements. It has been established that the company actively uses innovative technologies, which contributes to improving product quality. Most respondents believe that the strategy for developing the quality management system is clearly defined.

5. It has been established that the main source of quality information is internal audit reports. However, it is also necessary to actively use customer feedback and external audit results.

CHAPTER III
DEVELOPMENT OF RECOMMENDATIONS FOR IMPROVING THE QUALITY MANAGEMENT SYSTEM

3.1. Implementation of innovative methods of product quality control

We have developed recommendations for the further development of the quality management system: develop a detailed action plan to eliminate identified problems and implement new initiatives; increase the level of staff involvement in quality management processes; create a system of continuous training and staff development; provide sufficient funding for the implementation of quality improvement measures; introduce new technologies to increase the efficiency and quality of production; strengthen control over compliance with quality standards at all stages of production; expand the use of customer feedback data for continuous improvement of products and services [20].

To improve the quality management system, we have investigated innovative methods of product quality control, which are presented in Table 3.1.

Table 3.1

Characteristics of innovative methods of product quality control

Quality control method	Method description	Advantages	Disadvantages	Areas of application
Statistical Process Control (SPC)	Using statistical methods to monitor production processes and detect deviations from set parameters	High accuracy, early detection of problems, reduced costs for defect correction	Requires specialized statistical knowledge, can be difficult to implement	Mass production, processes with many variables
Six Sigma	A comprehensive methodology aimed at reducing costs, improving quality and customer satisfaction by identifying and	Systematic approach, high quality, cost reduction	Requires significant investment of time and resources, can be difficult to implement	Any industry

	eliminating the causes of defects			
Lean manufacturing	A production philosophy aimed at minimizing waste and maximizing value for the customer	Cost reduction, efficiency improvement, quality improvement	Requires significant changes in organizational culture, can be difficult to implement	Any industry
Using artificial intelligence	Application of machine learning algorithms for analyzing large amounts of data, predicting failures, and optimizing processes	High accuracy of forecasts, automation of control processes, detection of anomalies	Requires significant investment in IT infrastructure and specialists	Manufacturing with large amounts of data, complex processes
Blockchain	Technology that allows for the creation of secure, transparent and immutable records of product origin and history	Increased transparency, product traceability throughout the entire lifecycle, protection against counterfeiting	High implementation cost, requires integration with other systems	Pharmaceuticals, food industry, production of expensive goods
Augmented Reality (AR)	Technology that overlays virtual objects on the real world, allowing for improved instructions for operators and visualization of processes	Improving the accuracy of operations, reducing the number of errors, increasing the efficiency of learning	Requires special equipment, can be expensive	Difficult assembly, maintenance

3.2. Implementation of digital technologies to improve the efficiency of quality management

The modern approach to quality management requires the use of innovative digital technologies that allow to increase the accuracy, speed and efficiency of processes. The implementation of digital solutions opens up new opportunities for

optimizing production and management processes, reduces risks and ensures compliance with the highest quality standards [3].

The main directions of implementation of digital technologies: the use of automated control systems allows you to constantly monitor key quality indicators in real time. This allows you to quickly detect deviations, prevent production defects and ensure process stability. Implementation of electronic systems for document management, such as Document Management System, provides quick access to the necessary information, version control and reduction of errors due to the human factor. This is especially important for compliance with regulatory requirements and standards. Big Data Analysis allows you to identify patterns, predict possible problems and optimize processes. Thanks to analytical platforms, organizations can make informed decisions to improve quality. IT technologies allow you to connect equipment, sensors and systems into a single network. This provides continuous data collection from production lines, helps to instantly respond to changes and increases work efficiency. These technologies are used for staff training, simulations of complex processes and improving communications between departments. For example, VR trainings help employees better absorb knowledge about quality management. Cloud platforms allow you to centralize quality management, provide access to systems from anywhere and simplify collaboration between different teams or departments. Advantages of implementing digital technologies: automation reduces the number of human errors; technologies reduce the time for performing routine tasks and provide quick access to data; analytical tools allow you to identify potential risks before they are implemented; digital solutions simplify auditing and confirmation of compliance with regulatory requirements (GMP, ISO, etc.); process optimization and reduction of downtime reduce production costs [7].

