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QUALIFICATION WORK

on the topic: «**STUDY OF APPROACHES TO THE ORGANIZATION OF INTERNAL AUDIT IN PHARMACEUTICAL ENTERPRISES»**

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АНОТАЦІЯ

У роботі проведено ідентифікацію основних проблем і недоліків у системах внутрішнього аудиту та оцінку впливу внутрішнього аудиту на забезпечення відповідності вимогам стандартів. Кваліфікаційна робота охоплює 41 сторінку, містить 27 рисунків та 1 таблицю. У роботі представлено список використаних джерел, що налічує 30 найменувань.

Ключові слова: підхід, аудит, фармацевтичне підприємство, оцінка, ефективність.

ANNOTATION

The work identifies the main problems and shortcomings in internal audit systems and assesses the impact of internal audit on ensuring compliance with the requirements of the standards. The qualification work covers 41 pages, contains 27 figures and 1 table. The work presents a list of sources used, which includes 30 items.

Keywords: approach, audit, pharmaceutical company, assessment, efficiency.

CONTENT

INTRODUCTION

Relevance of the research topic. The pharmaceutical industry plays a leading role in maintaining and strengthening public health, as the quality of medicines is a determining factor in their effectiveness and safety for patients. In today's conditions of globalization, increasing competition and increased regulatory requirements, pharmaceutical companies must ensure that their products and processes comply with international standards and other regulatory acts [1].

One of the key tools to support the effective functioning of a quality management system is internal audit. This process allows you to assess the compliance of all aspects of the enterprise's activities with established standards and regulatory requirements. Internal audit helps to identify risks, identify shortcomings in processes and promptly implement corrective measures, which is critically important for ensuring product quality and its safety for end consumers [9].

Despite the importance of internal auditing, many pharmaceutical companies face problems in its organization. In particular, there is often a lack of clearly developed regulations, proper training of personnel and a systematic approach to analyzing audit results. Such shortcomings can lead to non-compliance of products with standards, financial losses and a decrease in the reputation of the pharmaceutical company in the market [6].

Given that in the pharmaceutical industry, product quality is a matter not only of competitiveness, but also of people's lives and health, the regulation of the internal audit procedure is of particular importance. A clear and structured regulation ensures the standardization of this process, increasing its efficiency, transparency, and compliance with international standards [20].

Therefore, this topic is extremely relevant. Its implementation will contribute to increasing the competitiveness of pharmaceutical enterprises, ensuring high quality of medicines and strengthening consumer confidence. The development and implementation of effective internal audit regulations will contribute to achieving

high quality standards and sustainable development of pharmaceutical companies [5].

The purpose of the qualification work is to study of approaches to the organization of internal audit in pharmaceutical enterprises.

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

- to reveal the essence and foundations of the concept of internal audit;
- to study principles of internal audit;
- to determine of major problems and weaknesses in internal audit systems;
- to assess of the impact of internal audit on ensuring compliance with standards
- to research of internal audit procedure;
- to develop of a scheme and criteria for assessing the effectiveness of the audit.

The object of the study is the process of organizing internal audit at pharmaceutical enterprises.

The subject of the study is methodological approaches, regulation and effectiveness of internal auditing to ensure compliance of the QMS with the requirements of international standards and regulatory legal acts in the pharmaceutical industry.

The study used various **methods**, including analysis and synthesis; comparative analysis; expert survey; systemic approach; modeling; empirical method; economic analysis methods; graphical method (used to visualize research results, build algorithms, and present the obtained data in graphical form).

Practical significance of the obtained results. The proposed regulations for conducting an internal audit of the quality management system at a pharmaceutical enterprise provide a standardized approach to organizing this process, which helps to increase the efficiency of audits. The implementation of a structured regulation allows you to identify and eliminate shortcomings in processes, minimize risks and

ensure stable compliance of products with the requirements of regulatory documents. The regulation helps to increase the transparency of audit procedures, creating uniform rules for audit activities, which facilitates interaction between divisions of the enterprise. The use of the proposed approaches allows to reduce production costs associated with the elimination of deficiencies identified at later stages of production, through early identification of problems and implementation of corrective measures. Clearly defined criteria and algorithms for conducting audits contribute to improving the professional training of auditors and employees involved in the quality management system. Improving internal audit allows a pharmaceutical company to improve its reputation, ensure the stability of product quality and compliance with the requirements of international standards, which contributes to strengthening its position in the market. The developed regulations can be adapted to the needs of different pharmaceutical companies, regardless of their size, scale of activity and product specificity. The results obtained can be used by pharmaceutical companies to improve the quality management system, as well as serve as the basis for developing methodological recommendations in the field of organizing internal audit.

Approbation of research results and publication. Qualification work is approved on II Scientific and practical Internet conference with international participation "Pharmaceutical technologies, standardization and quality assurance of medicines". Published abstracts of reports: Malyi V.V., Bondarieva I. V., Houasli E.O. Study of approaches to the organization of internal audit in pharmaceutical enterprises. Pharmaceutical technologies, standardization and quality assurance of medicines: materials II Scientific and practical Internet conference with international participation (May 22, 2025) – Kh.: NUPH, 2025. – P. 20.

Structure and scope of the qualification work. The qualification work includes an introduction, a literature review, an experimental part, general conclusions, a list of sources used and appendices. The total volume of the work is 41 pages, which contain 27 figures, 1 table. The study used and analyzed 30 literary sources.

CHAPTER I
THEORETICAL BASIS OF THE ORGANIZATION OF INTERNAL AUDIT

1.1. The essence and foundations of the concept of internal audit

The pharmaceutical industry is one of the most important sectors of the economy, which directly affects the health and quality of life of the population. Ensuring the quality of medicines is a key task for pharmaceutical enterprises. In this regard, the implementation of a quality management system becomes an integral part of the successful functioning of enterprises in this industry [3].

Internal audit is a systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. According to international standards such as ISO 9001, internal audits play a critical role in the maintenance and continual improvement of the quality management system. Their primary purpose is to verify the compliance of actual processes with established procedures and standards, as well as to identify areas for improvement. Steps of internal audit are presented in fig. 1.1. [18].

Fig. 1.1. Steps of internal audit

In the context of pharmaceutical enterprises, internal audits are particularly important due to the high regulatory demands placed on product quality, safety, and traceability. The internal audit serves not only as a compliance tool but also as a mechanism for risk mitigation and operational enhancement [11].

A quality management system is a set of interrelated and interdependent elements covering all aspects of an enterprise's activities, aimed at achieving and maintaining the quality of products and processes in accordance with established standards and requirements. It is based on principles such as customer orientation, leadership, staff involvement, a process approach, continuous improvement, evidence-based decision-making and relationship management [5].

Fig. 1.2. presents a diagram of the Internal audit cycle [4].

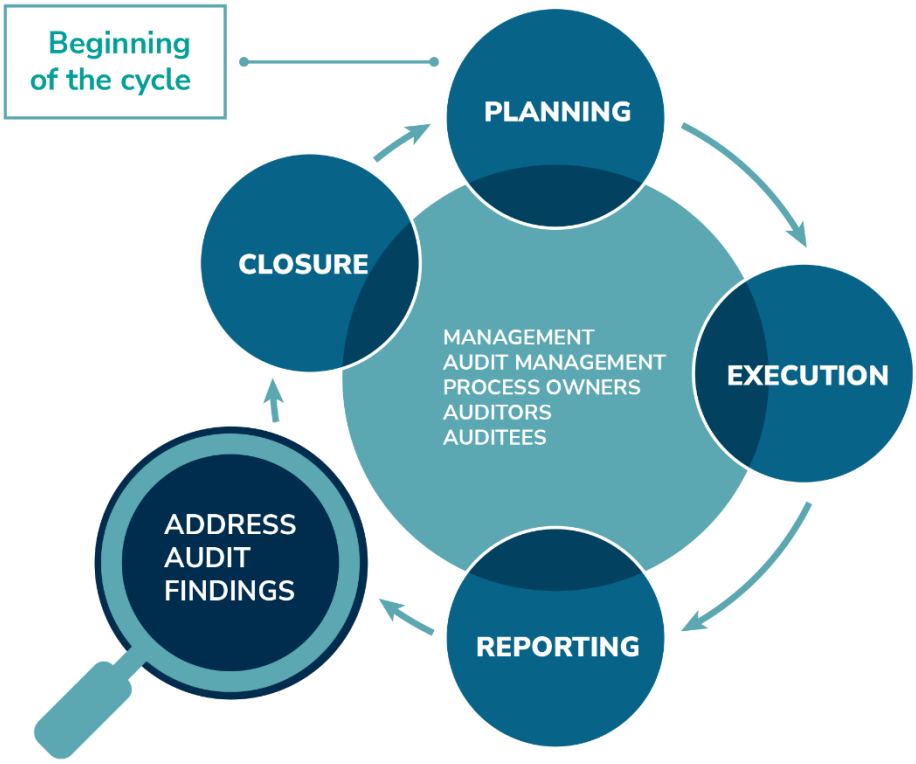

Fig. 1.2. Internal audit cycle

Fundamentals of the concept of a quality management system in the pharmaceutical industry: regulatory standards and regulations. The pharmaceutical industry is subject to strict regulatory requirements governing the production and control of medicinal products. The main documents are the international standards

ISO 9001, recommendations for good manufacturing practice (GMP), as well as local legislation. They define requirements for product quality, technological processes and risk management [18].

A schematic representation of the audit procedures is presented in Fig. 1.3. [30].

Fig. 1.3. Diagram of audit procedures

Process approach: the quality management system considers the activities of the enterprise as a set of interconnected processes. This ensures systematic control of each stage of production - from the supply of raw materials to the distribution of finished products [22].

The pharmaceutical industry places special emphasis on risk management. Identifying, analyzing, and minimizing risks at each stage of production helps prevent potential product quality problems [8].

Continuous control of all processes is the basis for ensuring consistent quality. This includes incoming control of raw materials, control of technological parameters

of production, and checking the quality of products at the stages of storage and transportation [11].

One of the main principles of QMS is the continuous improvement of processes and approaches to quality assurance. For this, tools such as the Deming cycle (PDCA), cause and effect analysis (FMEA), statistical quality control methods are used [20].

1.2. Study principles of internal audit

The organization of internal audits should be guided by key principles that ensure their effectiveness. Audits must be conducted by individuals who are impartial and free from conflicts of interest regarding the process being audited. Audits should follow a defined methodology, including planning, execution, reporting, and follow-up. Conclusions must be supported by verifiable audit evidence. Audits should prioritize high-risk areas, especially in pharmaceutical distribution where product integrity is paramount. Principles of good internal control system are presented in Fig. 1.4 [11].

Fig. 1.4. Principles of good internal control system

These principles ensure that internal audits contribute meaningfully to QMS performance and foster a culture of quality within the organization. We will consider the advantages of implementing a quality management system in the pharmaceutical industry in more detail [5].

The first is improving product quality. A quality management system ensures that products comply with international standards and regulatory requirements [22].

The second is a reduction in production costs. Process optimization allows for reduced losses and efficient use of resources. The third is increased consumer confidence. High quality products strengthen the company's reputation and contribute to an increase in market share [7].

Fourth, compliance with regulatory requirements. Compliance with standards allows you to avoid fines, product recalls , and other sanctions [11].

The quality management system is a set of key processes that ensure the organization of management, executive, reporting and control activities aimed at achieving harmonious interaction in order to achieve the set goals. For all QMS processes, a universal methodology is used, based on the Plan – Do – Check – Act (PDCA) management cycle , which can be described as follows : plan – determining the necessary processes to achieve results that meet customer requirements and the organization's policy ; perform – implementing QMS processes with high-quality performance of duties; check – monitoring and measuring processes and products in accordance with the policy, goals and requirements with subsequent reporting on the results; correct – implementing measures for continuous improvement of indicators, as well as implementing innovations [12].

The processes necessary for the effective functioning of the QMS, as well as their requirements, should be systematized and documented. The main tasks of documentation are to describe all processes in sufficient detail, to convey information to personnel, to ensure the convenience of data registration and monitoring of work. Documents should meet the internal needs of employees and managers, as well as confirm compliance with external regulatory requirements [20].

External documentation that influences internal regulations includes inter-

industry standards (DSTU, GOST, ISO, laws of Ukraine), industry regulatory acts (resolutions and orders of the Cabinet of Ministers of Ukraine, Ministry of Health, WHO recommendations, PIC/S, ICH, EDQM guidelines) and specific documents related to test methods (State and European Pharmacopoeia) [4].

