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QUALIFICATION WORK

on the topic: «**ASSESSMENT OF THE CURRENT LEVEL OF QUALITY MANAGEMENT IN A PHARMACEUTICAL DISTRIBUTION COMPANY»**

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АНОТАЦІЯ

Дослідження присвячене оцінці сучасного рівня управління якістю фармацевтичної дистрибуційної компанії. Кваліфікаційна робота охоплює 40 сторінок, містить 14 рисунків та 3 таблиці. У роботі представлено список використаних джерел, що налічує 32 найменування.

Ключові слова: оцінка, рівень управління, якість, фармацевтична дистрибуційна компанія, стандартизація.

ANNOTATION

The study is devoted to the assessment of the current level of quality management of a pharmaceutical distribution company. The qualification work covers 40 pages, contains 14 figures and 3 tables. The work presents a list of sources used, which includes 32 names.

Keywords: assessment, level of management, quality, pharmaceutical distribution company, standardization.

CONTENT

INTRODUCTION

Relevance of the research topic. Pharmaceutical distributors are an important component of the pharmaceutical market. In modern conditions, there are increasing requirements for improving the quality of products and services in various areas of business, and the distribution of medicines is no exception. The introduction of a management system at such enterprises contributes to their competitiveness, improves the quality of services and has a positive effect on the dynamics of company development. The use of international standards allows you to optimize business processes, ensure their compliance with international requirements, increase customer satisfaction, improve efficiency and gain additional competitive advantages [11].

The assessment of quality management in a pharmaceutical distribution company is a highly relevant and critical research topic due to its implications for public health, regulatory compliance, and operational efficiency. Below are the key points highlighting its significance [7]. Pharmaceutical distribution companies play a pivotal role in the supply chain, ensuring that medicines and healthcare products reach patients in safe and effective conditions. Poor quality management can lead to issues such as compromised drug efficacy, contamination, or counterfeit products, posing significant risks to patient safety. Assessing the current level of quality management helps identify gaps and implement measures to safeguard public health [18].

The pharmaceutical industry is subject to stringent regulations, such as Good Distribution Practices (GDP) and guidelines from bodies like the World Health Organization (WHO), U.S. Food and Drug Administration (FDA), and European Medicines Agency (EMA). Research into quality management ensures that distribution companies adhere to these standards, reducing the risk of non-compliance, legal penalties, and loss of licensure [5].

Effective quality management systems (QMS) streamline operations, reduce waste, and minimize errors in the distribution process. By assessing the current

QMS, companies can identify inefficiencies, such as improper inventory management or inadequate storage conditions, leading to cost savings and improved service delivery [12].

A robust quality management system enhances a company's reputation among stakeholders, including manufacturers, healthcare providers, and regulatory authorities. Research in this area can highlight best practices and areas for improvement, fostering trust and ensuring the company remains competitive in the market [12].

The pharmaceutical distribution sector is increasingly adopting technologies like blockchain, IoT for temperature monitoring, and automated inventory systems. Assessing quality management practices helps evaluate the integration of these technologies, ensuring they align with quality standards and enhance traceability and transparency in the supply chain [8].

Globalization has introduced complexities in pharmaceutical distribution, including cross-border logistics and varying regulatory requirements. Research on quality management can address challenges such as maintaining product integrity during long-distance transportation and ensuring compliance across different jurisdictions [21].

Quality management research can also explore the adoption of environmentally sustainable practices, such as optimizing transportation routes or reducing packaging waste, aligning with global sustainability goals while maintaining product quality [7].

The research topic is highly relevant as it addresses critical aspects of pharmaceutical distribution, including patient safety, regulatory compliance, operational efficiency, and technological adaptation. By assessing the current level of quality management, the study can provide actionable insights to improve practices, mitigate risks, and enhance the overall reliability of the pharmaceutical supply chain [17].

The purpose of the qualification work is to assess of the current level of quality management in a pharmaceutical distribution company.

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

- to consider the features of the activities of pharmaceutical distributors in the medical products market and to analyze the basics of standardization and certification in the pharmaceutical industry;
- to analyze the current state of quality management in a pharmaceutical distribution company;
- to assess the existing quality management system in the company;
- to identify the main shortcomings and problems in the quality management system and to develop proposals for implementing the provisions of the ISO 9001 standard to optimize the activities of the distribution company;
- to assess the effectiveness of implementing measures and predicting results to optimize activities;
- to develop recommendations for monitoring and analyzing the effectiveness of the quality management system;
- to develop practical advice on improving processes in pharmaceutical distribution companies.

The object of the study is the quality management system in a distribution company.

The subject of the study is assessment of the current level of quality management in a pharmaceutical distribution company.

Research methods: questionnaire, graphic, system, content analysis.

Practical significance of the obtained results. The results of the work can be used by pharmaceutical companies to improve the quality management system, increase business efficiency and customer satisfaction, and can also serve as the basis for further research in this area.

Approbation of research results and publication. Qualification work was approved on XXXI International Scientifical and Practical Conference of Young Scientists and Students «Topical issues of new medicines development». Abstracts

of the reports have been published: Chibani A., Bondarieva I. V., Malyi V.V. Assessment of the current level of quality management in a pharmaceutical distribution company. Topical issues of new medicines development : materials XXXI International Scientifical and Practical Conference of Young Scientists and Students (23-25 April 2025, Kharkiv). – Kharkiv: NUPh, 2025. – P. 415-416.

Structure and scope of the qualification work. The qualification work includes an introduction, a literature review, an experimental part, generalized conclusions, a list of sources used, and appendices. The total volume of the qualification work is 40 pages and includes 14 figures, 3 tables. The work also includes a list of references, which includes 32 titles.

PART I
THEORETICAL BASIS OF STANDARDIZATION AND CERTIFICATION IN THE DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

1.1. Features of the activities of pharmaceutical distributors in the medical products market

The modern market requires enterprises to adapt to new conditions to ensure competitiveness. In particular, it is important to implement international standards that contribute to the optimization of business processes, increasing efficiency and meeting consumer needs [11].

Process automation is becoming a key element of business organization, and the introduction of information technologies creates new competitive advantages. They allow you to reduce costs, increase the speed of order processing, and ensure high data accuracy [8].

Full-service healthcare distributors is presented on fig. 1.1.

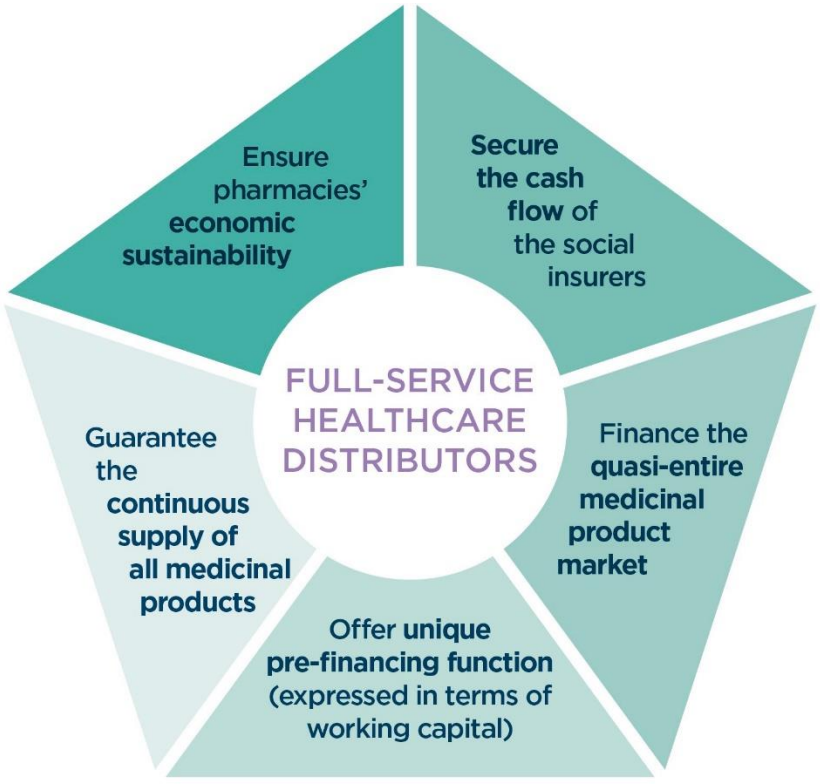

Fig. 1.1. Full-service healthcare distributors

Supply chain integration plays an important role in ensuring better quality control, reducing costs, and improving customer service. Modern pharmaceutical distribution companies focus on coordinating the actions of all participants in the supply chain, including suppliers, distributors, and end users [3].

Adapting a business to the conditions of rapid market changes involves constant monitoring of trends, analysis of consumer behavior and flexibility in the introduction of new products and services. The use of modern analytical tools allows you to quickly identify customer needs and adjust the assortment accordingly [4].

Pharmaceutical distributors pay significant attention to customer needs, implementing feedback mechanisms to collect and analyze data. This allows for personalized offerings, which increases consumer satisfaction [4].

There are always risks in the activities of companies, including changes in legislation, fluctuations in demand, instability of supply and logistical problems, in particular in war conditions. Modern approaches involve the implementation of risk management systems that allow assessing, controlling and minimizing the negative impact of these factors [9]. Traceability across the pharmaceutical industry value chain is presented on fig. 1.1.