Among the main challenges that may arise during the implementation of digital technologies, one can single out the high cost of equipment and software, the need for personnel training, as well as the complexity of integrating new solutions into existing processes. However, these challenges can be overcome through phased implementation, involving qualified consultants and investing in personnel

development. Digital technologies are an integral part of a modern quality management system [9]. Their implementation ensures the competitiveness of enterprises, increases consumer confidence and contributes to the achievement of the strategic goals of the organization. Corporation "ARTERIUM", focusing on digitalization, can strengthen its position as a leading manufacturer of high-quality pharmaceutical products.

Conclusions to chapter III

1. Recommendations have been developed to improve the quality management system.
2. The implementation of digital technologies to improve the efficiency of quality management is investigated.

GENERAL CONCLUSIONS

1. The essence of the concept of quality management and its significance for the pharmaceutical industry are described. The approaches to quality management in leading pharmaceutical companies are analyzed.

2. The current integrated pharmaceutical quality system of corporation "ARTERIUM" was analyzed. In order to improve the quality management system of corporation "ARTERIUM", a survey of 55 employees of the company was conducted. It was established that the company's quality management system demonstrates a high level of efficiency and responsibility for international standards. Most employees are satisfied with its functioning, which indicates trust in existing processes.

3. It was found that the company has a stable staff of experienced specialists. However, there is a need for further development of the competencies of middle and junior staff, particularly in the area of quality management. It has been established that the biggest problems affecting the system are the imperfect regulatory framework, insufficient employee motivation, and, in some cases, the lack of modern equipment. It was found that most employees have a high level of training, but there is potential for further development, especially for middle management. It was found that although most respondents are satisfied with the level of funding for quality improvement measures, there is a need for additional investments, especially for the introduction of innovative technologies.

4. It was found that the company actively uses automated control systems, which indicates a modern approach to quality assurance. However, it is necessary to pay attention to the constant updating and improvement of these systems. It was found that the feedback system functions effectively, but requires further development for a faster response to changes and customer needs. It was found that the main areas for improving the system are automation of processes, staff training, implementation of new standards and increasing employee motivation.

5. It has been established that employee motivation has a significant impact on product quality. It is necessary to continue to develop the motivation

system to increase employee engagement and efficiency. The company has modern equipment, but it is necessary to constantly monitor its condition and carry out timely modernization. The company adheres to international quality standards, which indicates a high level of responsibility. Regular audits of the quality management system allow for timely identification of shortcomings and implementation of improvements. It has been established that the company actively uses innovative technologies, which contributes to improving product quality. Most respondents believe that the strategy for developing the quality management system is clearly defined.

6. It has been established that the main source of quality information is internal audit reports. However, it is also necessary to actively use customer feedback and external audit results.

7. Recommendations have been developed to improve the quality management system.

8. The implementation of digital technologies to improve the efficiency of quality management is investigated.

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APPENDICES

APPENDIX A

Questionnaire to assess the main problems and areas for improving the quality management system.

We ask you to answer the proposed questions by choosing one or more answer options or by writing your own opinion where provided.

1. How do you assess the current state of the quality management system in the organization?

- very effective
- quite effective
- inefficient
- ineffective

2. Which of the following problems have the greatest impact on the quality management system?

- lack of qualified personnel
- lack of modern equipment
- imperfect regulatory framework
- low employee motivation
- other (specify) _____

3. How do you assess the level of staff training in the field of quality management?

- high
- average
- low

4. Is the level of funding for quality improvement activities sufficient?

- yes, completely
- part
- no, not enough

5. What quality control methods are used in your organization?

- periodic inspections
- constant monitoring of processes
- automated control systems
- other (specify) _____

6. Does your organization have a feedback system to identify quality issues?

- Yes
- No

7. How effective is the feedback system?

- very effectively
- satisfactorily
- ineffective

8. What are the most important areas for improving the quality management system?

- staff training

- process automation
- implementation of new standards
- increasing employee motivation
- other (specify) _____