QMS documentation includes:

- Quality Manual – a key document that describes the main elements of the QMS, including policies, programs, procedures and instructions that confirm the compliance of processes with the requirements of external regulations;
- Quality policy, standard operating procedures (SOPs), instructions, fillable forms (logs, protocols) [15].

Quality Guideline manual) is the main tool for ensuring that laboratory tests comply with regulatory requirements. It contains a concise description of the policies, procedures and processes required to demonstrate compliance with the QMS [3].

The quality management system is a key tool for ensuring stable product quality in the pharmaceutical industry. Its implementation allows enterprises to increase competitiveness, meet consumer demands and comply with strict regulatory standards. Continuous improvement of the quality management system is the key to sustainable development of a pharmaceutical enterprise and ensuring public trust in its products [11].

The quality management system covers all processes related to management activities, the supply of resources, the release of products and measurements. It provides for the documentation of quality policies and objectives, quality guidelines, documents necessary for the effective planning, operation and control of processes, as well as relevant documented procedures. The number and volume of documentation are determined by the size and type of activity of the organization, the complexity of processes and their interaction, as well as the competence of personnel. Documents can be stored in any format suitable for the organization [7]. Auditing principles are presented in Fig. 1.5.

Fig. 1.5. Auditing principles

One important component is the development and updating of protocols that provide evidence of compliance with requirements and confirm the effectiveness of the quality management system. Such documents should be accessible, understandable and easy to use [15].

The responsibility of management includes promoting among employees the importance of meeting customer requirements and compliance with legal norms, formulating quality policies, setting goals, providing resources, and systematically analyzing activities. This is done by using data obtained during audits, customer feedback, the results of previous analyses, and information about changes that may affect the quality management system. The output of the analysis is decisions and actions aimed at improving performance, product or service quality, and determining resource needs [23].

A quality management system requires the identification of necessary resources and their availability. Personnel involved in processes that affect product quality must meet standards of competence, have appropriate education, qualifications and experience. To do this, the organization determines the required

level of competence, records data on the education, training and experience of its employees [4].

The organization must also establish and maintain an infrastructure that includes buildings, production facilities, engineering structures, equipment, and support services necessary to ensure that products or services meet customer requirements. Product procurement is based on a thorough evaluation and selection of suppliers who are able to meet the specified requirements. Supplier evaluations and re-inspections are recorded, and, where necessary, the procurement documentation specifies the conditions for inspection and the procedure for product release [7].

The effectiveness of the quality management system is assessed by monitoring the level of customer satisfaction and conducting internal audits, which allow determining the compliance of the system with the requirements of the standard and assessing its effectiveness. The implementation of the ISO 9001 standard contributes to improving the quality of products and services, increasing customer satisfaction, the competitiveness of the organization, transparency of management and efficiency of work [29].

The implementation of ISO 9001 includes four main stages: development, which involves studying the requirements of the standard and analyzing the existing management system; implementation, which includes describing and standardizing processes; certification of the system by a certification body; maintenance, which ensures the clear functioning of the system and its further improvement [30].

The quality management system according to ISO 9001 ensures the controllability of the enterprise's activities, streamlines document flow, increases management efficiency and involves employees in achieving common goals. This leads to improved financial performance, increased sales, reduced illiquid goods and increased customer loyalty [26].

Thus, a quality management system is an effective tool that allows an enterprise to adapt to market changes, improve internal processes and increase competitiveness. It ensures the proper level of quality of products or services,

improves operational management and contributes to maintaining long-term customer loyalty [30].

Conclusions to chapter I

1. The essence and foundations of the concept of internal audit were analyzed.
2. The principles of internal audit were revealed.

CHAPTER II
RESEARCH OF APPROACHES TO ORGANIZING INTERNAL AUDIT IN PHARMACEUTICAL ENTERPRISES

2.1. Identification of major problems and weaknesses in internal audit systems

To assess the internal audit procedures of the quality management system at a pharmaceutical company, a survey was conducted among 57 employees of pharmaceutical companies (Appendix A).

The distribution of respondents by their positions shows that the largest share is occupied by department heads (30%) and quality managers (28%). Quality engineers make up 14% of the survey participants. Directors make up 8% of the respondents, administrative staff (HR, accounting) – 7%. Managers and support staff (IT) are represented by the same share – 5% each. The smallest share is occupied by pharmacovigilance specialists – 3% (Fig. 2.1).

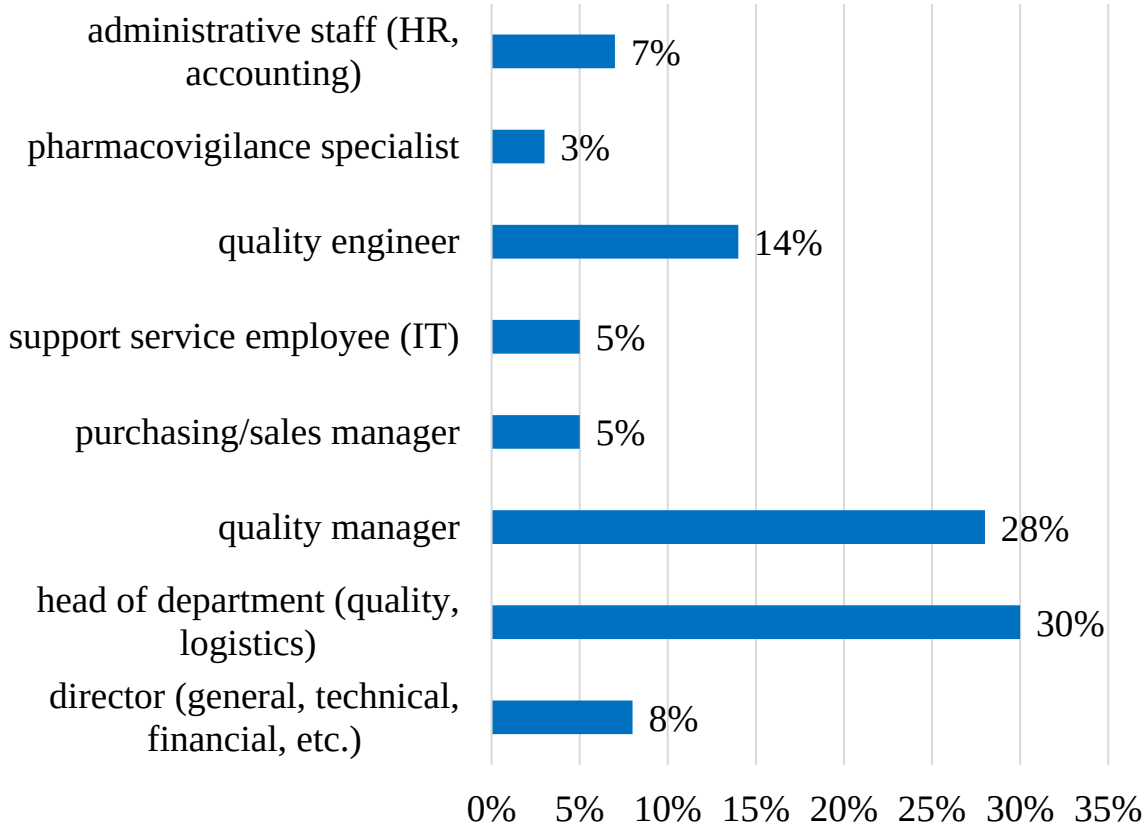

Fig. 2.1. Distribution of respondents by positions in the company

In the next stage of our work, we analyzed the respondents' length of work experience in the pharmaceutical industry (Fig. 2.2).

The analysis showed that the majority of respondents (47%) have experience in the pharmaceutical industry from 16 to 25 years. A significant proportion of respondents (31%) have been working in this field for 5 to 15 years. The proportion of respondents who have worked for over 25 years is 18%. The smallest proportion of respondents, namely 4%, have work experience of less than 5 years. These data indicate the high professional competence of the majority of survey participants.

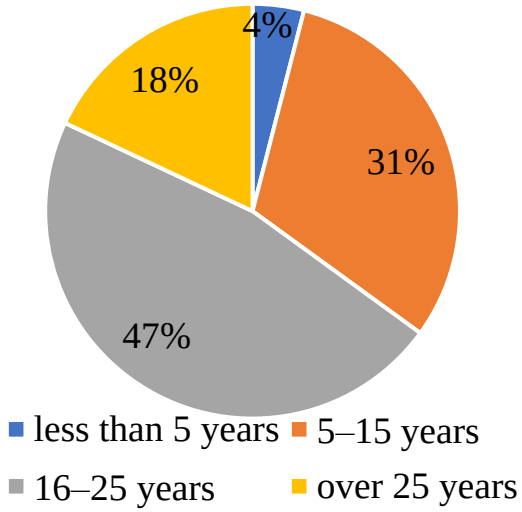

Fig. 2.2. Analysis of respondents’ work experience in the pharmaceutical industry

We further determined that 78% of respondents participated in internal quality management system audits (Fig. 2.3).

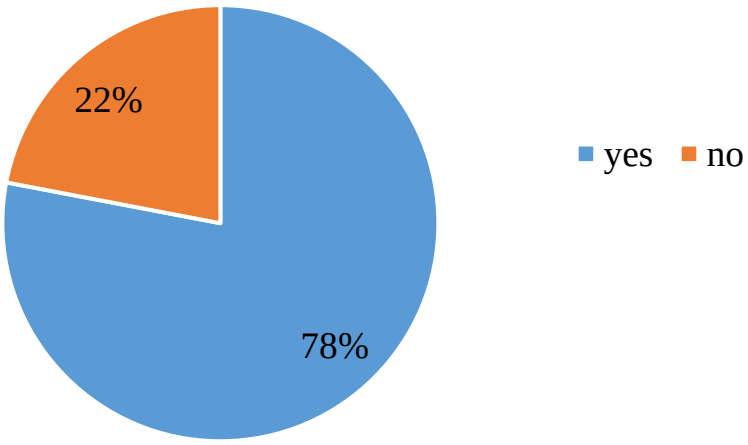

Fig. 2.3. Research on the participation of respondents in internal audits

Also, of interest was information on the level of familiarity with the internal audit procedure at a pharmaceutical company (Fig. 2.4).

It was found that 59% of respondents are very familiar with this procedure, 22% are partially familiar, and only 19% of respondents are poorly familiar with the internal audit procedure at the company.

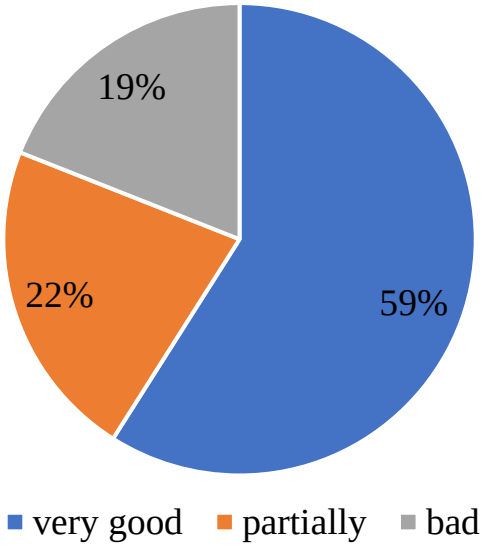

Fig. 2.4. Study of the level of familiarity with the internal audit procedure at a pharmaceutical company

We further determined that 45% of respondents had received training in conducting internal audits (Fig. 2.5).

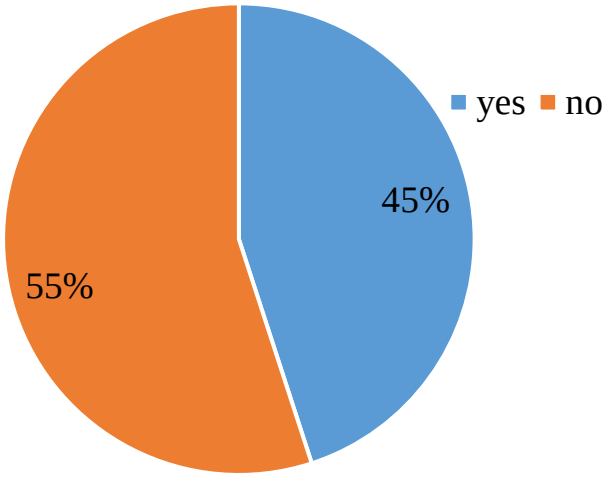

Fig. 2.5. Analysis of respondents' training in conducting internal audits

Also of interest was information on the analysis of clearly defined roles and responsibilities of internal audit participants (Fig. 2.6). It was found that 38% of respondents noted that the roles and responsibilities of internal audit participants are clearly defined; 40% of respondents noted that they are partially clear and for 22% of respondents, they are not defined.

