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IMPLEMENTATION OF THE CONTINUOUS IMPROVEMENT CYCLE FOR BUSINESS PROCESSES INTO THE QUALITY MANAGEMENT SYSTEM OF PHARMACEUTICAL INDUSTRY ENTERPRISES

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ABSTRACT

The economic situation in the global pharmaceutical market has undergone profound changes over the past decades, driven by various factors, including the advancement of technology, digitization, emergence of new epidemiological threats, geopolitical conflicts, and more. These factors increase the social significance of pharmaceutical production and stimulate heightened competition, thereby elevating the responsibility of manufacturers for the quality and safety of pharmaceutical products.
In this context, quality issues become vital for pharmaceutical enterprises, shaping the future of pharmacy in the 21st century.
The article explores the issue of quality management in pharmaceutical complex enterprises and substantiates the necessity of implementing the PDCA (Plan-Do-Check-Act) methodology in the operations of pharmaceutical industry enterprises during the regulation and documentation of quality management processes. The

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advantages that this methodology can provide in achieving the goals of continuous improvement and enhancing the efficiency of quality management system processes are discussed.
This article explores the integration of the PDCA (Plan-Do-Check-Act) methodology into the quality management system of pharmaceutical enterprises, leveraging insights from the ISO 9001 standard. The article offers recommendations for interpreting the PDCA cycle within the framework of ISO 9001 and proposes practical approaches to implementing the PDCA methodology in shaping pharmaceutical quality management systems.

Keywords: Quality management system, Deming-Shewhart cycle, Pharmaceutical quality system, ISO 9001 standard, Process approach, PDCA, ICH Q10.

IMPLEMENTAÇÃO DO CICLO DE MELHORIA CONTÍNUA DOS PROCESSOS DE NEGÓCIO NO SISTEMA DE GESTÃO DA QUALIDADE DAS EMPRESAS DA INDÚSTRIA FARMACÊUTICA

RESUMO

A situação económica no mercado farmacêutico global sofreu profundas mudanças nas últimas décadas, impulsionadas por vários factores, incluindo o avanço da tecnologia, a digitalização, o surgimento de novas ameaças epidemiológicas, conflitos geopolíticos, e muito mais. Estes factores aumentam a importância social da produção farmacêutica e estimulam o aumento da concorrência, elevando assim a responsabilidade dos fabricantes pela qualidade e segurança dos produtos farmacêuticos.
Neste contexto, as questões de qualidade tornam-se vitais para as empresas farmacêuticas, moldando o futuro da farmácia no século XXI.
O artigo explora a questão da gestão da qualidade nas empresas do complexo farmacêutico e fundamenta a necessidade de implementação da metodologia PDCA (Plan-Do-Check-Act) nas operações das empresas da indústria farmacêutica durante a regulação e documentação dos processos de gestão da qualidade. São discutidas as vantagens que esta metodologia pode proporcionar no alcance dos objetivos de melhoria contínua e aumento da eficiência dos processos do sistema de gestão da qualidade.
Este artigo explora a integração da metodologia PDCA (Plan-Do-Check-Act) no sistema de gestão da qualidade das empresas farmacêuticas, aproveitando os insights da norma ISO 9001. O artigo oferece recomendações para a interpretação do ciclo PDCA no âmbito da ISO 9001 e propõe abordagens práticas para a implementação da metodologia PDCA na formação de sistemas de gestão da qualidade farmacêutica.

Palavras-chave: sistema de gestão da qualidade, ciclo Deming-Shewhart, sistema de qualidade farmacêutica, norma ISO 9001, abordagem de processos, PDCA, ICH Q10.

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1 INTRODUCTION

In today's pharmaceutical landscape, the creation of effectively functioning quality management systems (QMS) has become a pivotal requirement for producing pharmaceuticals successfully and introducing them to domestic and international markets. This spans from institutions engaged in drug research and development to manufacturing, distribution, and retail enterprises. A robust quality management system for pharmaceutical companies must prioritize strict adherence to legislative and regulatory standards while ensuring the competitive edge of the products they manufacture.

While the implementation of QMS in Russian pharmaceutical enterprises began in the late 1990s, a significant portion of the market still operates under management models traditional to post-Soviet businesses. This often leads to underestimating the importance of continuous quality improvement in business processes and outcomes as a cornerstone of a pharmaceutical company's competitiveness. The global practice, which underscores the focus on continuous improvement in all organizational processes, attaining high product quality to meet customer and consumer demands as a core corporate objective, is often overlooked in the domestic pharmaceutical industry.

The establishment of this model should primarily occur through the implementation of a QMS based on the requirements of the universal ISO 9001 standard and industry regulations. This QMS embodies a network of interconnected and interacting elements utilized for directing and monitoring an enterprise's quality-related activities. The processes comprising the quality management system involve managerial interventions spanning information, material-technical, technical, technological, and logistic aspects of production, all of which directly or indirectly impact the compliance of the products with established requirements.