9. Does your organization conduct regular training for staff on quality issues?

- yes, regularly
- rarely
- No

10. How do you assess the impact of employee motivation on the quality of products/services?

- very significant
- moderate
- minor

11. Does your organization have modern equipment to ensure high quality?

- yes, fully meets the needs
- partially corresponds
- no, needs updating

12. What quality standards are applied in your organization?

- ISO 9001
- ISO 14001
- OHSAS 18001
- GMP
- SA8000
- ISO50001

13. How often are quality management system audits conducted?

- regularly (annually or more often)
- irregularly
- are not held

14. Are innovative technologies used to improve quality in your organization?

- Yes
- No

15. How satisfied are customers with the quality of products/services?

- completely satisfied
- partially satisfied
- dissatisfied

16. How do you assess the effectiveness of communication between departments in the field of quality management?

- very effective
- quite effective
- inefficient

- ineffective

17. Is there a strategy for developing a quality management system in your organization?

- yes, clearly designed
- partially defined
- absent

18. What sources of quality information are used in your organization?

- internal audit reports
- customer feedback data
- results of external audits

19. Are employees sufficiently involved in quality management processes?

- yes, fully involved
- partially involved
- no, engagement is insufficient

20. What do you think is the main obstacle to improving quality in your organization?

- lack of resources
- low qualification of personnel
- lack of modern equipment
- lack of management support

21. What is your experience working at the company?

- less than 5 years
- from 5 to 15 years
- from 15 to 25 years old
- over 25 years

22. What position do you hold?

- senior manager
- middle manager
- quality specialist
- production department employee
- quality control department employee

Thank you for your answers! Your thoughts will help improve the quality management system.

APPENDIX B

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

АКТУАЛЬНІ ПИТАННЯ СТВОРЕННЯ НОВИХ ЛІКАРСЬКИХ ЗАСОБІВ

МАТЕРІАЛИ
XXXI МІЖНАРОДНОЇ НАУКОВО-ПРАКТИЧНОЇ
КОНФЕРЕНЦІЇ МОЛОДИХ ВЧЕНИХ ТА СТУДЕНТІВ

23–25 квітня 2025 року
м. Харків

Харків
НФаУ
2025

УДК 615.1

Редакційна колегія: проф. Котвіцька А. А., проф. Владимирова І. М.
Укладачі: Сурікова І. О., Боднар Л. А., Комісаренко М. А., Коміссарова Є. Є.

Актуальні питання створення нових лікарських засобів: матеріали XXXI міжнародної науково-практичної конференції молодих вчених та студентів (23-25 квітня 2025 р., м. Харків). – Харків: НФаУ, 2024. – 515 с.

Збірка містить матеріали міжнародної науково-практичної конференції молодих вчених та студентів «Актуальні питання створення нових лікарських засобів, які представлені за пріоритетними напрямами науково-дослідної роботи Національного фармацевтичного університету. Розглянуто теоретичні та практичні аспекти синтезу біологічно активних сполук і створення на їх основі лікарських субстанцій; стандартизації ліків, фармацевтичного та хіміко-технологічного аналізу; вивчення рослинної сировини та створення фітопрепаратів; сучасної технології ліків та екстемпоральної рецептури; біотехнології у фармації; досягнень сучасної фармацевтичної мікробіології та імунології; доклінічних досліджень нових лікарських засобів; фармацевтичної опіки рецептурних та безрецептурних лікарських препаратів; доказової медицини; сучасної фармакотерапії, соціально-економічних досліджень у фармації, маркетингового менеджменту та фармакоекономіки на етапах створення, реалізації та використання лікарських засобів; управління якістю у галузі створення, виробництва й обігу лікарських засобів; суспільствознавства; фундаментальних та мовних наук.

УДК 615.1

distribution companies must adhere to stringent regulatory standards, such as Good Distribution Practices (GDP), to prevent contamination, mix-ups, or degradation of products. This article evaluates the current level of quality management in a pharmaceutical distribution company, identifying strengths, weaknesses, and opportunities for improvement. The assessment focuses on compliance with regulatory standards, operational processes, and employee training.

Aim. The aim is to assess the current quality management system (QMS) of a pharmaceutical distribution company, evaluate its compliance with GDP guidelines, and propose recommendations to enhance operational efficiency and regulatory adherence.

Materials and methods. The methods of questionnaire, analysis, comparison, generalization have been used in the study.