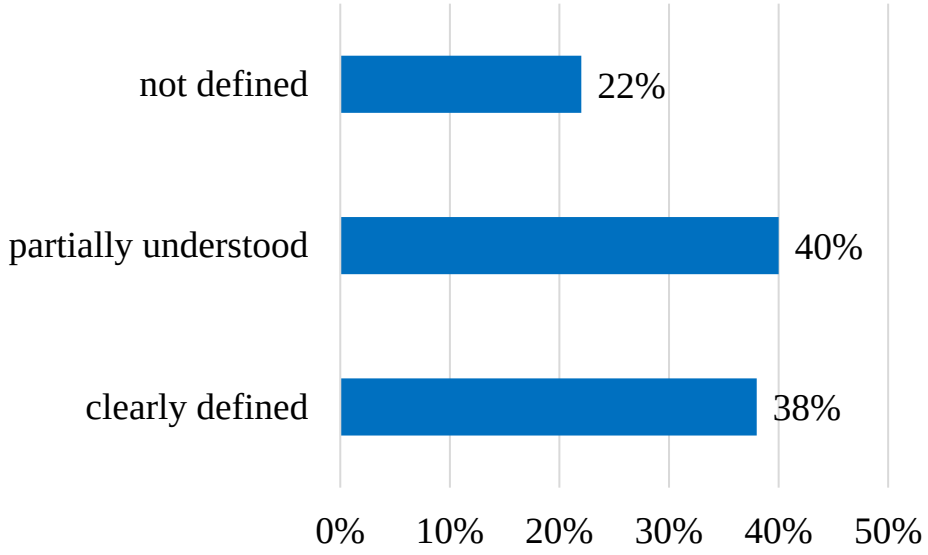

Fig. 2.6. Analysis of clearly defined roles and responsibilities of internal audit participants

It was found that the main difficulties that respondents observe when conducting internal audits are diverse and cover several key aspects (Fig. 2.7).

The most common problem reported by respondents is difficulty in identifying deficiencies – 24% of responses.

Employee resistance also occupies a significant share, accounting for 17%. Insufficient training of auditors took third place (15%). Lack of time and lack of resources equally affect the audit process, each of which received 10%.

Difficulties with documentation account for 9%, while insufficient management support is 6%. The least common, but still important, problems are the lack of proper tools (5%) and communication problems (4%). These results allow us to identify the main areas for improving the internal audit process.

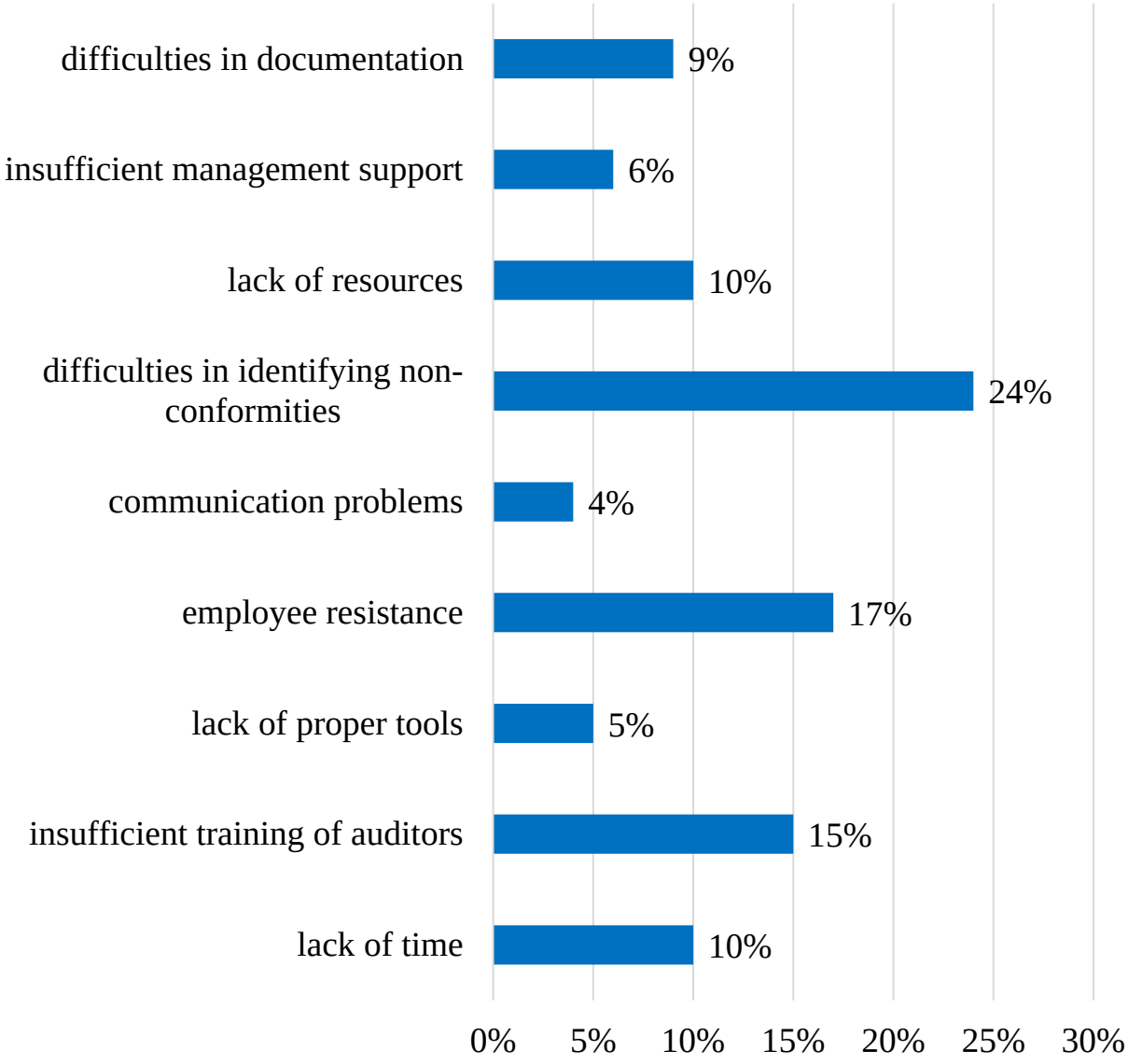

Fig. 2.7. Analysis of the main difficulties during internal audit

It was found that the majority of respondents consider the time frame for conducting internal audits insufficient to complete all necessary tasks (Fig. 2.8).

According to the survey results, only 40% of respondents agreed that the available time for conducting internal audits is sufficient.

However, 60% of respondents believe that the established timeframes are not sufficient to complete all necessary tasks, such as identifying deficiencies, analyzing data, preparing reports, and developing recommendations.

This indicates the need to review the planning and organization of the audit process to ensure its effectiveness.

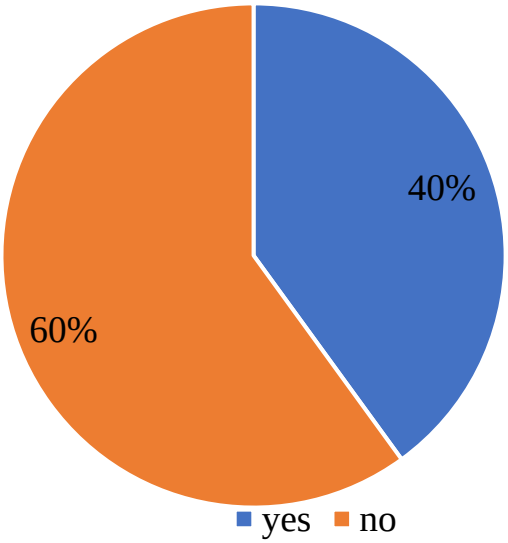

Fig. 2.8. Assessment of the adequacy of the timing of internal audits

It was found that the vast majority of respondents do not face problems documenting the results of internal audits (Fig. 2.9).

Data analysis showed that 92% of respondents do not experience difficulties in the process of documenting the results of internal audits. Only 8% of respondents reported the presence of such problems.

This indicates a well-established process of recording the results of audit activities, which includes the use of clear formats and documentation standards. At the same time, for those who encounter difficulties, it is advisable to provide additional instructions or resources to improve this component.

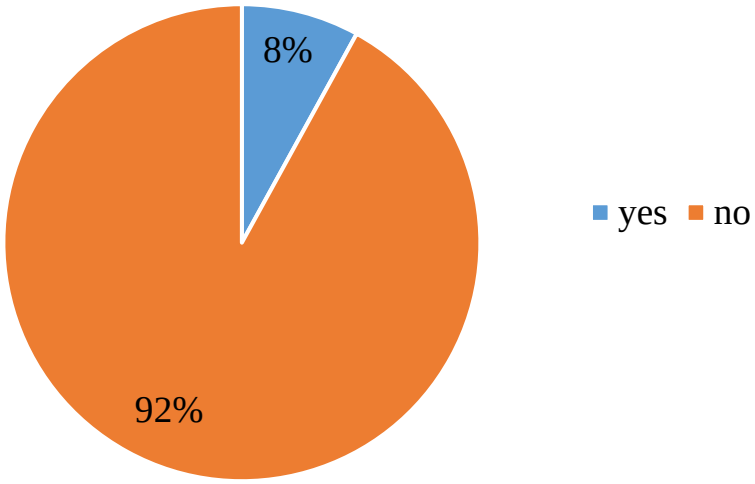

Fig. 2.9. Analysis problems with documenting the results of internal audits

2.2. Assessment of the impact of internal audit on ensuring compliance with standards requirements

It was found that 67% of respondents are completely satisfied with the availability of information resources, such as templates, checklists and instructions, for conducting internal audits. Another 28% of respondents indicated that the resources are partially sufficient, which may indicate a need for their updating or expansion. Only 5% of respondents reported that such materials are insufficient. The data obtained demonstrate the general satisfaction of respondents with the available resources, but emphasize the need for periodic review and improvement of these materials to ensure their compliance with current requirements (Fig. 2.10).

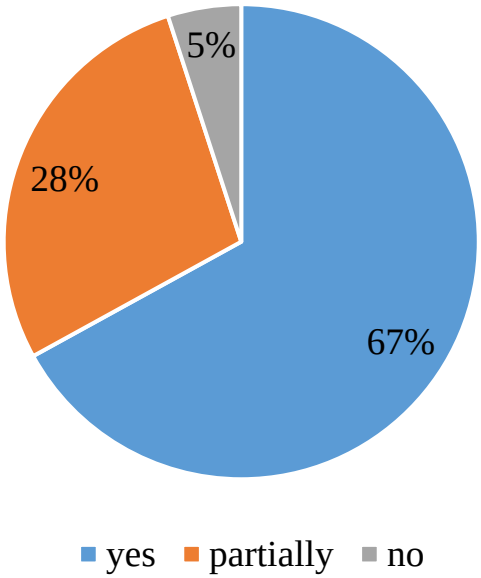

Fig. 2.10. Respondents' assessment of the sufficiency of information resources for conducting internal audits

The survey results showed that 59% of respondents rate internal audit as a very effective tool for identifying shortcomings in the activities of a pharmaceutical company. Another 30% of participants consider it moderately effective, which indicates the need to optimize individual procedures or approaches. Only 11% of respondents stated that internal audit does not contribute to identifying shortcomings. This may be due to shortcomings in the organization of the audit or

the lack of appropriate tools. The results obtained confirm the importance of further improving internal audit processes to increase their effectiveness (Fig. 2.11).