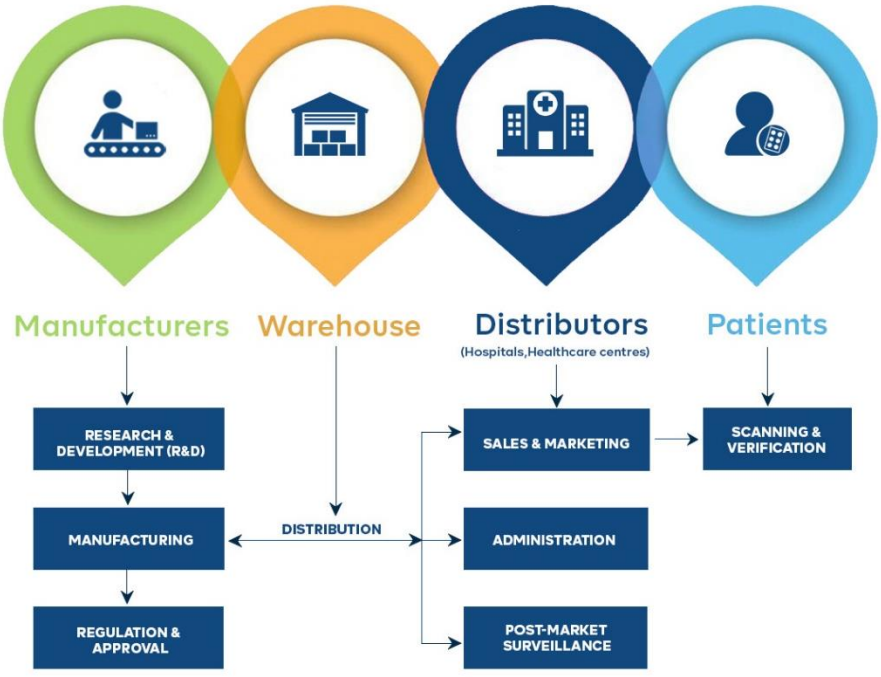

Fig. 1.2. Traceability across the pharmaceutical industry value chain

Today, special attention is paid to the consideration of environmental standards in the activities of enterprises, which contributes to increasing the level of their social responsibility. For this purpose, modern logistics centers are created and regular updating of vehicles used for the delivery of pharmaceutical products is carried out. This approach allows to reduce the negative impact on the environment and integrate ethical principles into business processes [11].

Pharmaceutical distributors actively establish partnerships, as the sharing of resources, information exchange and joint development of innovative solutions contribute to the development of enterprises. This allows optimizing costs, increasing efficiency and strengthening competitive positions in the market [10].

1.2. Basics of standardization and certification in the pharmaceutical industry

Standardization is an activity aimed at establishing unified provisions for multiple use in order to achieve an optimal level of regulation in a given area. Its results are to increase the conformity of products, processes and services to their functional purpose, eliminate barriers to trade and promote scientific and technical cooperation. In the context of the pharmaceutical industry, the objects of standardization are processes and services [13].

Standardization and certification in the pharmaceutical sector are key elements that ensure compliance of products and services with regulatory requirements, proper quality, and competitiveness in the market. The main international standard widely used in the field of quality management of pharmaceutical products is ISO 9001. Its provisions are aimed at creating a quality management system focused on meeting consumer needs, optimizing processes and minimizing risks [30].

The implementation of international standards is the basis for standardizing business processes in the pharmaceutical industry. This contributes to improving the quality and safety of products, optimizing logistics processes through the use of unified approaches to the transportation and storage of medicines, and also facilitates

the procedure for mutual recognition of quality certificates between countries and organizations [15].

Certification is an official confirmation that products, services or management systems comply with established standards. It is crucial for a company to enter the international market, confirm compliance with standards in the delivery and storage of medicines, and build trust among consumers and partners [3].

ISO 9001 is an international standard that sets requirements for a quality management system. Its main goal is to help businesses provide high-quality products and services that meet customer requirements and applicable legislation, and to contribute to increasing customer satisfaction [25].

Model of the product life cycle of pharmaceutical products is presented on fig. 1.1.

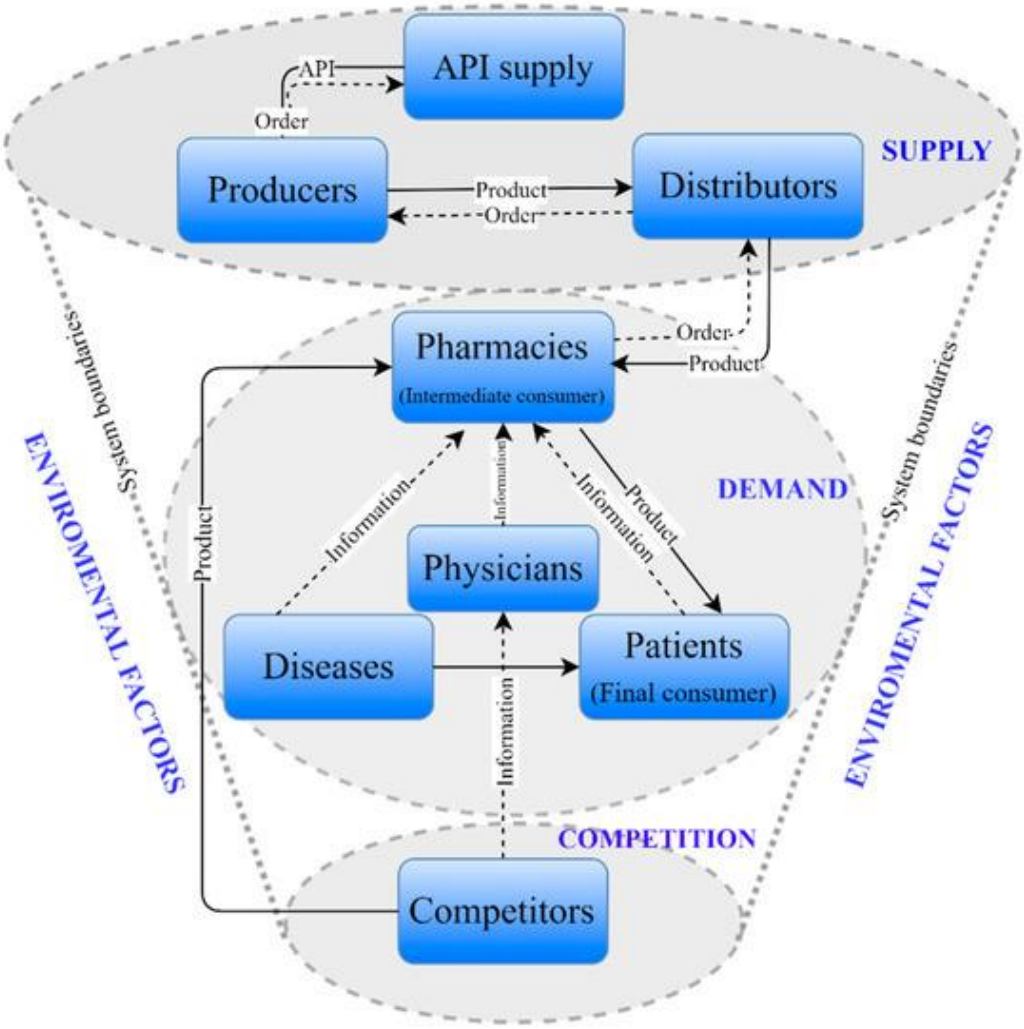

Fig. 1.3. Model of the product life cycle of pharmaceutical products

The main provisions of the ISO 9001 standard are aimed at identifying key external and internal factors that affect the achievement of planned results. This allows enterprises to analyze the market, competitive environment, as well as social and economic conditions of operation. One of the central aspects of the standard is leadership, which involves the active participation of management in the development and implementation of the quality management system for its improvement. The quality management system requires careful planning, which includes risk management, identification of opportunities, as well as the development of corrective and preventive actions. Enterprises must identify risks that affect the functioning of processes and develop appropriate strategies to overcome them. Resource planning covers human, material, infrastructure and information resources. Special attention is paid to training and improving the skills of personnel. This contributes to the successful implementation of the quality management system and reduces the risk of non-acceptance of changes. Operational efficiency is achieved through planning, control of all processes and ensuring that products and services comply with the requirements of the standard. Continuous improvement of services is based on providing feedback from customers, regular analysis and control of implemented changes. Internal audits are an important tool for assessing the compliance of the quality management system, identifying deficiencies and identifying opportunities for improvement. Regular analysis of data on products and services allows for a quick response to identified problems, which is the basis for continuous improvement in accordance with the requirements of the standard [14, 28].

Fig. 1.4 shows a diagram of a quality management system that illustrates a step-by-step action plan to ensure continuous improvement and achieve maximum results from the implementation of the ISO 9001 standard. This scheme demonstrates the optimal approach to organizing a quality management system at pharmaceutical enterprises engaged in the distribution of medicines. Documenting all processes and results of internal audits is mandatory, as it helps to identify deficiencies, quickly eliminate them, and implement measures to improve

operational efficiency. ISO 9001 provides tools for creating an effective quality management system that can meet international requirements, ensuring stability and high quality of business processes in distribution companies. Transparency and controllability of processes are key factors for successful implementation of the standard [25].

Fig. 1.4. Quality management system

This standard regulates the main elements for building an effective quality management system, which allows enterprises to standardize activities and improve business processes at all stages – from the procurement of products to their delivery to customers. The main goal of the standard is to implement processes that minimize risks and ensure that products and services meet the requirements of consumers and regulatory authorities [12].

In pharmaceutical distribution, the key aspects are defining and documenting processes, managing risks, planning corrective and preventive actions, monitoring and measuring results, quality control and interacting with customers. In such companies, implementing a quality management system involves creating a clear organizational structure where each employee has clearly defined responsibilities and understands their role in ensuring high quality products and services. Implementing ISO 9001 allows you to obtain significant benefits, including: reducing the risks of poor customer service; increasing the efficiency of resource

management through standardization of processes and distribution of roles; strengthening trust among partners by ensuring consistently high-quality products and services based on reliable processes [20].

In addition, the implementation of the standard requires constant monitoring of the functioning of the quality management system. It is recommended to conduct regular internal audits and assess the state of the processes operating at the enterprise in order to timely identify and eliminate shortcomings, which will ensure continuous improvement of activities.

Conclusions to part I

1. The features of the activities of pharmaceutical distributors in the medical products market are considered.
2. The basics of standardization and certification in the pharmaceutical industry are analyzed.

PART II
ANALYSIS OF THE CURRENT STATUS OF QUALITY MANAGEMENT IN A PHARMACEUTICAL DISTRIBUTION COMPANY

2.1. Assessment of the existing quality management system in a pharmaceutical distribution company

Pharmaceutical distribution company "BaDM", which is one of the leading distributors of pharmaceuticals in Ukraine, has been operating on the market since 1994. The company has a license for wholesale and retail trade in medicines. It actively cooperates with manufacturers of medicines and medical devices, which allows it to provide a wide range of products. The company has undergone significant changes in its distribution activities. Given this, it is necessary to conduct a detailed analysis of the current state of the company and assess the existing quality management system.

To assess the state of the management system at BaDM company, a survey of 36 employees was conducted (Appendix A).