Results and discussion. The results highlight that the company has a strong foundation for quality management, particularly in storage and cold chain logistics. The high compliance score reflects effective implementation of GDP standards in core operational areas. However, the lack of updated SOPs and incomplete transport validation documentation indicate gaps in document management that could lead to regulatory non-compliance. The absence of training for temporary workers is a significant concern, as untrained personnel may inadvertently compromise product quality. Delayed follow-up on audit findings further suggests inefficiencies in the corrective action process. To address these issues, the company should prioritize regular SOP updates, implement a robust document control system, and extend GDP training to all staff, including temporary workers. Additionally, adopting a digital audit management system could streamline follow-up actions and improve accountability. These improvements would enhance the company's ability to maintain compliance and adapt to evolving regulatory requirements.

Conclusions. The pharmaceutical distribution company demonstrates a high level of quality management.

ANALYSIS OF KEY PROBLEMS AND WAYS TO IMPROVE THE QUALITY MANAGEMENT SYSTEM IN A PHARMACEUTICAL ORGANIZATION

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Introduction. The pharmaceutical industry is one of the most regulated, as its products directly affect the safety and effectiveness of patient treatment. In the context of modern globalization and constant updating of the regulatory framework, companies need to adapt their quality management systems to new challenges, such as digitalization, process automation, strengthening internal control and risk management.

Aim. The aim is analysis of key problems and ways to improve the quality management system in a pharmaceutical organization.

Materials and methods. The methods of questionnaire, analysis, comparison, generalization have been used in study.

Results and discussion. The concept of quality management and its critical importance to the pharmaceutical industry are explored, with an analysis of quality management approaches adopted by leading pharmaceutical companies. A detailed examination of the integrated pharmaceutical

quality system at pharmaceutical company was conducted, including a survey of 55 employees to identify areas for improvement. The findings confirmed that pharmaceutical company's quality management system operates at a high level of efficiency and aligns with international standards, with most employees expressing satisfaction and trust in its processes. The company benefits from a stable team of experienced specialists, though there is a recognized need to enhance the competencies of middle and junior staff, particularly in quality management.

Key challenges impacting the system include an imperfect regulatory framework, insufficient employee motivation, and, in some instances, outdated equipment. While most employees are well-trained, there is room for further development, especially for middle management. Although funding for quality improvement initiatives is generally satisfactory, additional investments are needed to integrate innovative technologies. Pharmaceutical company actively employs automated control systems, reflecting a modern approach to quality assurance, but continuous updates and enhancements to these systems are necessary.

Conclusions. Analysis of key problems and ways to improve the quality management system in a pharmaceutical organization was conducted.

JUSTIFICATION OF THE APPLICATION OF THE "7P" MARKETING COMPLEX MODEL IN PHARMACY ACTIVITIES

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Introduction. Marketing management of an enterprise is based on the integration of the marketing complex, the key components of which are product, price, place of sale and promotion (the "4P" model). In the conditions of dynamic changes in the market environment, the "4P" model has undergone evolution, which is associated with the need to form sustainable competitive advantages through the synergy of marketing elements. One of the modern concepts that considers marketing activities from the perspective of the consumer and society is the "7P" model, which is supplemented by such elements as people, processes and physical evidence.

Aim. Substantiation and analysis of the application of the "7P" marketing complex model in the activities of pharmacy establishments.

Materials and methods. This study employs a systematic approach involving analytical and abstract reasoning.

Results and discussion. It has been established that the application of the "7P" concept in a pharmacy allows for a comprehensive approach to building an effective marketing strategy, ensuring a harmonious combination of product, price, communication, and personnel policies. As is known, the basic element of the marketing complex is a product that includes an assortment of medicines and other pharmaceutical products, consumer properties, brand, packaging, product life cycle. When forming such an element as price, it is necessary to take into account regulatory restrictions of the state, pricing for various sales channels, and socio-economic characteristics of consumers in order to ensure a balance between the profitability of the enterprise and the availability of medicines for the population. The "place" element is implemented through both traditional sales channels and e-commerce, strategically thought-out placement of pharmacies, which ensures accessibility for

Ф А 2.2.1–32-366

National University of Pharmacy

Faculty pharmaceutical
Department management, marketing and quality assurance in pharmacy
Level of higher education master
Specialty 226 Pharmacy, industrial pharmacy
Educational and professional program Pharmacy