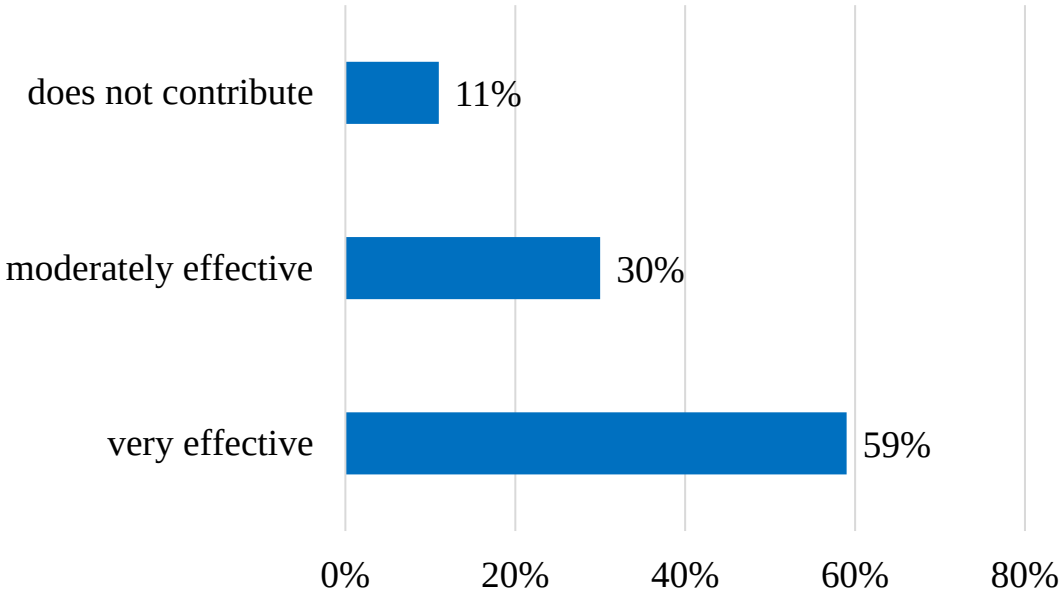

Fig. 2.11. Assessment of the effectiveness of internal audit in identifying deficiencies

The study showed that in 78% of cases, non-conformities identified during internal audits are always resolved in a timely manner (Figure 2.12).

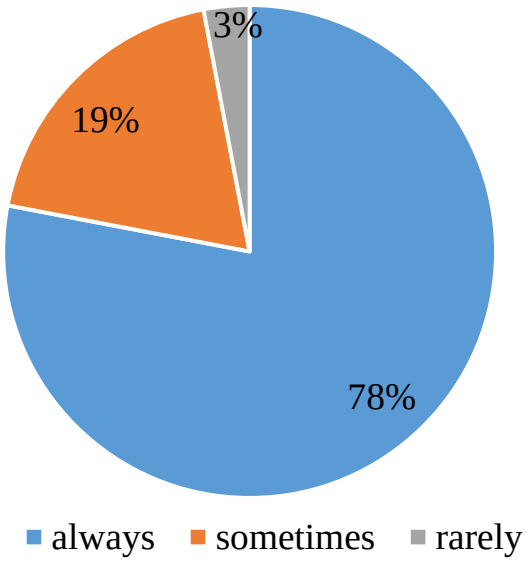

Fig. 2.12. Frequency of timely resolution of identified deficiencies

This indicates a high level of organization and responsibility in the pharmaceutical company. At the same time, 19% of respondents noted that problems are resolved on time only sometimes, and another 3% reported that this rarely happens. Such results indicate potential reserves for improving the defect management process, in particular, strengthening control over the implementation of corrective actions.

The survey results showed that 84% of respondents are confident that auditors are sufficiently qualified to perform their tasks. Another 15% of participants noted that auditors' competence is only partially sufficient, which may indicate the presence of certain gaps in knowledge or skills. Only 1% of respondents believe that auditors are not properly qualified. Such results indicate an overall satisfactory training of specialists, while emphasizing the need for periodic professional development to ensure maximum efficiency of audits (Fig. 2.13).

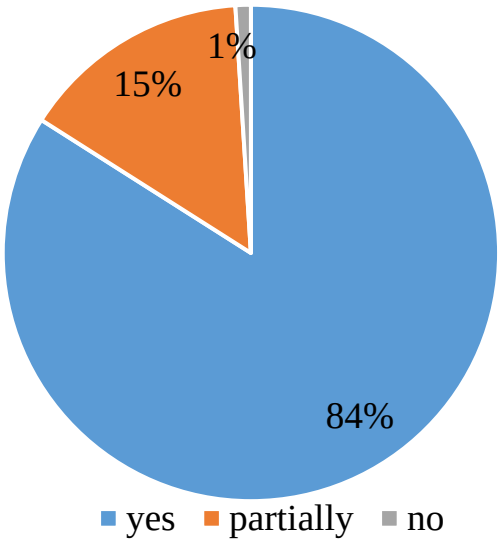

Fig. 2.13. Assessment of auditors' qualifications to perform their tasks

The results of the study show that 72% of respondents assess the impact of internal audit on compliance with GMP/GDP requirements as significant. Another 20% noted that the impact is moderate, which may indicate the need to optimize certain aspects of audit activities. At the same time, 8% of respondents believe that internal audit has no impact on ensuring compliance with standards. This

emphasizes the importance of further improving audit procedures to strengthen their impact on regulatory compliance (Figure 2.14).

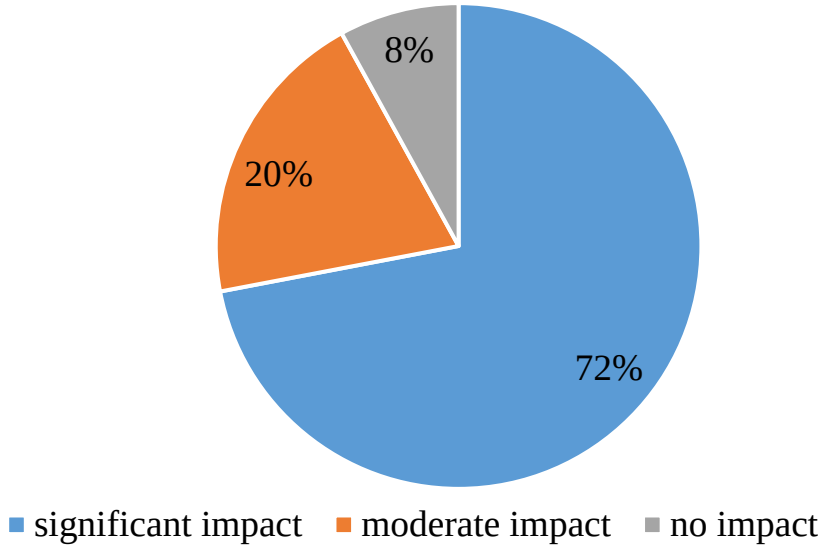

Fig. 2.14. Assessment of the role of internal audit in ensuring compliance with GMP/GDP standards

Next, we assessed the impact of internal audits on improving the performance of pharmaceutical companies (Fig. 2.15).

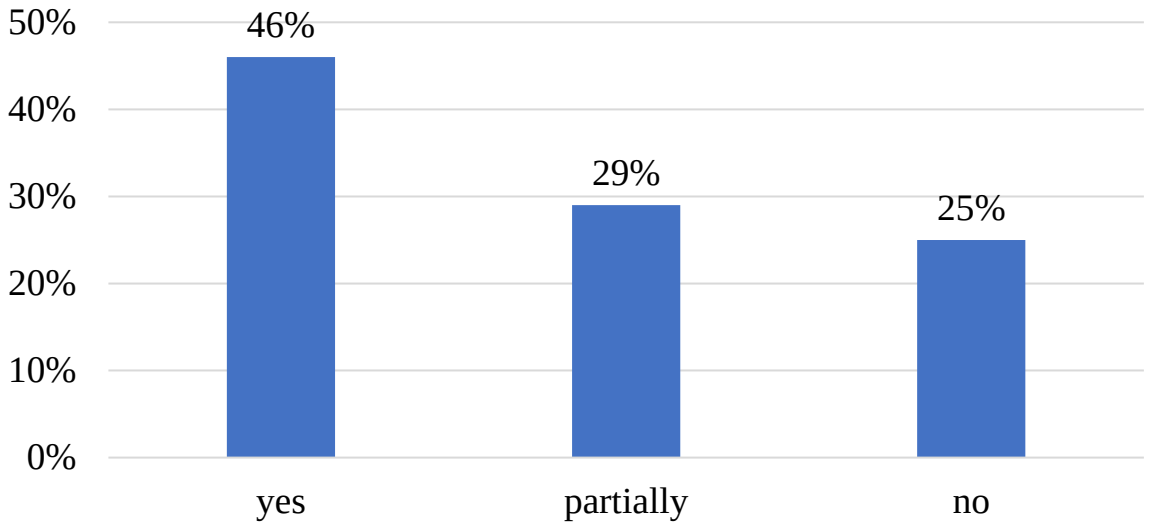

Fig. 2.15. Assessing the impact of internal audits on improving the performance of pharmaceutical companies

The study showed that 46% of respondents are confident that the work of pharmaceutical companies improves after internal audits. Another 29% note partial

improvement, which indicates the possibility of improving audit processes to achieve a more complete effect. However, 25% of respondents do not see positive changes after audits, which may be a sign of the need to review methodologies and approaches to conducting audits, as well as increasing the efficiency of implementing their results (Fig. 2.15).

Next, we analyzed the aspects of internal audit that require the greatest improvement (Fig. 2.16).

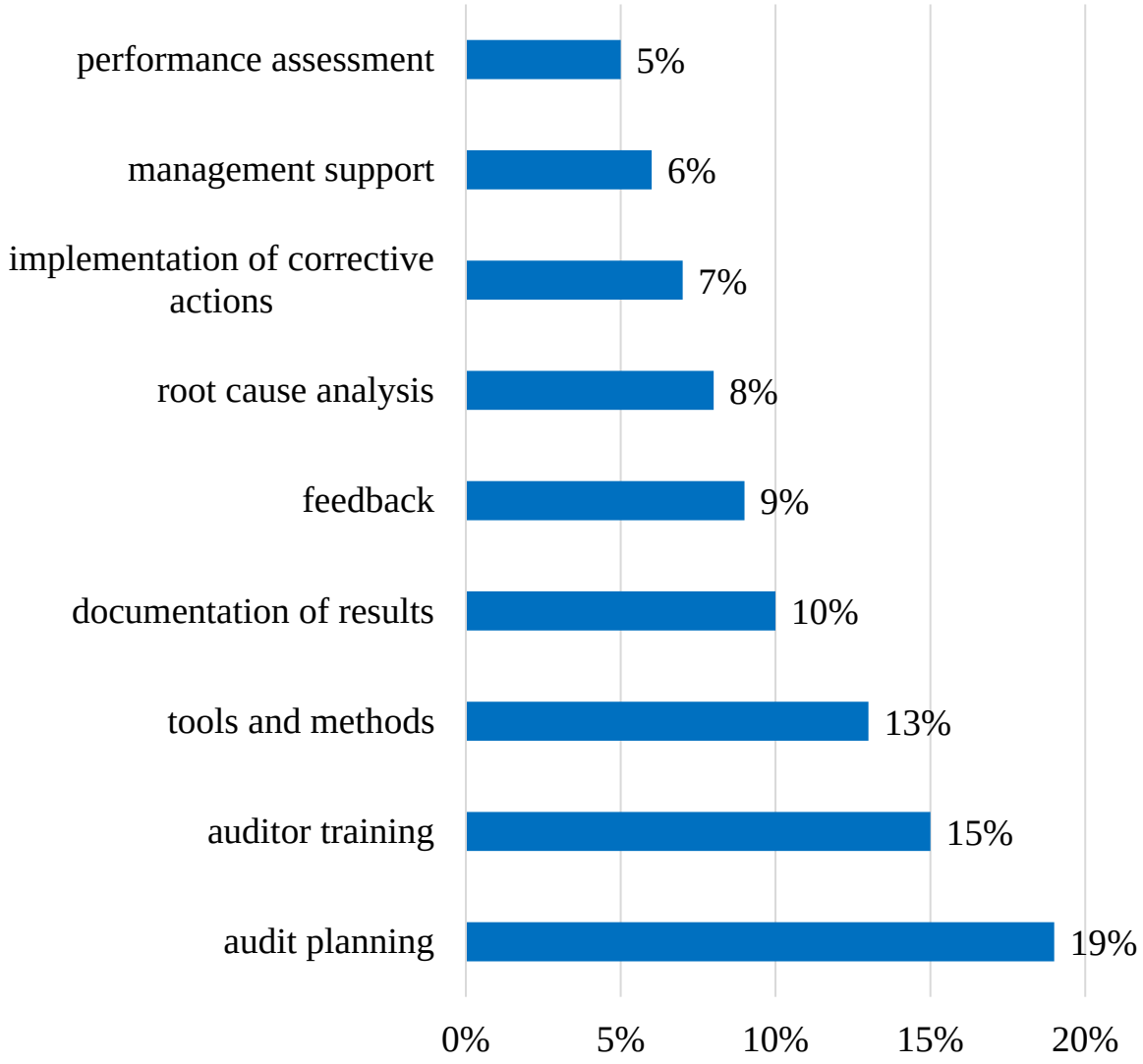

Fig. 2.16. Assessing the aspects of internal audit that need the most improvement

The results of the analysis show that the planning stage of internal audit needs the most improvement, indicated by 19% of respondents. Considerable attention

should also be paid to the training of auditors (15%) and the improvement of audit tools and methods (13%). Documenting results (10%) and improving feedback (9%) occupy a middle position on the list of priorities.