Respondents were asked what position they held in the company. It was determined that the largest share is occupied by sales managers (45%) and logistics managers (15%), managers, regional managers and technical managers together occupy a share of 30%, quality specialists – 5%, IT specialists – 5% (Fig. 2.1).

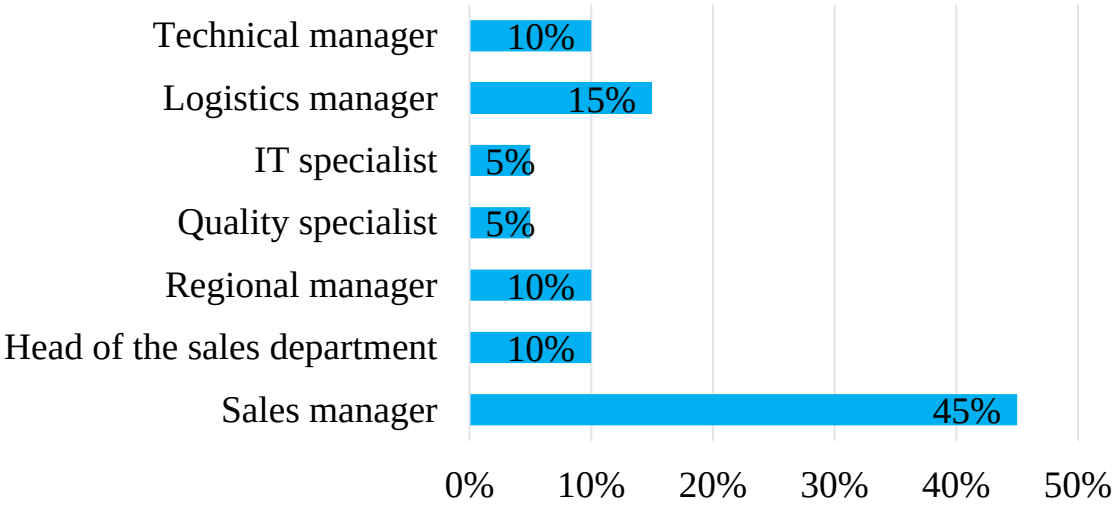

Fig. 2.1. Distribution of respondents by positions in the pharmaceutical distribution company

On next step of our research we analyzed the level of education of respondents of pharmaceutical distribution company. It was found that 55% of respondents have higher education and 45% of respondents have incomplete higher education (Fig. 2.2).

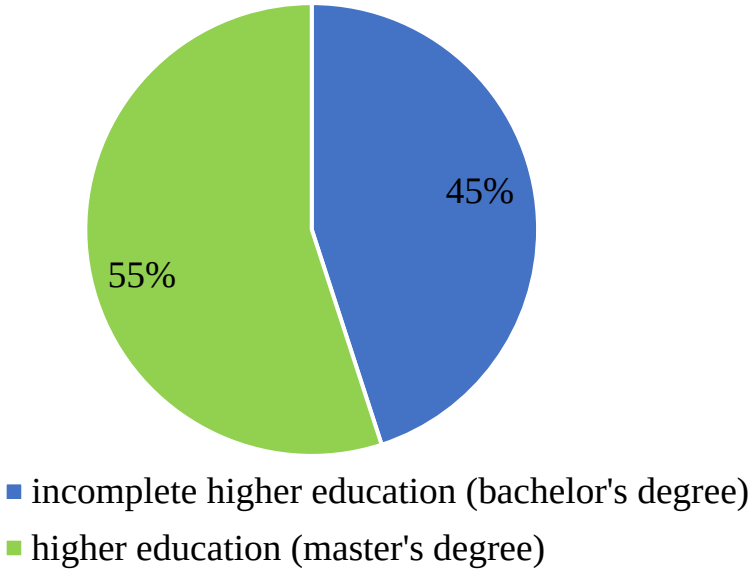

Fig. 2.2. Analysis of the level of education of respondents of pharmaceutical distribution company

According to the analysis, the majority of respondents (50%) have over 10 years of experience working in the company (fig. 2.3).

A significant number of respondents (25%) have been working for the company from 1 till 5 years. The share of respondents who have been working for less than 1 year is 15%.

The smallest share is occupied by respondents who have been working in the company from 5 till 10 years, which is 10%. These data indicate that pharmaceutical distribution company employs a significant number of experienced employees who prefer long-term cooperation.

Also, the largest share was occupied by respondents with over 10 years of work experience, which indicates high interest and the opportunity for personal growth within the company.

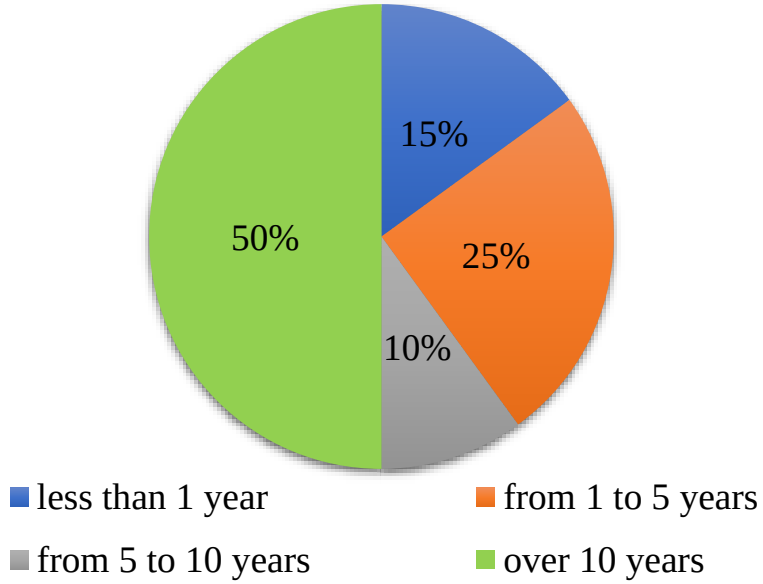

Fig. 2.3. Analysis of respondents' work experience at the of pharmaceutical distribution company

Activities as a leading pharmaceutical distributor in Ukraine meet many key requirements of the ISO 9001 standard, which ensures the stability and quality of its services.

It was determined that 25% of respondents were involved in the implementation of a QMS at the pharmaceutical distribution company (fig. 2.4).

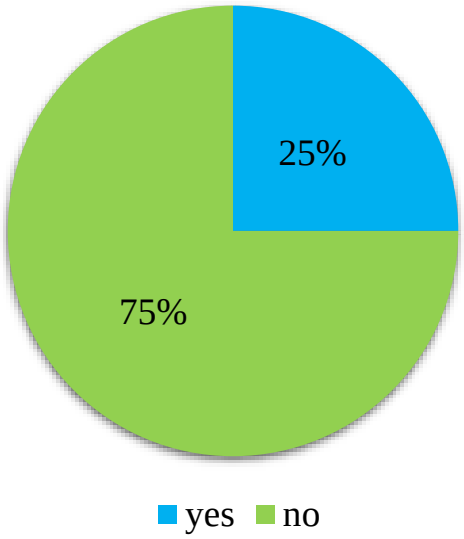

Fig. 2.4. Analysis of respondents' participation in the implementation of QMS at the pharmaceutical distribution company

The assessment of the implementation of a quality management system (QMS) at an enterprise engaged in distribution activities in the field of wholesale trade in medicines shows certain strengths and weaknesses of this process (fig. 2.5).

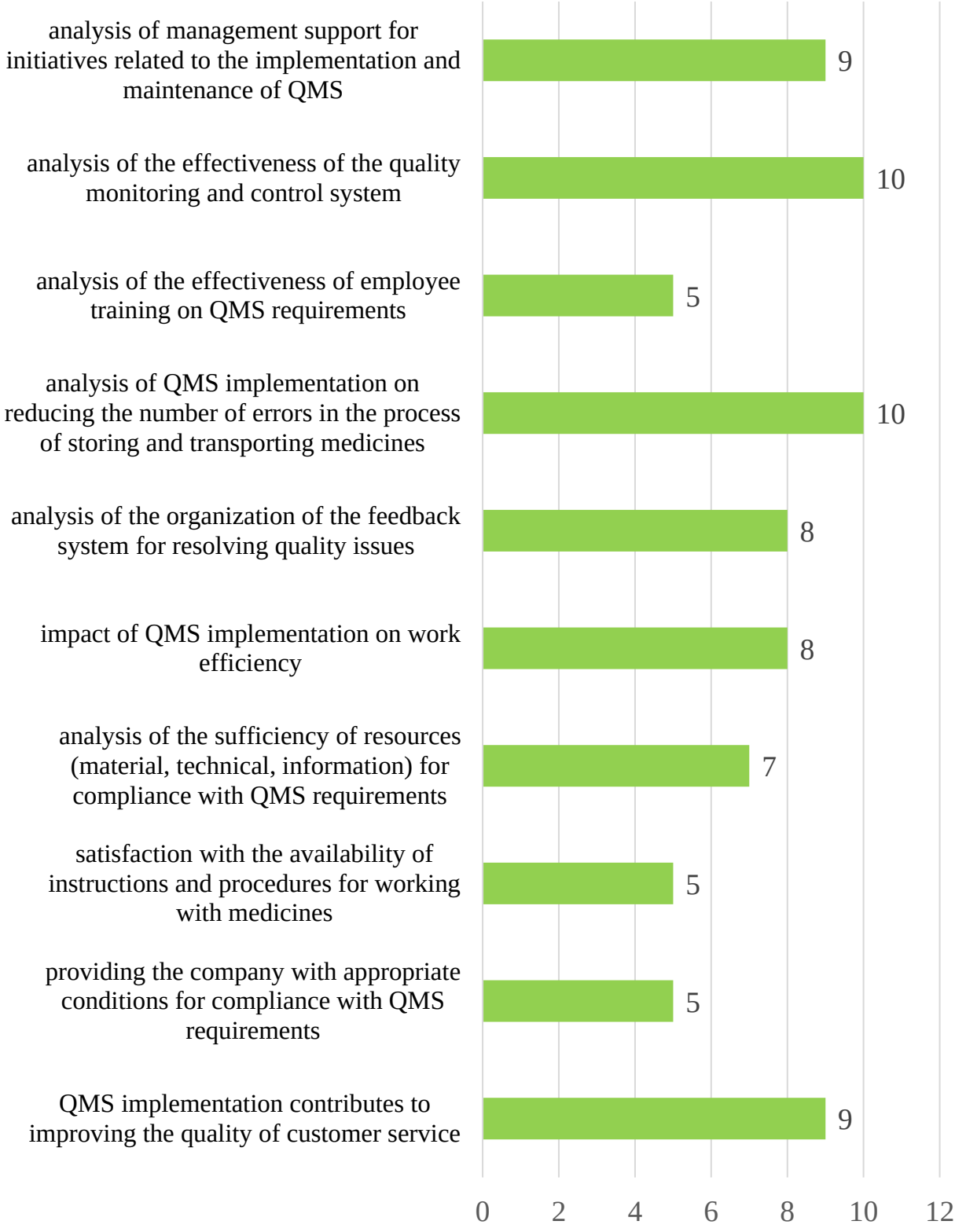

Fig. 2.5. Assessment of the implementation of the QMS at the pharmaceutical distribution company

According to the assessment results, the implementation of a QMS significantly contributes to improving the quality of customer service, receiving a high score of 9, which indicates the effectiveness of this aspect. However, there are certain shortcomings in ensuring proper conditions for compliance with the requirements of the QMS (5 points), which indicates the need to improve the infrastructure and resource base to support quality standards.