APPROVED
The Head of Department
management, marketing and quality assurance in pharmacy
_____
Volodymyr MALYI
«02» September 2024

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Daouia ESSAKHI

1. Topic of qualification work: «Analysis of key problems and ways to improve the quality management system in a pharmaceutical organization», supervisor of qualification work: Iryna BONDARIEVA, PhD, assoc. prof.

approved by order of NUPh from "27" of September 2024 № 237

2. Deadline for submission of qualification work by the applicant for higher education: May 2025

3. Outgoing data for qualification work: sources of scientific literature, directories, retail sector of the pharmaceutical market, legislative and regulatory framework, statistical and reporting data, activity of pharmacy enterprises, analysis of professional periodicals.

4. Contents of the settlement and explanatory note (list of questions that need to be developed): to reveal the essence of the concept of quality management and its importance for the pharmaceutical industry; to analyze approaches to quality management in leading pharmaceutical companies; to analyze the current integrated pharmaceutical quality system; to assess the main problems and areas for improving the quality management system; to develop recommendations for improving the quality management system; to implement innovative methods of product quality control; to explore the implementation of digital technologies to improve the efficiency of quality management.

5. List of graphic material (with exact indication of the required drawings):
Figures – 19, tables – 2.

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
1	Iryna BONDARIEVA, associate professor of higher education institution of department management, marketing and quality assurance in pharmacy	09.09.2024	09.09.2024
2	Iryna BONDARIEVA, associate professor of higher education institution of department management, marketing and quality assurance in pharmacy	18.11.2024	18.11.2024
3	Iryna BONDARIEVA, associate professor of higher education institution of department management, marketing and quality assurance in pharmacy	03.02.2025	03.02.2025

7. Date of issue of the assignment: «02» September 2024.

CALENDAR PLAN

№ з/п	Name of stages of qualification work	Deadline for the stages of qualification work	Notes
1	Collection and generalization of data from scientific literature by areas of qualification work	September 2024	**done**
2	Study of the essence of the concept of quality management and its importance for the pharmaceutical industry	September 2024	**done**
3	Identification of the current integrated pharmaceutical quality system	November 2024	**done**
4	Development of recommendations for improving the quality management system	February 2025	**done**
5.	Implementation of digital technologies to improve the efficiency of quality management	February 2025	**done**
6	Writing and design of qualification work	May 2025	**done**
7	Approbation of qualification work	May 2025	**done**
8	Submission of the qualification work to the EC of the National University of Pharmacy	May 2025	**done**

An applicant of higher education _____ Daouia ESSAKHI

Supervisor of qualification work _____ Iryna BONDARIEVA

ВИТЯГ З НАКАЗУ № 237

По Національному фармацевтичному університету

від 27 вересня 2024 року

Затвердити теми кваліфікаційних робіт здобувачам вищої освіти 5-го курсу Фм20(4,10д) 2024-2025 навчального року, освітньо-професійної програми – Фармація, другого (магістерського) рівня вищої освіти, спеціальності 226 – Фармація, промислова фармація, галузь знань 22 Охорона здоров'я, денна форма здобуття освіти (термін навчання 4 роки 10 місяців), які навчаються за контрактом (мова навчання англійська та українська) згідно з додатком № 1.

Прізвище, ім'я здобувача вищої освіти	Тема кваліфікаційної роботи		Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
по кафедрі менеджменту, маркетингу та забезпечення якості у фармації				
Ессахі Даоя	Аналіз ключових проблем і шляхів удосконалення системи управління якістю у фармацевтичній організації	Analysis of key problems and ways to improve the quality management system in a pharmaceutical organization	доц. Бондарєва І.В.	доц. Терещенко Л.В.