Less attention, but no less important, was paid by respondents to root cause analysis (8%), implementing corrective actions (7%), management support (6%) and assessing audit effectiveness (5%).

These results indicate a comprehensive approach necessary to improve the overall effectiveness of internal audit (Figure 2.16).

The next stage of our work revealed that the vast majority of respondents (80%) consider additional training necessary for employees involved in internal audits.

This indicates the need to improve the professional level of auditors and develop their competencies to ensure better and more effective audits.

Only 20% of the study participants believe that existing knowledge and skills are sufficient.

These results highlight the importance of investing in training programs as a key element in improving the internal audit system (Fig. 2.17).

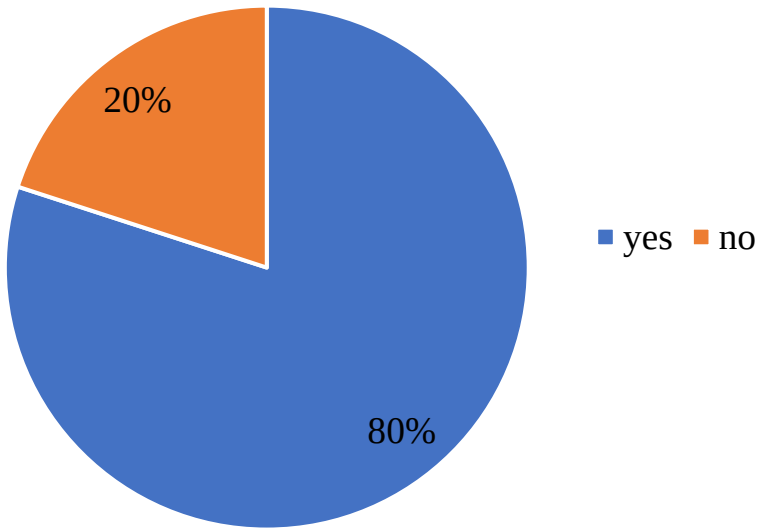

Fig. 2.17. Analysis of the need for additional training for employees involved in the audit

It was found that the most popular tools for improving the effectiveness of internal audits are quality management software, in particular MasterControl, which is used by 70% of respondents.

Also popular are systems for collecting and analyzing data, with Tableau and Power BI leading the way among the chosen tools.

Among the tools for document automation, Microsoft Power stands out Automate and DocuSign, which are actively used to improve documentation and reporting processes.

In addition, project management platforms such as Trello and Microsoft Project, as well as internal communication tools such as Microsoft Teams, are in high demand among respondents.

Specialized databases for the pharmaceutical industry, in particular PharmaSuite MES, as well as risk management systems such as LogicGate, are another important tool for ensuring high efficiency of internal audits (Fig. 2.18 and Fig. 2.19).

The next stage of our research was to analyze the level of feedback between management and auditors (Fig. 2.20).

It was found that the majority of respondents consider the feedback between management and auditors to be sufficient. In particular, 74% of respondents indicated that the feedback is sufficient, which indicates good interaction between management and auditors.

16% of respondents consider the feedback to be partially sufficient, which may indicate certain shortcomings in the communication process or the need for its improvement.

Only 10% of respondents indicated that feedback between management and auditors is insufficient, which may indicate communication problems or a lack of proper management support for audit activities (Figure 2.20).

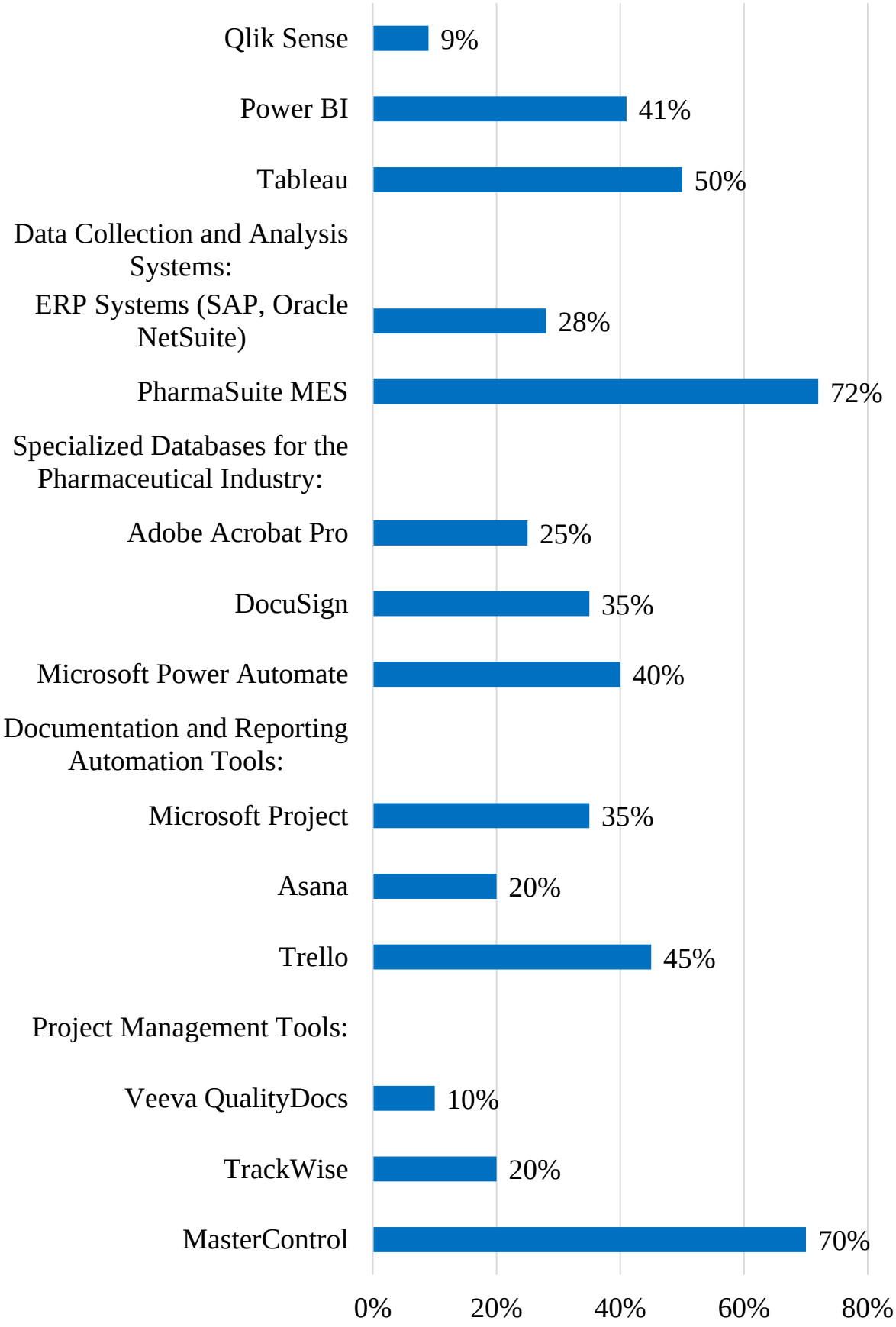

Fig. 2.18. Analysis tools to improve the effectiveness of internal audits

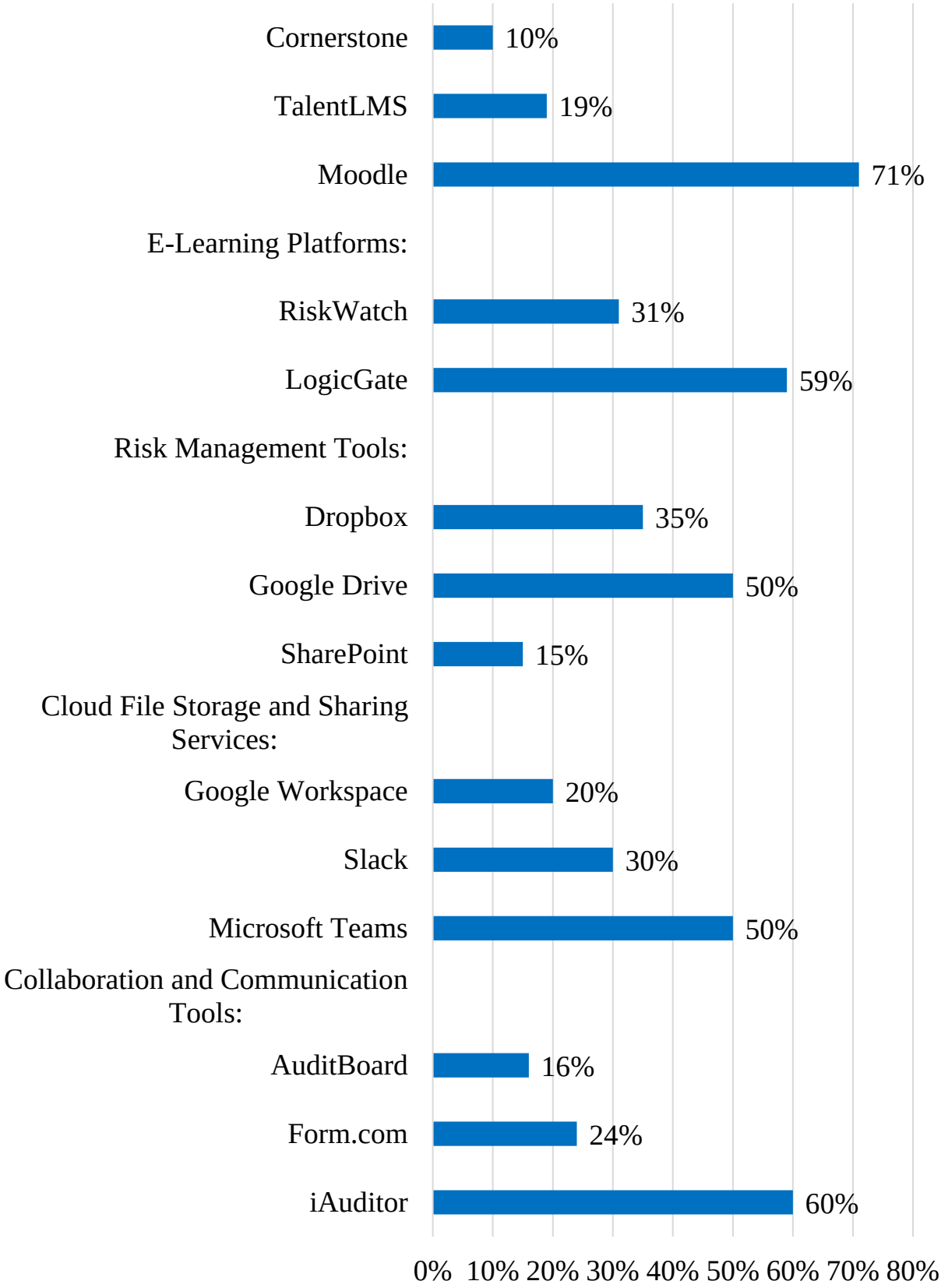

Fig. 2.19. Analysis of tools for improving the effectiveness of internal audits

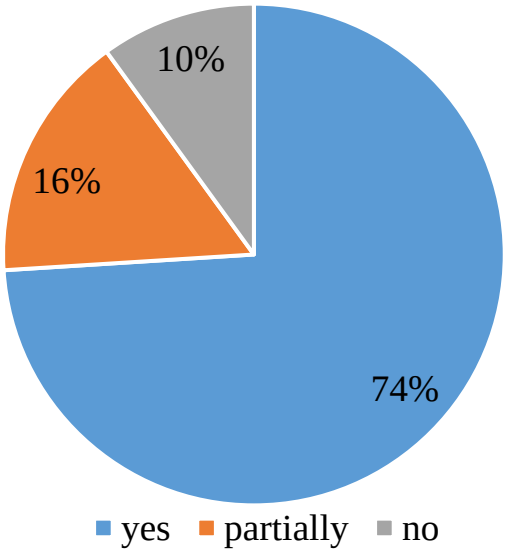

Fig. 2.20. Analysis of the level of feedback between management and auditors

It was found that respondents suggest several key actions to improve the effectiveness of internal audits (Figure 2.21).