The availability of instructions and procedures for working with medicines also received an average score of 5, which indicates the need to improve the organization of internal documentation. The analysis of the adequacy of resources to meet the requirements of the QMS received a score of 7, which is good, but shows that to achieve the highest standards it is necessary to invest in technical, material and information resources.

The impact of implementing a QMS on the efficiency of the enterprise is rated at 8, which indicates noticeable improvements in performance, but there is niche for further improvement.

The analysis of the organization of the feedback system for resolving quality issues received a score of 8, which indicates the presence of effective communication between the company and customers, however, there is niche for improvement in this process.

The implementation of a QMS significantly reduces the number of errors in the process of storing and transporting medicines, receiving a maximum score of 10, which indicates a high level of control and safety in these processes.

The assessment of the effectiveness of employee training regarding the requirements of the QMS is marked by 5, which indicates the need to improve training programs and improve the skills of personnel.

The analysis of the effectiveness of the quality monitoring and control system also received the maximum score of 10, which indicates a high level of process control and readiness to prevent defects.

Finally, management support for initiatives related to the implementation and maintenance of the QMS was rated at 9, which confirms the active involvement of

management in supporting the process of implementing the quality management system and its further improvement.

We determined the average score for the implementation of the QMS at the enterprise to be 7.6 (Fig. 2.5). This indicates a satisfactory level, but a detailed analysis is required to identify weaknesses.

The next step was to determine the importance of factors that determine the efficiency of the enterprise (Fig. 2.6). An indicator such as compliance with legislative requirements was highlighted, which respondents identified as the most critically important factor.

Reliability of logistics processes is considered critically important by 80% of respondents, the remaining 20% identified it as moderately important.

Also, half (50%) of respondents consider QMS, ensuring compliance with GPD standards, GMP and personnel qualifications to be critically important.

It was found that the management information system was an underestimated factor, 5% of respondents considered it unimportant, 5% considered it of little importance, but 60% considered it moderately important, and only 30% considered it critically important.

90% of respondents considered inventory management an important factor for the effective operation of the enterprise.

75% of respondents voted for the importance of reputation and trust among customers and partners, and 25% considered this factor critically important.

This figure illustrates the importance of identifying key factors for assessing the effectiveness of the enterprise.

By analyzing these indicators, management will be able to clearly plan resources for improving certain indicators and, during a repeated internal audit, will be able to compare the results.

It will also help to identify weaknesses and possible problems that the enterprise can prevent in the future (Fig. 2.6).

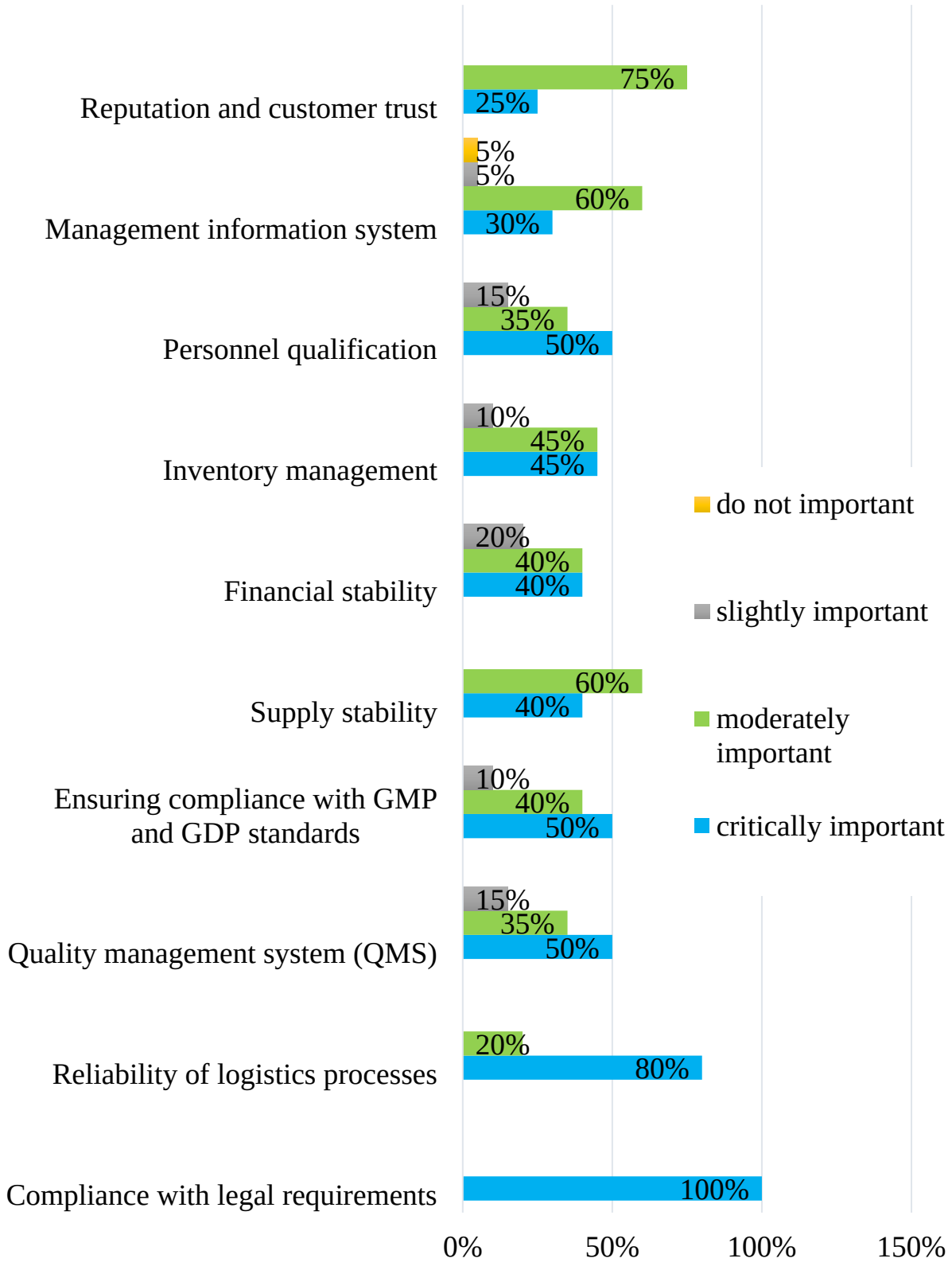

Fig. 2.6. Assessment of the importance of factors that determine the efficiency of the pharmaceutical distribution company

2.2. Identification of major shortcomings and problems in the quality management system

Respondents were surveyed regarding the importance of factors and their impact on the company's operations. For LLC "BaDM", the factors were divided into 5 blocks. First, were studied the importance of implementing innovative technologies for process optimization (fig. 2.7).

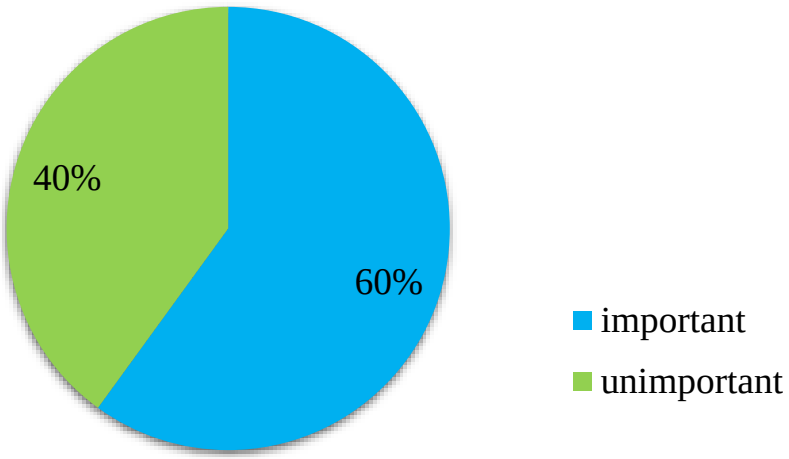

Fig. 2.7. Analysis of the implementation of innovative technologies for process optimization in pharmaceutical distribution company

The importance of implementing digital tools for quality and process monitoring was analyzed, with 60% of respondents considering this factor important (Fig. 2.8).

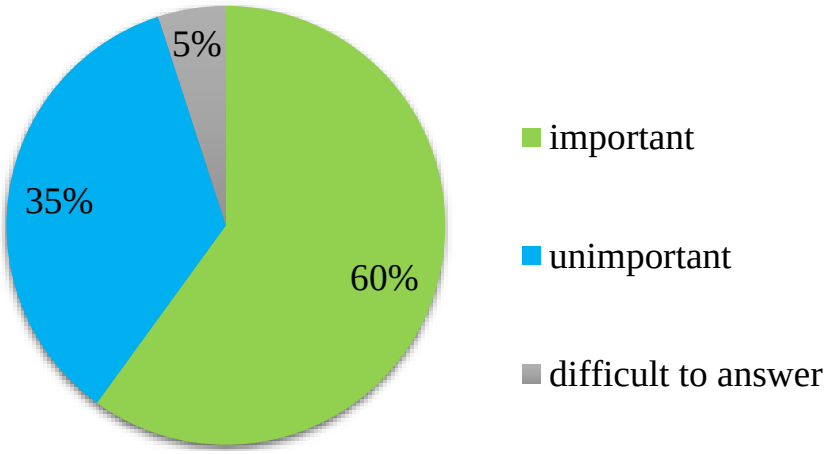

Fig. 2.8. Analysis of the importance of implementing digital tools in pharmaceutical distribution company

The next block analyzed the importance of organizational culture on the quality and productivity of work; 40% of respondents considered this factor unimportant, 35% considered it important, and 25% found it difficult to answer (fig. 2.9).