Ректор

Вірно, Секретар

ФА2.8-03-317

ВИСНОВОК

експертної комісії про проведену експертизу
щодо академічного плагіату у кваліфікаційній роботі

здобувача вищої освіти

«30» квітня 2025 р. № 331090679

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти Ессахі Даоя, групи Phm20(4,10)eng-03, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» навчання на тему: «Аналіз ключових проблем і шляхів удосконалення системи управління якістю у фармацевтичній організації / Analysis of key problems and ways to improve the quality management system in a pharmaceutical organization», експертна комісія дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

Голова комісії,
проректор ЗВО з НПР,
професор **Інна ВЛАДИМИРОВА**

Ф А 2.2.1-32-353

REVIEW

of scientific supervisor for the qualification work of the master's level of higher education of the specialty 226 Pharmacy, industrial pharmacy

Daouia ESSAKHI

on the topic: «Analysis of key problems and ways to improve the quality management system in a pharmaceutical organization»

Relevance of the topic. The relevance of the topic is due to the increasing role of digital technologies in quality management processes. The use of modern tools, such as data management systems, analytical platforms and automated control modules, opens up new opportunities in monitoring, analysis and development of production processes. For corporation "ARTERIUM", the introduction of such technologies can become a significant factor in increasing competitiveness in the international market.

Practical value of conclusions, recommendations and their validity. The results obtained can be used by pharmaceutical enterprises to improve the quality of the enterprise's products, reducing the number of defects and ensuring compliance of products with international standards.

Assessment of work. Daouia ESSAKHI conducted a significant research work and successfully coped with it, showed the ability to analyze and summarize data from literary sources, to work independently. In the work, the research results are properly interpreted and illustrated with figures. While completing the qualification work, the higher education applicant showed creativity, purposefulness, independence, and perseverance.

General conclusion and recommendations on admission to defend. The qualification work of the 5th year applicant of higher education Phm20(4,10) eng-03 group Daouia ESSAKHI on the topic: "Analysis of key problems and ways to improve the quality management system in a pharmaceutical organization" is a completed scientific study, which in terms of relevance, scientific novelty, theoretical and practical significance meets the requirements for qualification works, and can be presented to the EC of the National University of Pharmacy.

Scientific supervisor _____ Iryna BONDARIEVA

14 May 2025

Ф А 2.2.1-32-356

REVIEW

for qualification work of the master's level of higher education, specialty 226 Pharmacy, industrial pharmacy

Daouia ESSAKHI

on the topic: «Analysis of key problems and ways to improve the quality management system in a pharmaceutical organization»

Relevance of the topic. A quality management system (QMS) is a key element of the successful operation of any business, especially in the pharmaceutical industry, on which people's health and lives directly depend. In addition to modern market requirements, increased competition and compliance with international standards such as ISO 9001, GMP and ICH Q10, the development of a quality management system is a strategic task for pharmaceutical companies.

Theoretical level of work. The qualification work reveals theoretical approaches to quality management in pharmaceutical production.

Author's suggestions on the research topic. The author has developed recommendations for improving the quality management system.

Practical value of conclusions, recommendations and their validity. The results of the study have practical significance and can be used to optimize production processes.

Disadvantages of work. As a remark, it should be noted that some results of the literature review, which are presented in the first chapter, need stylistic refinement. In general, these remarks do not reduce the scientific and practical value of the qualification work.

General conclusion and assessment of the work. Daouia ESSAKHI qualification work "Analysis of key problems and ways to improve the quality management system in a pharmaceutical organization" is a scientifically based analytical study that has theoretical and practical significance. The qualification work meets the requirements for qualification papers and can be submitted to the EC of the National University of Pharmacy.

Reviewer _____ assoc. prof. Lyubov TERESHCHENKO

15 May 2025

Ф А2.2.1-91-287

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ВИТЯГ З ПРОТОКОЛУ № 15

16 травня 2025 року

м. Харків

засідання кафедри менеджменту, маркетингу
та забезпечення якості в фармації

Голова: завідувач кафедри ММЗЯФ, доктор фарм. наук, професор Малий В. В.

Секретар: доцент ЗВО, канд. фарм. наук, доц. Жадько С.В.