The proposal to conduct regular training for auditors and employees received the most support, which was mentioned by 18% of respondents.

The development and use of clear checklists is also important, as noted by 14% of respondents. 12% support the idea of implementing modern digital tools to optimize the audit process.

11% indicated the need to ensure transparency of the audit process, which will increase trust and efficiency.

Other important suggestions include improving communication between departments (10%), increasing motivation of auditors and employees (9%), and optimizing audit schedules (8%).

7% of respondents noted the importance of focusing on root cause analysis of deficiencies, which will help eliminate problems at an early stage.

Creating a knowledge base for internal audits was suggested by 6% of respondents, and 5% consider it important to implement a corrective action monitoring system (Fig. 2.21).

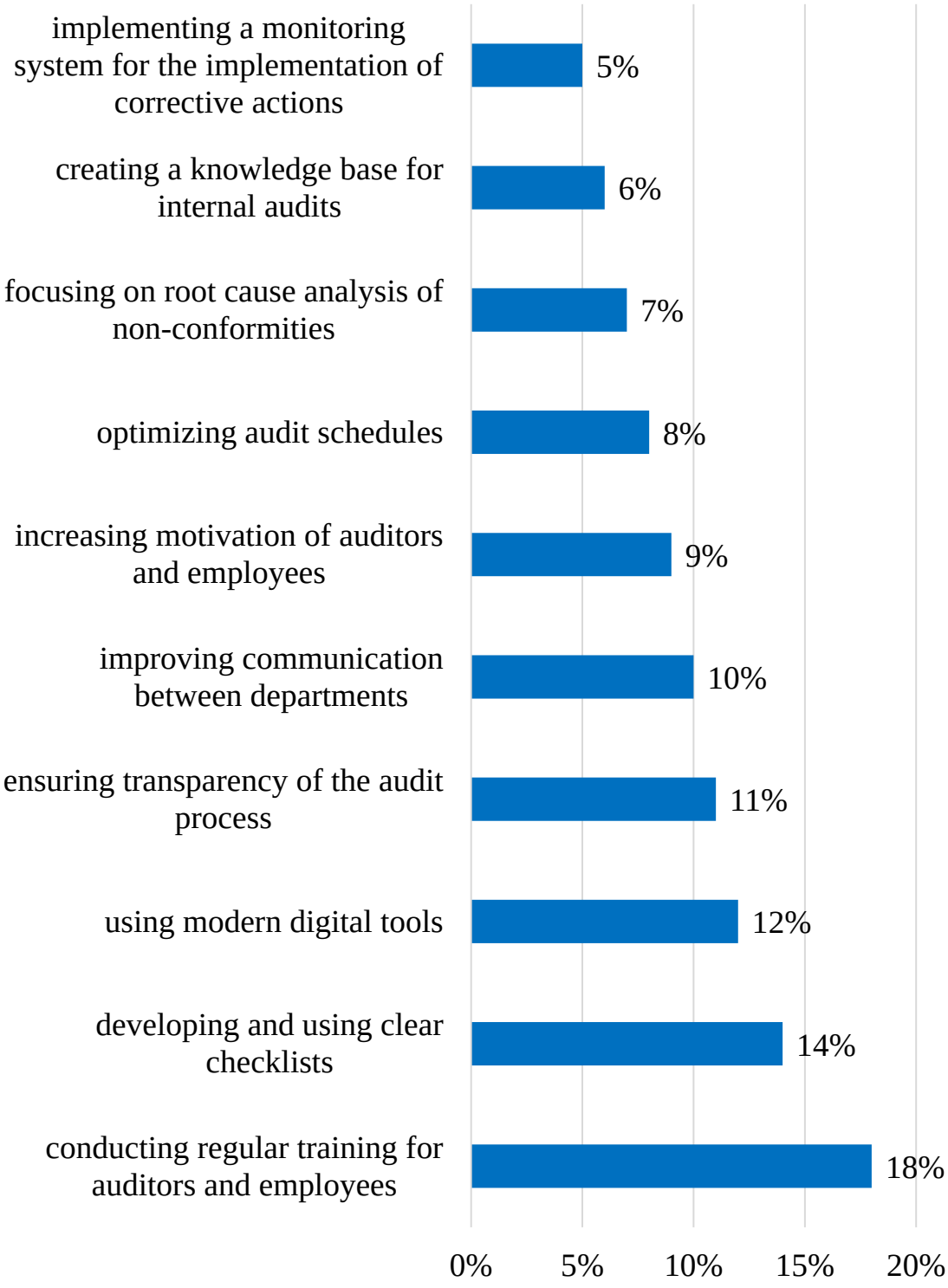

Fig. 2.21. Analysis of proposals for improving the effectiveness of internal audits

Conclusions to chapter 2

1. To assess the internal audit procedures of the quality management system at a pharmaceutical company, 57 employees of pharmaceutical companies

were interviewed. The largest share of respondents was made up of department heads (30%) and quality managers (28%). Other categories included quality engineers (14%), directors (8%), administrative staff (7%), managers and IT specialists (5% each), and pharmacovigilance specialists (3%).

2. 47% of respondents have over 16 years of experience in the pharmaceutical industry, 31% have worked for 5 to 15 years, and 18% have over 25 years of experience. The least represented are specialists with less than 5 years of experience (4%).

3. Among the respondents, 78% participated in internal audits, of which 59% are well acquainted with the audit procedure, 22% - partially, and 19% - poorly. Only 45% of respondents have received training in internal auditing. Clearly defined roles and responsibilities of auditors were noted by 38% of respondents, partially understood - by 40%, and for 22% these roles are not defined.

4. The main challenges of internal audits were identified as identifying deficiencies (24%), employee resistance (17%), insufficient training of auditors (15%), and lack of time and resources (10% each). Other issues include difficulties with documentation (9%), insufficient management support (6%), lack of tools (5%), and communication barriers (4%).

5. 60% of respondents consider the timing of internal audits to be insufficient. At the same time, 92% do not experience problems with documenting results, and 67% are satisfied with the availability of information resources. Regarding the effectiveness of internal audit, 59% consider it very effective, 30% - moderately effective, and 11% do not see any results.

6. 78% of respondents stated that identified non-conformities are always resolved in a timely manner, while 19% noted that this happens sometimes, and 3% rarely . Regarding the qualifications of auditors, 84% of respondents are confident in their sufficient competence, 15% are partially confident, and 1% are doubtful.

7. The impact of internal audits on compliance with GMP/GDP requirements is assessed as significant by 72% of respondents, moderate by 20%,

and absent by 8%. According to 46% of respondents, the performance of enterprises after audits improves, partially by 29%, and does not improve by 25%.

8. The most important areas for improvement are audit planning (19%), auditor training (15%) and improving methods (13%). Only 20% of respondents consider the current knowledge of employees to be sufficient, while 80% emphasize the need for additional training.

9. MasterControl software (70%), Tableau (50%), Power Automate (40%) and other digital platforms were analyzed. Most respondents (74%) are satisfied with feedback to management, while 16% consider it partial and 10% consider it insufficient.

10. Regular training (18%), clear checklists (14%), digital tools (12%) and increased transparency (11%) are suggested to improve the effectiveness of audits.

CHAPTER III

DEVELOPMENT OF REGULATIONS FOR CONDUCTING INTERNAL AUDITS OF THE QUALITY MANAGEMENT SYSTEM

3.1. Research of internal audit procedure

The algorithm for conducting an internal audit at a pharmaceutical company consists of several stages. At the preparatory stage, audit objectives are determined, such as checking the compliance of activities with GMP/GDP requirements, internal standards and policies, identifying shortcomings and assessing the effectiveness of the quality management system. Next, audit planning is carried out, which includes drawing up a schedule, determining audit objects, appointing a team of auditors considering their competencies and developing checklists and assessment criteria. Training auditors involves providing them with the necessary knowledge about the audit objects, as well as instructions and materials [4].

During the audit, an introductory meeting is held, where the audit team introduces itself, announces the purpose and plan of the audit, and agrees on the details with the heads of departments. This is followed by a review of documents to verify their compliance with the requirements of the standards, and an analysis of the records of the enterprise's activities. At this stage, observations of work processes and interviews with employees are also carried out to assess compliance with procedures. Identification of deficiencies is carried out by comparing the actual state with the established criteria, and all deviations are recorded [8].

Documenting the results involves analyzing and summarizing the data obtained, prioritizing deficiencies, and determining their root causes. Based on this, a report is compiled that documents the facts, inconsistencies, observations, and recommendations for eliminating deficiencies. The final meeting includes presenting the audit results to management and employees, agreeing on corrective actions to eliminate deficiencies, and discussing possible issues [1].

The next step is the implementation of corrective actions, which involve the development of a plan to eliminate deficiencies with the identification of responsible

persons and deadlines. The implementation of these actions is monitored, and their effectiveness is checked at the final stage. The process is completed by preparing a final report on the measures taken and their impact on improving the company's performance. Based on the results obtained, an analysis is carried out and recommendations are developed to improve the quality management system and increase the effectiveness of subsequent audits [13].

3.2. Development of a scheme and criteria for assessing the effectiveness of the audit

Evaluating the effectiveness of internal audit is an important stage in improving the quality management system at the enterprise. The main criteria for analyzing audit effectiveness can be divided into quantitative and qualitative indicators [19].

1. Compliance with established standards and regulatory requirements. The effectiveness of the audit depends on the extent to which it ensures compliance with GMP/GDP requirements, internal regulations and company policies. The assessment includes an analysis of the identified deficiencies and their impact on the company's operations [22].

2. Number and nature of identified deficiencies. The number of deficiencies recorded is determined in comparison with previous audits. The types of deficiencies (critical, serious, minor) and their distribution by work area are analyzed [23].

3. Timeliness of elimination of identified deficiencies. The time spent on the development and implementation of corrective and preventive actions is assessed. An important indicator is compliance with the deadlines for the implementation of relevant measures [14].

4. Assessment of the accuracy, completeness, and structure of the audit report. Includes an analysis of recommendations, which should be clear and focused on eliminating risks [7].

A scheme for conducting an internal audit for a pharmaceutical company has been developed (Fig. 3.1).