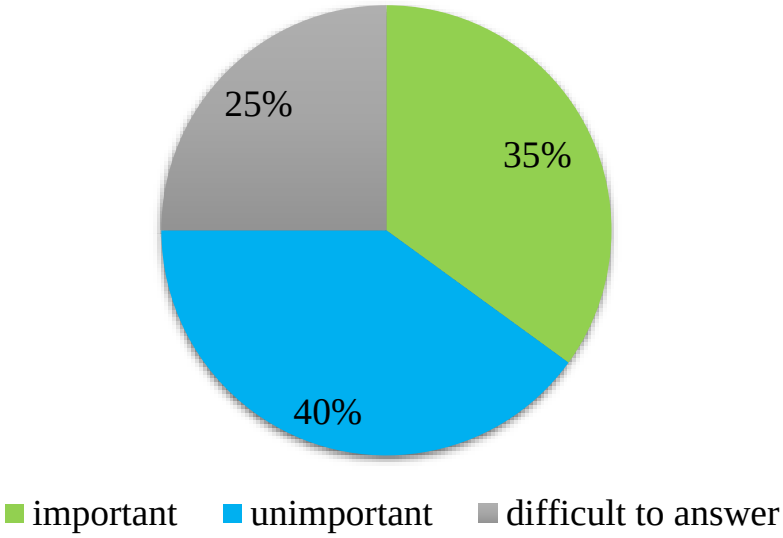

Fig. 2.9. Analysis of the importance of corporate culture on the quality and productivity of work

The next question determined that 50% of respondents consider process flexibility important for the ability to adapt to market changes and external factors. 30% of respondents believe otherwise, that this factor is not important, and 20% hesitated to answer (fig. 2.10).

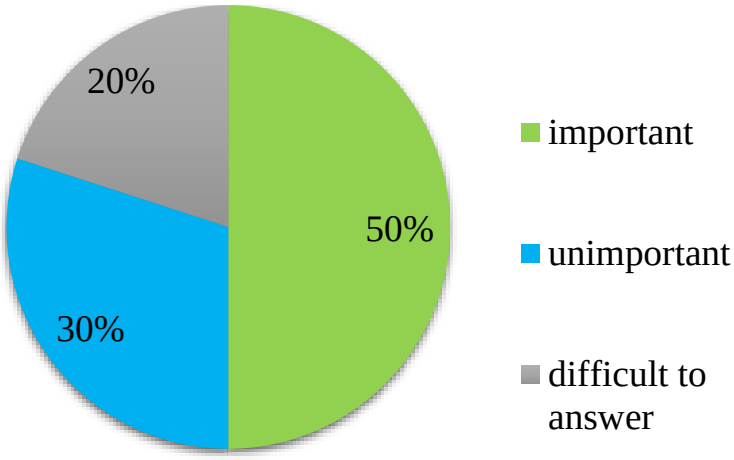

Fig. 2.10. Analysis of the importance of process flexibility in pharmaceutical distribution company

Next, employees were asked whether transparency of business processes is important for increasing the trust of customers and partners. 40% of respondents consider it important, 20% — unimportant, and the rest hesitated in their answer (fig. 2.11).

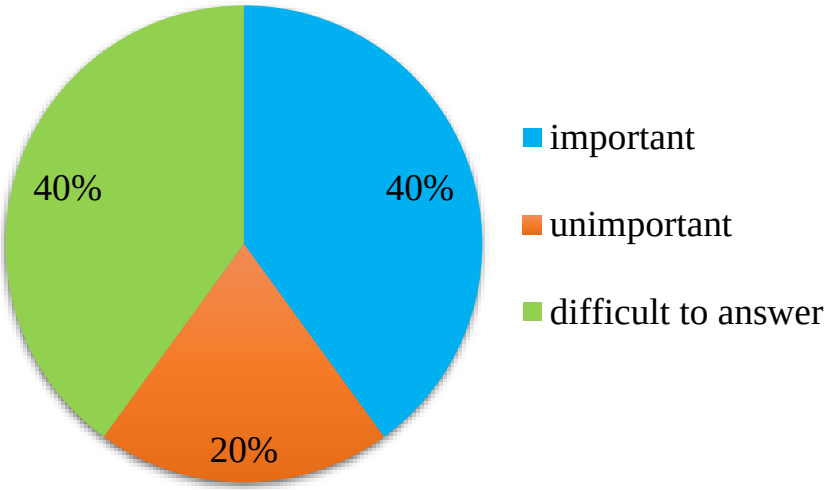

Fig. 2.11. Analysis of the importance of transparency of business processes in pharmaceutical distribution company

The survey determined that the majority of respondents (60%) consider process automation to be an important factor in reducing human errors, 5% do not consider this factor important, and the rest (35%) hesitated to answer (fig. 2.12).

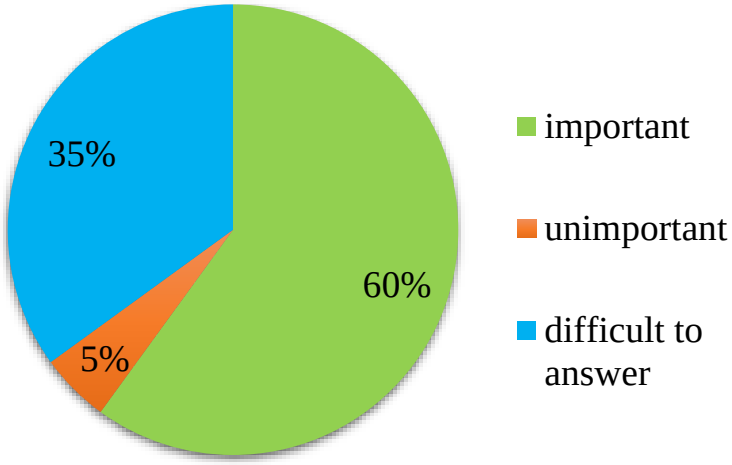

Fig. 2.12. Analysis of the importance of process automation in pharmaceutical distribution company

Next, the issue of adaptation to international standards was analyzed. Only 30% of respondents consider it important to adapt the enterprise to the requirements of international standards and their implementation will create additional competitive advantages.

Instead, 70% of respondents hesitated to answer, which suggests that the company's management does not provide sufficient information about the importance of implementing such standards at the enterprise (fig. 2.13).

It was found the importance of regular training and advanced training, to which the respondents answered unanimously (100%) - it is important.

The importance of regular training is also evidenced by the previous answers of the respondents. After all, the majority hesitates to answer the question, so it is very good to recognize that all the surveyed employees of the enterprise are ready to learn and understand the importance of improving their qualifications for their own career growth.

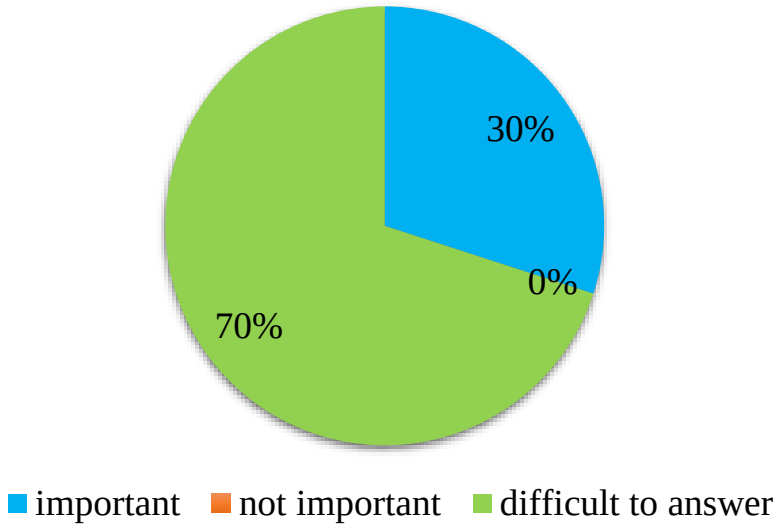

Fig. 2.13. Analysis of the importance of adaptation to international standards in pharmaceutical distribution company

The disadvantages of implementing a QMS are insufficient awareness among the company's employees, lack of automation of certain processes, and insufficient emphasis on staff training, which may lead to resistance to the implementation of

new changes, as 70% of the surveyed respondents do not understand the importance of implementing an international standard at the company and what advantage the company will have after receiving this certificate.

Conclusion to chapter II

1. To assess the state of the management system at pharmaceutical distribution company «BaDM», a survey of 36 employees was conducted. It was determined that largest share are sales managers (45%) and logistics managers (15%), managers, regional managers and technical managers together occupy a share of 30%. It was found that 55% of respondents have higher education and 45% of respondents have incomplete higher education. The majority of respondents (50%) have over 10 years of experience working in the company. A significant number of respondents (25%) have been working for the company from 1 till 5 years.

2. It was determined that 25% of respondents were involved in the implementation of a QMS at the pharmaceutical distribution company. According to the assessment results, the implementation of a QMS significantly contributes to improving the quality of customer service, receiving a high score of 9, which indicates the effectiveness of this aspect. However, there are certain shortcomings in ensuring proper conditions for compliance with the requirements of the QMS (5 points), which indicates the need to improve the infrastructure and resource base to support quality standards. The availability of instructions and procedures for working with medicines also received an average score of 5, which indicates the need to improve the organization of internal documentation. The analysis of the adequacy of resources to meet the requirements of the QMS received a score of 7, which is good, but shows that to achieve the highest standards it is necessary to invest in technical, material and information resources. The impact of implementing a QMS on the efficiency of the enterprise is rated at 8, which indicates noticeable improvements in performance, but there is niche for further improvement. The analysis of the organization of the feedback system for resolving quality issues received a score of 8, which indicates the presence of effective communication

between the company and customers, however, there is niche for improvement in this process. The implementation of a QMS significantly reduces the number of errors in the process of storing and transporting medicines, receiving a maximum score of 10, which indicates a high level of control and safety in these processes. The assessment of the effectiveness of employee training regarding the requirements of the QMS is marked by 5, which indicates the need to improve training programs and improve the skills of personnel. The analysis of the effectiveness of the quality monitoring and control system also received the maximum score of 10, which indicates a high level of process control and readiness to prevent defects. Finally, management support for initiatives related to the implementation and maintenance of the QMS was rated at 9, which confirms the active involvement of management in supporting the process of implementing the quality management system and its further improvement.