ПРИСУТНІ: зав. кафедри ММЗЯФ, доктор фарм. наук, проф. Малий В.В., професор ЗВО, докт. фарм. наук, проф. Пестун І.В., професор ЗВО, докт. фарм. наук, проф. проф. Літвінова О.В., професор ЗВО, докт. фарм. наук, проф. проф. Коваленко С.М., професор ЗВО, докт. фарм. наук, проф. Крутських Т.В., професор ЗВО, докт. фарм. наук, проф. проф. Посилкіна О.В., доцент ЗВО, канд. фарм. наук, доц. Бабічева Г.С., доцент ЗВО, канд. фарм. наук, доц. Бондарєва І.В., канд. екон. наук, доц. Гладкова О.В., канд. екон. наук, доц. Глєбова Н.В., канд. екон. наук, доц. Деренська Я.М., доцент ЗВО, канд. фарм. наук, доц. Жадько С.В., канд. фарм. наук, доц. Зборовська Т.В., канд. юрид. наук, доц. Коляда Т.А., канд. екон. наук, доц. Ковальова В.І., канд. фарм. наук, доц. доц. Лісна А.Г., доцент ЗВО, канд. фарм. наук, доц. Малініна Н.Г., доцент ЗВО, канд. фарм. наук, доц. Рогуля О.Ю., асистент, канд. фарм. наук Шуванова О.В., здобувачі вищої освіти факультету фармацевтичного.

ПОРЯДОК ДЕННИЙ: Про допуск здобувачів вищої освіти випускного курсу факультету фармацевтичного спеціальності 226 Фармація, промислова фармація, освітньо-професійної програми Фармація до захисту кваліфікаційних робіт в Екзаменаційній комісії НФаУ.

СЛУХАЛИ: Про допуск здобувача вищої освіти факультету фармацевтичного випускного курсу спеціальності 226 Фармація, промислова фармація освітньо-професійної програми Фармація групи Фм20(4,10д)англ-03 Даоя ЕССАХІ до захисту кваліфікаційної роботи в Екзаменаційній комісії НФаУ. Кваліфікаційна робота на тему «Аналіз ключових проблем і шляхів удосконалення системи управління якістю у фармацевтичній організації».

ВИСТУПИЛИ: В обговоренні кваліфікаційної роботи взяли участь проф. ЗВО Пестун І.В., доц. ЗВО Бабічева Г.С. Керівник кваліфікаційної роботи: доц., канд. фарм. наук Бондарєва І.В.

УХВАЛИЛИ: Допустити здобувача вищої освіти Даоя ЕССАХІ до захисту кваліфікаційної роботи на тему «Аналіз ключових проблем і шляхів удосконалення системи управління якістю у фармацевтичній організації» в Екзаменаційній комісії НФаУ.

Зав. каф. ММЗЯФ, доктор фарм. наук,
професор Володимир МАЛИЙ

Секретар, доцент ЗВО,
канд. фарм. наук, доцент Світлана ЖАДЬКО

Ф А2.2.1-32-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ
ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувач вищої освіти Даоя ЕССАХІ до захисту кваліфікаційної роботи
за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньо-професійною програмою Фармація
на тему: «Аналіз ключових проблем і шляхів удосконалення системи управління якістю у фармацевтичній організації».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Микола ГОЛІК /

Висновок керівника кваліфікаційної роботи

Здобувач вищої освіти Даоя ЕССАХІ виконав на кафедрі менеджменту, маркетингу та забезпечення якості у фармації НФаУ кваліфікаційну роботу, яка присвячена аналізу ключових проблем і шляхів удосконалення системи управління якістю у фармацевтичній організації.

Перший розділ висвітлює концепцію управління якістю у фармацевтичному виробництві. У другому розділі проаналізовано систему управління якістю фармацевтичної організації, зокрема інтегровану фармацевтичну систему якості, її проблеми та шляхи вдосконалення. Третій розділ містить рекомендації щодо покращення управління якістю, зокрема впровадження інноваційних методів контролю та цифрових технологій.

У цілому подана до захисту кваліфікаційна робота Даоя ЕССАХІ на тему «Аналіз ключових проблем і шляхів удосконалення системи управління якістю у фармацевтичній організації» відповідає вимогам, що висуваються до кваліфікаційних робіт, оцінюється позитивно і може бути рекомендована для захисту в Екзаменаційну комісію НФаУ.

Керівник кваліфікаційної роботи
_____ Ірина БОНДАРЄВА

14 травня 2025 р.

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Даоя ЕССАХІ допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.
Завідувач кафедри
менеджменту, маркетингу та
забезпечення якості у фармації
_____ Володимир МАЛИЙ

16 травня 2025 р.

Qualification work was defended

of Examination commission on

« » of June 2025

With the grade _____

Head of the State Examination commission,

D.Pharm.Sc, Professor

_____ /Volodymyr YAKOVENKO/