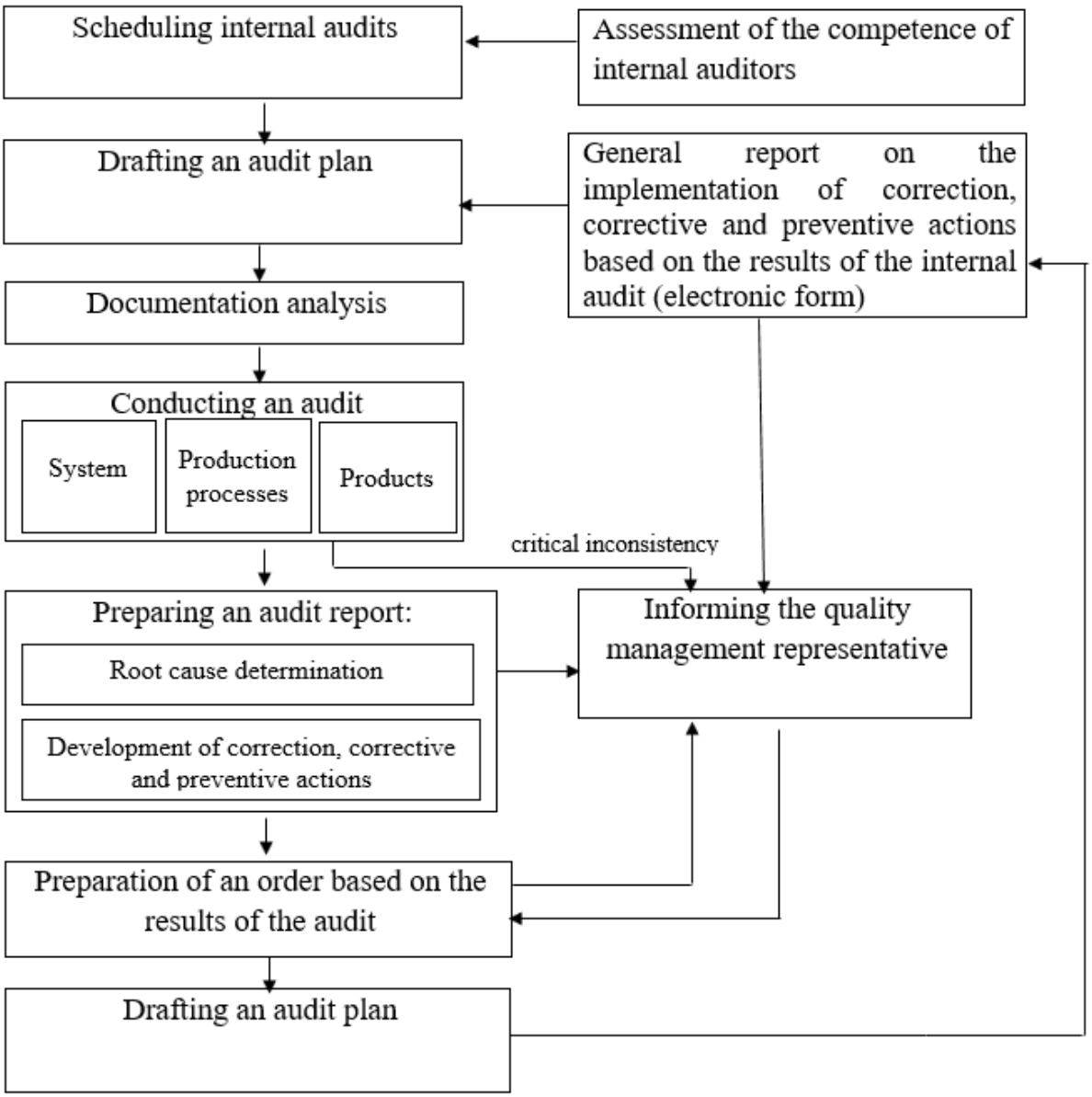

Fig. 3.1. Internal audit scheme

5. Auditors' qualification level. Effectiveness depends on the competence of auditors. The criterion includes an assessment of their professional level, work experience, knowledge of GMP/GDP standards and auditing skills.

6. Employee satisfaction with the audit process. The level of trust and openness during the audit, employee feedback on its objectivity, transparency, and communication with the audit team are taken into account [12].

7. The impact of the audit on improving the company's activities. It assesses the extent to which the audit results contributed to improving product quality, reducing the number of deviations in processes, and improving compliance with standards [3].

8. Use of modern tools and technologies. Availability and use of digital platforms, software and automated tools for conducting audits and processing results.

9. Economic efficiency. The ratio of audit costs to the results obtained (reduction in the number of complaints, etc.) is analyzed.

10. Periodicity and compliance with the schedule. It is assessed whether audits are carried out on time and at the specified frequency according to the plan.

The development and implementation of these criteria contributes to the systematic analysis of audit results, identification of weaknesses and development of a strategy for their elimination, which allows to increase the overall effectiveness of internal audits [6].

We conducted a SWOT analysis of the internal audit of the quality management system at a pharmaceutical company (Table 3.1).

Table 3.1.

SWOT analysis of internal audit of the quality management system at a pharmaceutical company

Strengths	**Weaknesses**
▪ auditor qualifications ▪ regularity of audits ▪ use of modern tools ▪ strong management support ▪ ttimeliness of problem solving	▪ lack of time to conduct audits ▪ insufficient training of employees ▪ partial lack of clarity of roles and responsibilities
Opportunities	**Threats**
▪ improving curricula ▪ process automation ▪ optimization of audit schedules ▪ expansion of information resources	▪ employee resistance ▪ lack of management support ▪ risk of ineffective actions ▪ rapid changes in pharmaceutical legislation

To improve the effectiveness of internal audit, it is necessary to focus on improving training, automating processes, improving planning, and reducing employee resistance [20]. This will minimize weaknesses and use opportunities to overcome threats.

Conclusions to chapter III

1. A procedure for conducting an internal audit has been developed.
2. A scheme and criteria for assessing the effectiveness of the audit have been developed.

GENERAL CONCLUSIONS

1. The essence and foundations of the concept of internal audit were analyzed. The principles of internal audit were revealed.

2. To assess the internal audit procedures of the quality management system at a pharmaceutical company, a survey was conducted among 57 employees of pharmaceutical companies.

3. The distribution of respondents by their positions shows that the largest share is occupied by department heads (30%) and quality managers (28%). Quality engineers make up 14% of the survey participants. It was found that the majority of respondents (47%) have experience in the pharmaceutical industry from 16 to 25 years. It was found that 78% of respondents participated in internal audits of the quality management system. It was found that 59% of respondents are very familiar with the internal audit procedure at a pharmaceutical company, 22% - partially. It was found that 45% of respondents have undergone training in conducting internal audits.

4. It was found that 38% of respondents noted that the roles and responsibilities of internal audit participants are clearly defined for them; 40% of respondents noted that they are partially understood. It was found that the main difficulties that respondents observe during internal audits include: identifying shortcomings - 24% of responses, employee resistance (17%); insufficient training of auditors (15%). It was found that the majority of respondents consider the terms of internal audits to be insufficient to complete all necessary tasks.

5. It was found that 92% of respondents do not experience difficulties in the process of documenting the results of internal audits. 67% of respondents are completely satisfied with the availability of information resources, such as templates, checklists and instructions, for conducting internal audits.

6. The survey results showed that 59% of respondents rate internal audit as a very effective tool for identifying shortcomings in the activities of a

pharmaceutical company. The study showed that in 78% of cases, non-conformities identified during internal audits are always resolved in a timely manner.

7. The survey results showed that 84% of respondents are confident that auditors are sufficiently qualified to perform their tasks. The results of the study indicate that 72% of respondents assess the impact of internal audits on compliance with GMP/GDP requirements as significant. The study showed that 46% of respondents are confident that the work of pharmaceutical companies improves after internal audits.

8. Next, we analyzed the aspects of internal audit that need the most improvement: 19% of respondents pointed to the planning stage; training of auditors (15%) and improving audit tools and methods (13%).

REFERENCES

1. Бичкова М. В. Пошук актуальних шляхів вдосконалення проведення внутрішнього аудиту. *Актуальні проблеми якості, менеджменту і економіки у фармації і охороні здоров'я* : матеріали II міжнарод. наук.-практ. internet-конф. з міжнар. участю, м. Харків, 19 січ. 2024 р. Харків : НФаУ, 2024. С. 166-168.

2. Гладкова О. В. Цифрові технології в системі менеджменту якості компанії. *Управління якістю в фармації* : матеріали XV наук.-практ. конф. з міжнар. участю, м. Харків, 25 трав. 2021 р. Харків : НФаУ, 2021. С. 41-42.

3. Доровський О. В., Козирєва О. В. Побудова системи аудиту персоналу на фармацевтичному підприємстві. *Актуальні проблеми розвитку галузевої економіки та логістики* : матеріали IV міжнарод. наук.-практ. конф. 2-3 квіт. 2015 р. Харків: Вид-во НФаУ, 2015. С. 75-76.

4. Жуковина О. В. Аудит безопасности. *Управління якістю в фармації* : матеріали XI наук.-практ. конф. з міжнар. участю, м. Харків, 19 трав. 2017 р. Харків, 2017. С. 66.

5. Зборовська Т. В., Губін Ю. І. Статистичний огляд впровадження вимог інформаційної безпеки як складової менеджменту якості підприємств. *Професійний менеджмент в сучасних умовах розвитку ринку* : матеріали доп. VII наук.-практ. конф. з міжнар. участю, м. Харків, 1 листоп. 2018 р. Харків, 2018. С. 269-271.

6. Зоідзе Д. Р., Одинець О. В. Застосування системи НАССР в управлінні ризиками для якості на фармацевтичних підприємствах. *Менеджмент та маркетинг у складі сучасної економіки, науки, освіти, практики* : зб. наук. ст. IV Міжнар. наук.-практ. Internet-конф., м. Харків, 24-25 берез. 2016 р. Харків : НФаУ, 2016. С. 243–245.

7. Зупанець К. О., Ратушна К. Л., Доброва В. Є. Оцінка ризиків щодо якості даних за методом FMEA аналізу. *Клінічна фармація*. 2015. № 3. С. 4-10.

8. Карамаврова Т. В., Лебединець В. О., Пляка Л. В. Визначення підходів до оцінки особистісних якостей аудиторів фармацевтичних систем якості. *Соціальна фармація в охороні здоров'я*. 2018. Т. 4, № 3. С. 33-41.

9. Коваленко С. М. Основні цілі проведення аудитів систем управління якістю. *Управління якістю в фармації* : матеріали XVI наук.-практ. internet-конф. з міжнар. участю, м. Харків, 20 трав. 2022 р. Харків : НФаУ, 2022. С. 54.

10. Козирєва О. В. Дослідження сутності аудиту персоналу як механізму регулювання трудових відносин в сучасних умовах. *Актуальні проблеми розвитку галузевої економіки та логістики* : матеріали IV міжнарод. наук.-практ. конф., 2-3 квіт. 2015 р. Харків : Вид-во НФаУ, 2015. С. 89-91.

11. Козирєва О. В., Козирєва А. К. Визначення стадії проблемності соціально-економічного розвитку регіонів країни. *Фінанси, аудит та соціальна економіка: аналіз тенденцій та науково-економічний розвиток* : матеріали Міжнар. наук.-практ. конф., м. Львів, 28-29 лип. 2017 р. Львів : ЛЕФ, 2017. С. 72-75.

12. Козирєва О. В., Худошин В. А. Дослідження теоретичних засад аудиту персоналу. *Професійний менеджмент в сучасних умовах розвитку ринку* : матеріали конф. VI наук.-практ. конф. з міжнар. участю, м. Харків, 1 листоп. 2017 р. Харків, 2017. С. 402-405.

13. Лебединець В. О., Зарічкова М. В., Петровський М. О., Должнікова О. М. Організація оглядів функціонування системи управління якістю фармацевтичного підприємства. *Актуальні проблеми якості, менеджменту і економіки у фармації і охороні здоров'я* : матеріали І міжнар. наук.-практ. internet-конф. з міжнар. участю, м. Харків, 19 трав. 2023 р. Харків : НФаУ, 2023. С. 47-56.

14. Лебединець В. О., Карамаврова Т. В. Аналіз функціонування процесу внутрішнього аудиту на вітчизняних фармацевтичних підприємствах. *Соціальна фармація в охороні здоров'я*. 2017. Т. 3, № 3. С. 58-65.

15. Лебединець В. О., Карамаврова Т. В. Визначення підходів до застосування опитувальних листів (чек-листів) при проведенні аудитів фармацевтичних систем якості. *Актуальні проблеми розвитку галузевої економіки та логістики* : матеріали V наук.-практ. конф. з міжнар. участю, м. Харків, 20-21 квіт. 2017 р. Х., 2017. С. 366-370.

16. Лебединець В. О., Прохоренко О. В., Зарічкова М. В. Організація оглядів функціонування системи управління якістю фармацевтичного підприємства. *Соціальна фармація в охороні здоров'я*. 2024. Т. 10, № 2. С. 81-91.

17. Мала Ж. В., Посилкіна О. В., Нессонова М. М. Аналіз факторів впливу на динаміку конкурентоспроможності аптечних мереж у залежності від їх типу. *Управління, економіка та забезпечення якості в фармації*. 2017. № 1. С. 57-65.

18. Могилко В. О. Контроль і звітність міжнародних корпорацій. *Соціальна фармація: стан, проблеми та перспективи* : матеріали наук. симпозіуму у рамках VIII Нац. з'їзду фармацевтів України, м. Харків, 15-16 верес. 2016 р. Харків, 2016. С. 199-200.

19. Назаркіна В. Н., Сапсай Р. В. Впровадження принципів аудиту і контролінгу в аптечну практику. *Соціальна фармація: стан, проблеми та перспективи* : матеріали наук. симпозіуму у рамках VIII Нац. з'їзду фармацевтів України, м. Харків, 15-16 верес. 2016 р. Харків, 2016. С. 147-149.

20. Недбайло Ю. В., Літвінова О. В. Розробка пропозицій щодо удосконалення системи управління якістю фармацевтичного підприємства АТ «Лубнифарм». *Актуальні проблеми якості, менеджменту і економіки у фармації і охороні здоров'я* : матеріали II міжнарод. наук.-практ. internet-конф. з міжнар. участю, м. Харків, 19 січ. 2024 р. Харків : НФаУ, 2024. С. 210-211.