3. We determined the average score for the implementation of the QMS at the enterprise to be 7.6. This indicates a satisfactory level, but a detailed analysis is required to identify weaknesses.

4. Compliance with legislative requirements was highlighted, which respondents identified as the most critically important factor. Reliability of logistics processes is considered critically important by 80% of respondents, the remaining 20% identified it as moderately important. Also, half (50%) of respondents consider QMS, ensuring compliance with GPD standards, GMP and personnel qualifications to be critically important. It was found that the management information system was an underestimated factor, 5% of respondents considered it unimportant, 5% considered it of little importance, but 60% considered it moderately important, and only 30% considered it critically important. 90% of respondents considered inventory management an important factor for the effective operation of the enterprise. 75% of respondents voted for the importance of reputation and trust among customers and partners, and 25% considered this factor critically important.

5. Respondents were surveyed regarding the importance of factors and their impact on the company's operations. For LLC "BaDM", the factors were

divided into 5 blocks. First, were studied the importance of implementing innovative technologies for process optimization. The importance of implementing digital tools for quality and process monitoring was analyzed, with 60% of respondents considering this factor important. The next block analyzed the importance of organizational culture on the quality and productivity of work; 40% of respondents considered this factor unimportant, 35% considered it important, and 25% found it difficult to answer.

6. It was determined that 50% of respondents consider process flexibility important for the ability to adapt to market changes and external factors. 30% of respondents believe otherwise, that this factor is not important, and 20% hesitated to answer.

7. It was found that 40% of respondents consider transparency of business processes important, 20% — unimportant, and the rest hesitated in their answer.

8. The survey determined that the majority of respondents (60%) consider process automation to be an important factor in reducing human errors, 5% do not consider this factor important, and the rest (35%) hesitated to answer.

9. Only 30% of respondents consider adaptation to international standards important and their implementation will create additional competitive advantages. Instead, 70% of respondents hesitated to answer, which suggests that the company's management does not provide sufficient information about the importance of implementing such standards at the enterprise.

10. It was found the importance of regular training and advanced training, to which the respondents answered unanimously (100%) - it is important.

11. The disadvantages of implementing a QMS are insufficient awareness among the company's employees, lack of automation of certain processes, and insufficient emphasis on staff training, which may lead to resistance to the implementation of new changes, as 70% of the surveyed respondents do not understand the importance of implementing an international standard at the company and what advantage the company will have after receiving this certificate.

PART III
DEVELOPMENT OF PROPOSALS FOR THE IMPLEMENTATION OF THE PROVISIONS OF THE ISO 9001 STANDARD FOR OPTIMIZATION OF THE ACTIVITIES OF A DISTRIBUTION COMPANY

3.1 Suggestions for improving internal processes and procedures based on ISO 9001

The implementation of ISO 9001 in distribution activities requires a comprehensive analysis of internal processes with the aim of improving them, as well as the development of clear procedures that meet the requirements of this standard. The main goal is to create a quality management system that will ensure the stability of processes, their transparency and efficiency, and will also provide an opportunity for further monitoring [1].

The results of the analysis indicate significant problems, in particular, instability of supplies and rising prices for raw materials. To improve this process, it is necessary to implement clear criteria for evaluating suppliers in accordance with the requirements of ISO 9001, which will include constant monitoring of supplier activities, checking product quality and timeliness of deliveries [8].

An important stage is the conclusion of service level agreements with suppliers, which will determine delivery times, product quality and responsibility of the parties. To automate the procurement process, it is proposed to implement a management system that will ensure effective analysis of supplier data [3].

The analysis also showed that warehouses do not always meet modern requirements, and limited access to resources can affect the efficiency of their use. The solution to this problem is the implementation of an automated warehouse management system, which will optimize inventory management, control storage conditions and ensure accurate accounting [11].

It is also necessary to conduct an internal audit of warehouses to ensure compliance with sanitary requirements and standards for storing medicines and

medical devices. It is important to organize training for warehouse personnel, focusing them on improving the efficiency of work with automated systems [4].

This will optimize delivery routes, reduce transportation time and costs, and provide backup logistics routes in case of emergencies. An important element is the creation of a real-time transportation monitoring system that will ensure transparency of logistics operations [5].

To assess the effectiveness of existing processes, it is necessary to implement a system of key performance indicators, such as order processing accuracy, complaint rate, and delivery time. The results of monitoring indicators should be included in monthly reports, which will be analyzed in meetings and discussed by management [6].

One of the problems is the insufficient level of communication between employees and their awareness of the issues of implementing a quality management system. To solve this problem, it is necessary to develop a training program that will cover the basics of ISO 9001, quality principles, risk management and a process approach.

An important step is the introduction of regular training for employees using modern training methods, in particular through simulations of business situations. It is also proposed to create an additional motivational system for employees aimed at supporting the company's corporate culture [8].

To ensure transparency and management efficiency, it is necessary to organize regular internal audits that will cover all key processes of the company, which will allow identifying opportunities for improvement and further development of the quality management system [5].

For effective implementation and maintenance of the quality management system, the standard requires clear planning of resources: financial, human, material and information. They are discussed in more detail in table 3.1.

The effectiveness of implementing a quality management system (QMS) according to ISO 9001 is assessed through the achievement of goals aimed at improving internal processes, increasing customer satisfaction and optimizing the

company's activities. To determine effectiveness, it is necessary to apply a comprehensive approach that includes monitoring key performance indicators (KPIs), conducting regular audits and detailed analysis of the results obtained [7].

Table 3.1

Resource planning

Resource category	Description	Implementation measures
Human	Personnel responsible for implementing, monitoring, and improving the quality management system	• conducting trainings • development of training programs • involvement of experts
Material	Equipment, tools, storage facilities, vehicles	• equipment updates • implementation of modern systems for warehouse automation • ensuring compliance with storage conditions
Informational	Databases are necessary for analysis and control	• implementation of innovative monitoring systems • ensuring data security and access to information • automation of data collection and analysis
Financial	Budget required for quality management system implementation, training, equipment procurement and certification	• budgeting for the implementation of the standard • costs of external and internal audits • investments in long-term personnel development programs

We propose to evaluate the effectiveness of the implemented measures according to the following criteria, which are given in table 3.2.

Table 3.2.

The effectiveness of implemented process improvement measures according to defined criteria

Criterion	Performance Indicator (KPI)	Measurement method	Expected results	Responsible persons	Deadline
Improving logistics	Order delivery lead time	Monitoring using automated analysis systems	Reduction in average delivery time by 15%	Logistics Department	6 months
	Delivery error rate	Reporting in the CRM system	Reducing delivery errors to 1%		
Process automation	Level of process automation	Analysis of the implementation of warehouse accounting and inventory management systems	Automation of 80% of warehouse and accounting processes	IT department	6 months
	Number of manual operations	Process monitoring	30% reduction in manual operations		
Staff training	Level of competence	Questionnaire before and after training	Increase in average competency level by 20%	HR department	3 months
	Number of trainings conducted	Maintaining statistics of training events	Conducting at least 5 trainings		
Quality control	Frequency of product non-conformity	Tracking through inventory control system and CRM	Reduction of non-conformities by 15%	Quality Department	Constantly
	Number of successfully	Statistics of internal and	Successful completion		

	Number of successfully completed audits	Statistics of internal and external audits conducted	Successful completion of 95% of internal and external audits		
Cost efficiency	Operating expenses	Comparison of costs before and after implementing changes	Reduction of operating costs by 10%	Finance Department	12 months
	Saving time on operations	Monitoring work processes	Reduction of average task completion time by 20%		

3.2. Development of recommendations for monitoring and analyzing the effectiveness of the quality management system

After conducting an analysis of the enterprise, the need for an additional internal audit was identified to assess and monitor the effectiveness of the quality management system [2].

Defining key performance indicators (KPIs) is an important step, followed by a detailed analysis of the company's activities in order to identify the most important aspects that require immediate improvement. Given this, it is recommended to use a risk-based approach, focusing on processes that have a significant impact on the quality of products or services [19].

It is also advisable to involve independent auditors or conduct cross-functional audits, which allows you to evaluate processes that are not related to daily activities, thereby ensuring objectivity of the assessment [11].

In addition, it is important not only to evaluate current indicators, but also to identify trends, causes of deviations and opportunities for improvement. As part of monitoring, it is necessary to assess the effectiveness of the implemented measures, comparing data before and after changes, as well as compare costs and benefits, considering the level of risks [4].

It is recommended to use statistical analysis tools, such as control charts and trend analysis, to ensure objective assessment of results [8].

To effectively collect and analyze data, it is necessary to attract qualified personnel, as well as regularly conduct quality management training for employees, which will contribute to a better understanding of the requirements of the ISO 9001 standard and its application in practice [4].

At the same time, to achieve stable results and increase the efficiency of the enterprise, it is necessary to implement a systematic approach to monitoring and analyzing the effectiveness of the QMS, which will not only ensure compliance with the standard, but also significantly increase operational efficiency, customer satisfaction and business sustainability in the long term [7].

To ensure compliance with the ISO 9001 standard, a pharmaceutical distributor must implement a clearly defined system of corrective and preventive actions that allow for timely response to identified nonconformities and prevent their recurrence [11].

The development of such procedures is an important element of continuous improvement and ensuring high quality of the company's products and services. We propose the following algorithm for implementing corrective and preventive actions [20]:

1. The first stage is to identify non-conformities through an audit of the quality management system, followed by documenting details such as time, place, circumstances and responsible persons.
2. We use SWOT analysis to identify the root causes of the problem and analyze the main factors that led to the non-compliance (table 3.3).
3. We plan measures to eliminate the identified non-conformity, focusing on solving the root causes of the problem. We draw up an action plan with the identification of responsible persons and deadlines.
4. We implement planned activities, including updating procedures, training staff, and implementing new tools to improve processes, and if necessary, we change documentation.