21. Посилкіна О. В., Мусієнко Н. М. До питань впровадження менеджменту якості на фармацевтичних підприємствах. *Фармакоекономіка в Україні : стан та перспективи розвитку* : матеріали X наук.-практ. конф., м. Харків, 21 трав. 2018 р. Харків : Вид-во НФаУ, 2018. С. 103-105.

22. Разумна С. Г., Лебединець В. О., Литка В. В. Ризик-орієнтований підхід до проведення зовнішніх аудитів підприємством ТОВ "ВАЛАРТІН ФАРМА". *Управління якістю в фармації* : матеріали XI наук.-практ. конф. з міжнар. участю, м. Харків, 19 трав. 2017 р. Харків, 2017. С. 141-142.

23. Сагайдак-Нікітюк Р. В., Голубцова К. К., Вельма В. І. Екологічний аудит як скадова екологічного менеджменту фармацевтичого підприємства. *Управління якістю в фармації* : матеріали XI наук.-практ. конф. з міжнар. участю, м. Харків, 19 трав. 2017 р. Харків, 2017. С. 154-155.

24. Світлична К. С., Літвінов Р. О. Актуальність впровадження системи менеджменту якості у центри клінічних досліджень. *Професійний менеджмент в сучасних умовах розвитку ринку* : матеріали X наук.-практ. конф. з міжнар. участю, м. Харків, 1 листоп. 2021 р. Харків : Вид-во Іванченка І. С., 2021. С. 420-422.

25. Чегринець А. А. Маркетингові дослідження якості обслуговування в аптечних закладах. *Менеджмент та маркетинг у складі сучасної економіки, науки, освіти, практики* : матеріали IX міжнар. наук.-практ. дистанц. конф., м. Харків, 18 берез. 2021 р. Харків, 2021. С. 355-356.

26. Бабенко А. В., Крутських Т. В., Зборовська Т. В. Удосконалення процесу комунікацій в діяльності фармацевтичної компанії. Актуальні проблеми якості, менеджменту і економіки у фармації і охороні здоров’я : матеріали III міжнар. наук.-практ. internet-конф. з міжнар. участю, м. Харків, 17 січ. 2025 р. Харків : НФаУ, 2025. С. 136-137.

27. Bondarieva I. V., Saadi Mohammed Saad. Study of directions of marketing audit in pharmacies. *Менеджмент та маркетинг у складі сучасної економіки, науки, освіти, практики* : зб. наук. ст. IV Міжнар. наук.-практ. Internet-конф., м. Харків, 24-25 берез. 2016 р. Харків : НФаУ, 2016. С. 86–88.

28. Karamavrova T. V., Lebedynets V. O. Classification of questions used to obtaining internal audit evidence for pharmaceutical quality. *Topical issues of new medicines development* : матеріали XXVII Міжнар. наук.-практ. конф. молодих

учених та студентів, м. Харків, 8-10 квіт. 2020 р. Харків : НФаУ, 2020. С. 353-354.

29. Kopchyshyn H. K., Lebedynets V. O. Optimization of the internal audit procedures at a pharmaceutical enterprises. *Topical issues of new medicines development* : materials of the XXVII International Scientific-Practical Conference of Young Scientists and Students, Kharkiv, April 8-10, 2020 Kharkiv : National University of Physics and Technology, 2020. P. 361-362.

30. Zdoryk O. A. Organization of the quality assurance system of compounding pharmacies in Ukraine: results of the survey. *Вісник фармації*. 2014. № 4. С. 64-68.

APPENDICES

APPENDIX A

Questionnaire
for assessing internal audit procedures at a pharmaceutical company

1. What is your position in the company?
- director (general, technical, financial, etc.)
- department head (e.g. quality, logistics)
- quality manager
- purchasing /sales manager
- group/team leader
- quality engineer
- pharmacovigilance specialist
- production technologist
- production line operator
- packer/labeler
- warehouse specialist
- administrative staff (HR, accounting)
- support staff (e.g. IT)

2. How many years have you worked in the pharmaceutical industry?
- ☐ less than 5 years
- ☐ 5–15 years
- ☐ 16–25 years old
- ☐ over 25 years old

3. Have you participated in internal audits of the quality management system?
- ☐ yes
- ☐ no

4. How well are you familiar with the internal audit procedure at your company?
- ☐ very good
- ☐ partially
- ☐ bad

5. Have you received formal training in conducting internal audits?
- ☐ yes
- ☐ no

6. How clearly are the roles and responsibilities of internal audit participants defined?
- ☐ clearly defined
- ☐ partially understood
- ☐ not specified

7. **What are the main difficulties you observe when conducting an internal audit?**
- lack of time
- insufficient training of auditors
- lack of proper tools
- employee resistance
- communication problems
- difficulties in identifying deficiencies
- lack of resources
- insufficient management support
- difficulties with documentation

8. Do you believe that the timing of internal audits is sufficient to complete all necessary tasks?
- ☐ yes
- ☐ no

9. Are there problems with documenting the results of internal audits?
☐ yes
☐ no
10. Are there enough information resources (templates, checklists, instructions) to conduct audits?
☐ yes
☐ partially
☐ no
11. To what extent does internal audit contribute to identifying shortcomings in the work of an enterprise?
☐ very effective
☐ moderately effective
☐ does not contribute
12. How often are identified non-conformities resolved in a timely manner?
☐ always
☐ sometimes
☐ rarely
13. Do you believe that the auditors are sufficiently qualified to perform their tasks?
☐ yes
☐ partially
☐ no
14. How do you assess the impact of internal audit on compliance with GMP/GDP requirements?
☐ significant impact
☐ moderate impact
☐ no impact
15. Does the company's performance improve after internal audits?
☐ yes
☐ partially
☐ no
16. What aspects of internal audit need the most improvement?
 audit planning
 training of auditors
 tools and methods
 documenting results
 feedback
 root cause analysis
 implementation of corrective actions
 management support
 performance assessment
16. Is additional training required for employees involved in the audit?
☐ yes
☐ no
17.**What tools (software, databases) can improve the effectiveness of internal audits?**
Quality Management Software (QMS):
 MasterControl
 TrackWise
 Veeva QualityDocs
Project management tools:
 Trello
 Asana
 Microsoft Project

Tools for automating documentation and reporting:
- Microsoft Power Automate
- DocuSign
- Adobe Acrobat Pro

Specialized databases for the pharmaceutical industry:
- PharmaSuite MES
- ERP systems (SAP, Oracle NetSuite)

Systems for data collection and analysis:
- Tableau
- Power BI
- Qlik Sense

Platforms for creating checklists and conducting audits:
- iAuditor
- Form.com
- Audit Board

Collaboration and communication tools:
- Microsoft Teams
- Slack
- Google Workspace

Cloud services for storing and sharing files:
- SharePoint
- Google Drive
- Dropbox

Risk management tools:
- LogicGate
- RiskWatch

E-learning platforms:
- Moodle
- TalentLMS
- Cornerstone

19. Is there sufficient feedback between management and auditors?

☐ yes
☐ partially
☐ no

20. What specific actions would you suggest to improve the effectiveness of internal audits?

- conducting regular training for auditors and employees
- development and use of clear checklists
- use of modern digital tools
- ensuring transparency of the audit process
- improving communication between departments
- increasing the motivation of auditors and employees
- optimization of audit schedules
- focus on root cause analysis of non-conformities
- creating a knowledge base for internal audits
- implementation of a monitoring system for the implementation of corrective actions

Thank you for your answers!

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

Oumaima EL HOUASLI

1. Topic of qualification work: «Study of approaches to the organization of internal audit in pharmaceutical enterprises», 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 reveal the essence and foundations of the concept of internal audit; to study principles of internal audit; to determine of major problems and weaknesses in internal audit systems; to assess of the impact of internal audit on ensuring compliance with standards to research of internal audit procedure; to develop of a scheme and criteria for assessing the effectiveness of the audit.

5. List of graphic material (with exact indication of the required drawings):
Figures – 17, table – 1.

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 the essence and foundations of the concept of internal audit	September 2024	**done**
3	Assessment of the impact of internal audit on ensuring compliance with standards to research of internal audit procedure	November 2024	**done**
4	Identification of major problems and weaknesses in internal audit systems	February 2025	**done**
5.	Development of a scheme and criteria for assessing the effectiveness of the audit	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 _____ Oumaima EL HOUASLI

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				
Ель Хуаслі Умаіма	Дослідження підходів до організації внутрішнього аудиту на фармацевтичних підприємствах	Study of approaches to the organization of internal audit in pharmaceutical enterprises	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. № 331090725

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти Ель Хуаслі Умаіма, групи Фм20(4.10) англ-01, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» навчання на тему: «Дослідження підходів до організації внутрішнього аудиту на фармацевтичних підприємствах / Study of approaches to the organization of internal audit in pharmaceutical enterprises», 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

Oumaima EL HOUASLI

on the topic: «Study of approaches to the organization of internal audit in pharmaceutical enterprises»

Relevance of the topic. One of the key tools to support the effective functioning of the quality management system is internal audit. This process allows you to assess the compliance of all aspects of the enterprise's activities with established standards and regulatory requirements. Internal audit helps to identify risks, identify shortcomings in processes and promptly implement corrective measures, which is critically important for ensuring product quality and its safety for end consumers.

Practical value of conclusions, recommendations and their validity. The results obtained can be used by pharmaceutical companies to improve the quality management system, as well as serve as the basis for developing methodological recommendations in the field of organizing internal audit.

Assessment of work. Oumaima EL HOUASLI 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 Oumaima EL HOUASLI on the topic: "Study of approaches to the organization of internal audit in pharmaceutical enterprises" 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

Oumaima EL HOUASLI

on the topic: «Study of approaches to the organization of internal audit in pharmaceutical enterprises»

Relevance of the topic. Today, many pharmaceutical companies are faced with problems of organizing internal audits. In particular, there is often a lack of clearly developed regulations, proper training of personnel and a systematic approach to analyzing audit results. Such shortcomings can lead to non-compliance of products with the requirements of standards, financial losses and a decrease in the reputation of the pharmaceutical company in the market.

Theoretical level of work. The author has investigated the essence and foundations of the concept of internal audit; to study principles of internal audit.

Author's suggestions on the research topic. The author has developed a scheme and criteria for assessing the effectiveness of the audit.

Practical value of conclusions, recommendations and their validity. The results of the study have practical significance and can be used to improve the organization of internal audits. **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. Oumaima EL HOUASLI qualification work "Study of approaches to the organization of internal audit in pharmaceutical enterprises" 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-03 Умаіма ЕЛЬ ХУАСЛІ до захисту кваліфікаційної роботи в Екзаменаційній комісії НФаУ. Кваліфікаційна робота на тему «Дослідження підходів до організації внутрішнього аудиту на фармацевтичних підприємствах».

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 Умаіма ЕЛЬ ХУАСЛІ до захисту кваліфікаційної роботи на тему «Дослідження підходів до організації внутрішнього аудиту на фармацевтичних підприємствах» 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 Умаіма ЕЛЬ ХУАСЛІ до захисту кваліфікаційної роботи
за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньо-професійною програмою Фармація
на тему: «Дослідження підходів до організації внутрішнього аудиту на фармацевтичних підприємствах».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Микола ГОЛІК /

Висновок керівника кваліфікаційної роботи

Здобувач вищої освіти Умаіма ЕЛЬ ХУАСЛІ виконав на кафедрі менеджменту, маркетингу та забезпечення якості у фармації НФаУ кваліфікаційну роботу, яка присвячена дослідженню підходів до організації внутрішнього аудиту на фармацевтичних підприємствах.

Перший розділ присвячено сутності і основним концепціям внутрішнього аудиту, а також принципам його проведення. У другому розділі проаналізовано основні проблеми та слабкі сторони у системах внутрішнього аудиту на фармацевтичних підприємствах, а також оцінено вплив внутрішнього аудиту на забезпечення відповідності вимогам стандартів. Третій розділ містить процедуру проведення внутрішнього аудиту, розроблено схему та критерії для оцінки ефективності аудиту системи управління якістю.

У цілому подана до захисту кваліфікаційна робота Умаіма ЕЛЬ ХУАСЛІ на тему «Дослідження підходів до організації внутрішнього аудиту на фармацевтичних підприємствах» 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 Умаіма ЕЛЬ ХУАСЛІ 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/