5. We evaluate the results of implemented corrective actions through re-audits and process testing to confirm the effectiveness of the measures.

6. We analyze potential situations that could lead to a recurrence of the problem using risk management tools. We create a list of potential risks and develop strategies to eliminate them.

7. We plan measures to prevent the recurrence of similar problems, identifying the necessary resources and responsible persons.

8. We are implementing measures to reduce risks, including through process automation, employee training, and standards review, which will help avoid potential problems in the future.

9. All stages of corrective and preventive actions are recorded in the company's internal documentation, which ensures readiness for internal and external audits.

10. We regularly review corrective and preventive actions to assess their effectiveness and relevance, which ensures continuous improvement of the quality management system.

A SWOT analysis of the internal audit of the quality management system at an enterprise engaged in distribution activities was conducted (table 3.3) [20].

Therefore, to increase the effectiveness of the internal audit, it is important to focus on improving the training process for employees, automating processes, improving planning and reducing resistance on their part [30].

Algorithms should be carefully described in the company's documentation, considering all possible risks and problems that may arise at different stages of activity [2].

Continuous improvement of these algorithms and their adaptation to changes in the external environment allow the enterprise to maintain high quality of its products and services [8].

Documentation of each stage is critically important when implementing a quality management system at a pharmaceutical enterprise engaged in the distribution of medicines, as it helps to minimize losses and prevent risks [14].

Table 3.3

SWOT analysis of internal audit of QMS at a distribution company

Strengths	Weaknesses
• personnel qualifications • consistently high company reputation and trust among customers • availability of modern logistics facilities • previous experience in implementing quality standards	• insufficient documentation of internal processes • low level of automation of individual processes • limited feedback mechanism • insufficient investment in training new staff • low frequency of internal audits
Opportunities	**Threats**
• increasing competitiveness through ISO 9001 certification • expanding partnerships through the implementation of international standards • integration of the latest technologies into logistics processes • increasing customer satisfaction	• increasing competition • personnel resistance to change • financial risks • disruptions in the supply of pharmaceutical goods and instability of logistics in wartime • changes in legislation

Continuous process improvement is a key element for ensuring the efficiency and competitiveness of pharmaceutical distribution companies [20].

According to the requirements of ISO 9001:2015, every organization must develop strategies for continuous improvement of its quality management system (QMS) [11].

The improvement process not only improves the efficiency of internal operations, but also contributes to maintaining high product quality, which is a critical aspect in the pharmaceutical industry, where consumer safety is paramount [8].

Risk management is also an important aspect, especially in the pharmaceutical sector, where the presence of risks that can affect product quality is a significant factor. To reduce risks, methods of predicting risks, assessing their probability and impact, and developing measures aimed at preventing them or minimizing their consequences should be applied [16].

Equally important is the involvement of employees at all stages of the improvement process. Only with the active participation of staff can sustainable improvement be achieved. This requires training, feedback, and encouragement of ideas for a quality management system. A culture of continuous improvement within a company helps to increase its performance [9].

Changes in processes should also consider the constant monitoring of regulatory and legislative requirements in the pharmaceutical sector. Given that not only the internal environment but also the external environment of the pharmaceutical company is changing, it is important to regularly update procedures in accordance with new requirements, especially regarding the storage and transportation of medicines. To do this, the company should develop a system for monitoring legislative changes and automatically adapt processes to new standards [15].

For the purpose of improvement, it is also necessary to regularly conduct internal audits, which allow assessing the compliance of processes with the requirements of ISO 9001 and other regulatory acts. Audits ensure timely detection of shortcomings and assessment of the effectiveness of the implemented changes [21].

The implementation of the ISO 9001 standard offers a robust framework for optimizing the operations of a distribution company, enhancing both efficiency and customer satisfaction. The proposals developed in part III focus on aligning internal processes with ISO 9001 requirements and establishing effective mechanisms for continuous improvement. By standardizing critical processes such as inventory management, order processing, and delivery scheduling, the company can achieve consistency, reduce errors, and streamline employee training. Integrating customer

feedback into decision-making processes ensures that service delivery and product quality remain responsive to market needs. Regular employee training fosters a culture of quality, while lean principles and risk-based thinking optimize resource use and proactively address potential disruptions. To sustain the effectiveness of the quality management system, the company should define measurable performance indicators, conduct periodic internal audits, and hold management reviews to evaluate progress and set objectives. Leveraging data analytics and the Plan-Do-Check-Act cycle supports evidence-based decisions and ongoing optimization. Collectively, these measures enable the distribution company to achieve ISO 9001 certification, enhance operational resilience, and position itself for long-term success in a competitive market [2].

Conclusions to part III

1. Suggestions for improving internal processes and procedures based on ISO 9001 were studied.
2. Recommendations for monitoring and analyzing the effectiveness of the quality management system were developed.

GENERAL CONCLUSIONS

1. The features of the activities of pharmaceutical distributors in the medical products market are considered. The basics of standardization and certification in the pharmaceutical industry are analyzed.

2. To assess the state of the management system at pharmaceutical distribution company «BaDM», a survey of 36 employees was conducted. It was determined that largest share are sales managers (45%) and logistics managers (15%), managers, regional managers and technical managers together occupy a share of 30%. It was found that 55% of respondents have higher education and 45% of respondents have incomplete higher education. The majority of respondents (50%) have over 10 years of experience working in the company.

3. We determined the average score for the implementation of the QMS at the enterprise to be 7.6. This indicates a satisfactory level, but a detailed analysis is required to identify weaknesses.

4. Compliance with legislative requirements was highlighted, which respondents identified as the most critically important factor. Reliability of logistics processes is considered critically important by 80% of respondents, the remaining 20% identified it as moderately important. Also, half (50%) of respondents consider QMS, ensuring compliance with GPD standards, GMP and personnel qualifications to be critically important. It was found that the management information system was an underestimated factor, 5% of respondents considered it unimportant, 5% considered it of little importance, but 60% considered it moderately important, and only 30% considered it critically important. 90% of respondents considered inventory management an important factor for the effective operation of the enterprise. 75% of respondents voted for the importance of reputation and trust among customers and partners, and 25% considered this factor critically important.

5. Respondents were surveyed regarding the importance of factors and their impact on the company's operations. For LLC "BaDM", the factors were divided into 5 blocks. First, were studied the importance of implementing innovative

technologies for process optimization. The importance of implementing digital tools for quality and process monitoring was analyzed, with 60% of respondents considering this factor important. The next block analyzed the importance of organizational culture on the quality and productivity of work; 40% of respondents considered this factor unimportant, 35% considered it important, and 25% found it difficult to answer. 6. It was determined that 50% of respondents consider process flexibility important for the ability to adapt to market changes and external factors. 30% of respondents believe otherwise, that this factor is not important, and 20% hesitated to answer.

6. It was found that 40% of respondents consider transparency of business processes important, 20% — unimportant, and the rest hesitated in their answer. The survey determined that the majority of respondents (60%) consider process automation to be an important factor in reducing human errors, 5% do not consider this factor important, and the rest (35%) hesitated to answer. Only 30% of respondents consider adaptation to international standards important and their implementation will create additional competitive advantages. Instead, 70% of respondents hesitated to answer, which suggests that the company's management does not provide sufficient information about the importance of implementing such standards at the enterprise.

7. It was found the importance of regular training and advanced training, to which the respondents answered unanimously (100%) - it is important. The disadvantages of implementing a QMS are insufficient awareness among the company's employees, lack of automation of certain processes, and insufficient emphasis on staff training, which may lead to resistance to the implementation of new changes, as 70% of the surveyed respondents do not understand the importance of implementing an international standard at the company and what advantage the company will have after receiving this certificate.

8. Suggestions for improving internal processes and procedures based on ISO 9001 were studied. Recommendations for monitoring and analyzing the effectiveness of the quality management system were developed.

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APPENDICES

APPENDIX A

Questionnaire
to assess the state of the management system at a pharmaceutical company

1. Gender

☐ Male

☐ Female

2. Age

☐ Under 25 years old

☐ 25–35 years old

☐ 36–45 years old

☐ 46–55 years old

☐ Over 55 years old

3. Education level

☐ Secondary education

☐ Secondary specialized education

☐ Higher education (bachelor's degree)

☐ Higher education (Master's degree)

4. Length of service in the company

☐ less than 1 year

☐ from 1 to 5 years

☐ from 5 to 10 years

☐ over 10 years

5. Position (specify): _____

6. Have you participated in the implementation of quality management systems at the enterprise?

☐ Yes

☐ No

7. Evaluate the implementation of quality management systems at a distribution company (wholesale of pharmaceuticals).

The table contains a rating scale from 1 to 10, where:

1 means "strongly disagree/not satisfied",

10 — "completely agree/very satisfied."

No.	Question	Rating (1–10)									
		1	2	3	4	5	6	7	8	9	10
1	Do you think that implementing a QMS helps improve the quality of customer service?										
2	Does the company provide appropriate conditions for compliance with the requirements of the QMS in your work?										

Continuation app. A

3	How satisfied are you with the availability of instructions and procedures for working with medicines?										
4	Are there sufficient resources (material, technical, information) to comply with the requirements of the QMS?										
5	Do you believe that implementing a QMS has a positive impact on the efficiency of your work?										
6	How well organized is the feedback system for resolving quality issues?										
7	Does implementing a QMS help reduce the number of errors in the storage and transportation of medicines?										
8	How effectively is employee training conducted regarding QMS requirements?										
9	Do you consider the monitoring and quality control system to be sufficiently effective?										
10	How well does management support initiatives related to the implementation and maintenance of the QMS?										

8.Assessment of the importance of factors that determine the efficiency of the enterprise

Please put a "+" in one of the cells in each question.

N	**Factor**	**Answer options**			
		Critically important	Moderately important	It doesn't matter much	It doesn't matter
1	Compliance with legal requirements				
2	Reliability of logistics processes				
3	Quality Management System (QMS)				
4	Ensuring compliance with GMP and GDP standards				
5	Supply stability				
6	Financial stability				
7	Inventory management				

Continuation app. A

8	Personnel qualifications				
9	Management information system				
10	Reputation and customer trust				

9. Assess the importance of factors and their impact on the operation of the enterprise. Choose only one answer for each question.

N	**Question**	**Answer options**
	Innovation and ecology	
1	How important is the implementation of innovative technologies for process optimization?	☐ Important ☐ Not important ☐ Difficult to answer
2	Is it important for a company to implement an environmental management system?	☐ Important ☐ Not important ☐ Difficult to answer
3	How important is the implementation of digital tools for quality and process monitoring?	☐ Important ☐ Not important ☐ Difficult to answer
	Organizational culture and flexibility	
4	Does corporate culture affect the quality and productivity of work?	☐ Yes ☐ No ☐ Difficult to answer
5	Is process flexibility important for adapting to market changes or external circumstances (in particular, war)?	☐ Yes ☐ No ☐ Difficult to answer
	Transparency and automation	
6	Is transparency of business processes important for increasing the trust of customers and partners?	☐ Yes ☐ No ☐ Difficult to answer
7	Does process automation reduce human errors?	☐ Yes ☐ No ☐ Difficult to answer
	Adaptation to international standards	
8	Should we pay more attention to adapting the enterprise to international standards (e.g., ISO 9001, GDP)?	☐ Yes ☐ No ☐ Difficult to answer
9	Will the implementation of international standards create additional competitive advantages?	☐ Yes ☐ No ☐ Difficult to answer
	Training and development	
10	How do you assess the importance of regular training and advanced training for staff?	☐ Important ☐ Not important ☐ Difficult to answer

Thank you for your answers!

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

shifts in consumer behavior, and increasingly stringent regulatory requirements, communication policy plays a crucial role in shaping a company's image, promoting products, and increasing customer loyalty. Therefore, studying the impact of marketing communications on company performance remains a highly relevant area of research.

Aim. The objective of this study was to analyze and evaluate marketing communication policy as a factor in enhancing the competitiveness of pharmaceutical enterprises.

Materials and methods. The research was conducted using a combination of qualitative and quantitative methods. The materials for the study included: scientific literature on pharmaceutical marketing, advertising content from regional pharmacy chains, online platforms, and social media channels. The following research methods was employed: content analysis, comparative analysis.

Results and discussion. At the initial stage, the research involved an in-depth review of literature sources and a content analysis of advertising campaigns conducted by regional pharmacy chains. The findings indicated that the most effective marketing communication tools in the pharmaceutical industry include digital marketing, social media, direct interaction with consumers through advisory programs, and educational initiatives. Implementing communication strategies fosters consumer trust and facilitates market expansion. The management of a pharmaceutical enterprise is inherently linked to a communication system that aligns with the company's goals, functions, organizational structure, information flow directions, and communication technology. The development of communication strategies within management forms an integrated marketing communication framework. It is evident that a well-structured marketing communication strategy is fundamental to establishing a strong corporate image and ensuring competitiveness. The rational use of marketing communications strengthens a company's market position, differentiates its products from competitors, enhances access to information and financial resources, and ultimately increases its market influence.

An effective marketing communication policy serves as a critical tool for ensuring the competitiveness of a pharmaceutical enterprise. A combination of traditional and digital communication channels enhances consumer engagement, builds a positive brand image, and drives sales growth. Aligning marketing communication strategies with current industry trends enables enterprises to adapt to changing market conditions and improve overall operational efficiency.

Conclusions. Development of a well-planned communication policy is essential for strengthening market positions. Marketing technologies play a pivotal role in the efficient operation of domestic enterprises. The proper selection and application of modern marketing techniques empower companies to optimize marketing management processes, expand their target audience, boost sales volumes, gain competitive advantages, and achieve sustainable growth. Furthermore, these strategies contribute to elevating corporate image and increasing brand awareness both in national and international markets.

ASSESSMENT OF THE CURRENT LEVEL OF QUALITY MANAGEMENT IN A PHARMACEUTICAL DISTRIBUTION COMPANY

Chibani Anass, Bondarieva I.V.
Scientific supervisor: Malyi V.V.
National University of Pharmacy, Kharkiv, Ukraine
fmmqaph@nuph.edu.ua

Introduction. Quality management in pharmaceutical distribution is critical to ensure the safety, efficacy, and integrity of medicinal products throughout the supply chain. Pharmaceutical

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

Daouia Essakhi
Scientific supervisor: Bondarieva I.V.
National University of Pharmacy, Kharkiv, Ukraine
fmmqaph@nuph.edu.ua

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

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

Anass CHIBANI

1. Topic of qualification work: «Assessment of the current level of quality management in a pharmaceutical distribution company», supervisor of qualification work: Volodymyr MALYI, D.Sc.Ph, 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 consider the features of the activities of pharmaceutical distributors in the medical products market and to analyze the basics of standardization and certification in the pharmaceutical industry; to analyze the current state of quality management in a pharmaceutical distribution company; to assess the existing quality management system in the company; to identify the main shortcomings and problems in the quality management system and to develop proposals for implementing the provisions of the ISO 9001 standard to optimize the activities of the distribution company; to assess the effectiveness of implementing measures and predicting results to optimize activities; to develop recommendations for monitoring and analyzing the effectiveness of the quality management system; to develop practical advice on improving processes in pharmaceutical distribution companies.

5. List of graphic material (with exact indication of the required drawings):
Figures – 14, tables – 3.

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
1	Volodymyr MALYI, professor of department management, marketing and quality assurance in pharmacy	09.09.2024	09.09.2024
2	Volodymyr MALYI, professor of department management, marketing and quality assurance in pharmacy	18.11.2024	18.11.2024
3	Volodymyr MALYI, professor 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 features of the activities of pharmaceutical distributors in the medical products market	September 2024	**done**
3	Assessment of the existing quality management system in a pharmaceutical distribution company	November 2024	**done**
4	Identification of major shortcomings and problems in the quality management system	February 2025	**done**
5.	Development of recommendations for monitoring and analyzing the effectiveness of the quality management system	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 _____ Anass CHIBANI

Supervisor of qualification work _____ Volodymyr MALYI

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				
Чібані Анасс	Оцінка сучасного рівня управління якістю у фармацевтичній дистриб'юторській компанії	Assessment of the current level of quality management in a pharmaceutical distribution company	проф. Малий В.В.	доц. Волкова А.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. № 331090673

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти Чібані Анасс, групи Phm20(4,10) eng-05, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» навчання на тему: «Оцінка сучасного рівня управління якістю у фармацевтичній дистриб'юторській компанії / Assessment of the current level of quality management in a pharmaceutical distribution company», 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

Anass CHIBANI

on the topic: «Assessment of the current level of quality management in a pharmaceutical distribution company»

Relevance of the topic. The requirements for improving the quality of products and services in all areas of business are constantly growing, and the distribution of medicines is no exception, because the implementation of a management system at such an enterprise allows it to compete with other companies, and also improves the quality of service provision, which cannot but be reflected in the positive dynamics of the enterprise's development.

Practical value of conclusions, recommendations and their validity. The results of the work can be used by pharmaceutical companies to improve the quality management system, increase business efficiency and customer satisfaction, and can also serve as the basis for further research in this area.

Assessment of work. Anass CHIBANI 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-05 group Anass CHIBANI on the topic: "Assessment of the current level of quality management in a pharmaceutical distribution company" 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 _____ Volodymyr MALYI

15 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

Anass CHIBANI

on the topic: «Assessment of the current level of quality management in a pharmaceutical distribution company»

Relevance of the topic. Modern market conditions dictate new rules that all enterprises must follow in order to be competitive, which is why it is important to implement international standards that will optimize current business processes, increase efficiency and satisfy consumer needs.

Theoretical level of work. The author has investigated the basics of standardization and certification in the pharmaceutical industry, which provide the basis for quality management of distribution companies. An analysis of an enterprise engaged in distribution activities has been conducted.

Author's suggestions on the research topic. The author has developed recommendations for optimizing the activities of a pharmaceutical distribution company.

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. Anass CHIBANI qualification work "Assessment of the current level of quality management in a pharmaceutical distribution company" 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. Alina VOLKOVA

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-05 Анасс ЧІБАНІ до захисту кваліфікаційної роботи в Екзаменаційній комісії НФаУ. Кваліфікаційна робота на тему «Оцінка сучасного рівня управління якістю у фармацевтичній дистриб'юторській компанії».

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

УХВАЛИЛИ: Допустити здобувача вищої освіти Анасс ЧІБАНІ до захисту кваліфікаційної роботи на тему «Оцінка сучасного рівня управління якістю у фармацевтичній дистриб'юторській компанії» 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 Анасс ЧІБАНІ до захисту кваліфікаційної роботи
за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньо-професійною програмою Фармація
на тему: «Оцінка сучасного рівня управління якістю у фармацевтичній дистриб'юторській компанії».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Микола ГОЛІК /

Висновок керівника кваліфікаційної роботи

Здобувач вищої освіти Анасс ЧІБАНІ виконав на кафедрі менеджменту, маркетингу та забезпечення якості у фармації НФаУ кваліфікаційну роботу, яка присвячена оцінці сучасного рівня управління якістю у фармацевтичній дистриб'юторській компанії.

Перший розділ присвячено теоретичним засадам стандартизації та сертифікації у сфері дистрибуції фармацевтичної продукції. У другому розділі проаналізовано поточний стан системи управління якістю у компанії, що займається дистрибуцією лікарських засобів. Третій розділ містить рекомендації щодо удосконалення внутрішніх процесів і процедур, а також розроблено шляхи моніторингу та аналізу ефективності функціонування системи управління якістю.

У цілому подана до захисту кваліфікаційна робота Анасса ЧІБАНІ на тему «Оцінка сучасного рівня управління якістю у фармацевтичній дистриб'юторській компанії» відповідає вимогам, що висуваються до кваліфікаційних робіт, оцінюється позитивно і може бути рекомендована для захисту в Екзаменаційну комісію НФаУ.

Керівник кваліфікаційної роботи
_____ Володимир МАЛИЙ

15 травня 2025 року

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Анасс ЧІБАНІ допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувач кафедри
менеджменту, маркетингу та
забезпечення якості у фармації
_____ Володимир МАЛИЙ

16 травня 2025 року

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/