The principle of a process approach, fundamental to the formation of a QMS, calls for establishing conditions for interactions between organizational processes. This is achieved by defining the inputs and outcomes of these processes, developing regulations, execution algorithms, and evaluation methods, thereby enhancing the controllability of the enterprise and improving the overall reliability of the production system. For enterprises operating with a process-oriented organizational structure,

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horizontal connections are strengthened, bureaucratization is reduced, and information processing and operational activities are expedited, leading to improved pharmaceutical product quality.

1.1 Research Objective

The central research question driving this study, and subsequently its objective, revolves around elucidating the specifics of creating a quality management system in pharmaceutical enterprises using the Deming-Shewhart PDCA cycle.

1.2 Primary Research Goal

Given the justified relevance of the raised question, the main objective of this article is to develop general recommendations for forming an effective mechanism for implementing the PDCA concept in pharmaceutical industry enterprises. This encompasses determining levels of PDCA implementation and establishing rational approaches to regulating activities using the PDCA methodology.

2 METHODOLOGY OF RESEARCH

The research methodology employed in this study encompasses the use of historical retrospection, logical analysis, and systematic analysis methods to ascertain the level of problem development in both domestic and international literature. The structural-logical modeling method was utilized to provide a substantive description of conceptual approaches to the formation and development of Quality Management Systems (QMS) based on the implementation of the PDCA concept.

Descriptive and abstract modeling methods, along with the method of synthesis, were employed to illustrate the structure of QMS processes and their decomposition schemes. These methods were instrumental in formulating conclusions, recommendations, and proposals for substantiating scientific approaches to QMS development. The graphical method was employed to visually represent statistical data and schematic depictions of various theoretical and practical findings of the research.

To address specific research tasks, problem-oriented and diagnostic methods were

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employed, enhancing the precision and depth of analysis.

2.1 Internal background

The term "process approach" entails the delineation of a set of business processes within an organization, their identification, determination of interaction conditions, and specification of process management conditions to achieve the desired outcome (Fadeeva, 2022). The advantage of the process approach lies in ensuring continuous monitoring of the behavior (effectiveness, efficiency) of individual processes within the production and organizational system. Additionally, it establishes optimal conditions for their interaction, thereby ensuring alignment of the final product with all prescribed requirements. When employing such an approach within a quality management system, special attention must be paid to defining the requirements for the outcomes of each individual process and measuring the ultimate effectiveness of each business process (Bastas & Liyanage, 2019).

Within the ISO 9001 standard, a comprehensive model of quality management system is outlined, rooted in the process approach. This model showcases the cyclic nature of the interrelated business processes (independent and distinct types of activities within the operation of a production enterprise), as stipulated by this standard (International Standard ISO 9001:2015). Furthermore, the standard highlights that the methodology known as the Deming-Shewhart cycle, "Plan-Do-Check-Act" (PDCA), can be applied to all processes of the quality management system (International Standard ISO 9001:2015; Guidance on the Concept and Use of the Process Approach for Management Systems).

The PDCA cycle in the ISO 9000 series standards is described as a set of sequentially executed phases within each business process, enabling their management. In the ISO 9001 standard, the PDCA cycle phases for the entire quality management system of the organization are outlined as follows:

Plan: Establish objectives and processes necessary to achieve results that meet customer requirements and the organization's policies.

Do: Implement the processes.

Check: Monitor and measure processes and products, considering the organization's policies, objectives, and product requirements, and report results.

Act: Take actions to continually improve process performance.

This PDCA cycle provides a structured approach to ensure continuous improvement and effective management of processes within an organization's quality management

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system.

However, a number of other ISO standards vividly demonstrate the applicability of the PDCA cycle in implementing various specific activities. Examples of such standards include: ISO 10015 (management of training cycle for personnel); ISO 10012 (measurement management system); ISO 10002 (complaint handling system); ISO 10013 (document management system); ISO 19011 (management of audit programs), and so forth.

In terms of historical retrospective, it is noteworthy that the cycle later named the Deming-Shewhart Cycle was initially proposed by American scholar W. Shewhart in 1939. He laid the foundation for the necessity of continual and systematic management of production processes to ensure their consistent improvement.

W. Shewhart demonstrated the necessity of implementing a three-stage quality improvement cycle, which involved the development of specifications for each type of product, including calculated tolerances for each quality attribute, the production of goods under specified conditions, and the selective control of all specified attributes.

Shewhart proposed using the results of the control process for making changes in subsequent cycles, aiming to adjust production processes. This concept involves making alterations to production processes solely based on the results of a thorough analysis of production performance, obtained through feedback.

Subsequently, this approach evolved into one of the fundamental principles of modern quality management, namely the principle of "decision-making based on facts," which forms the basis of the ISO 9000 series standards (Antonova et al., 2016).

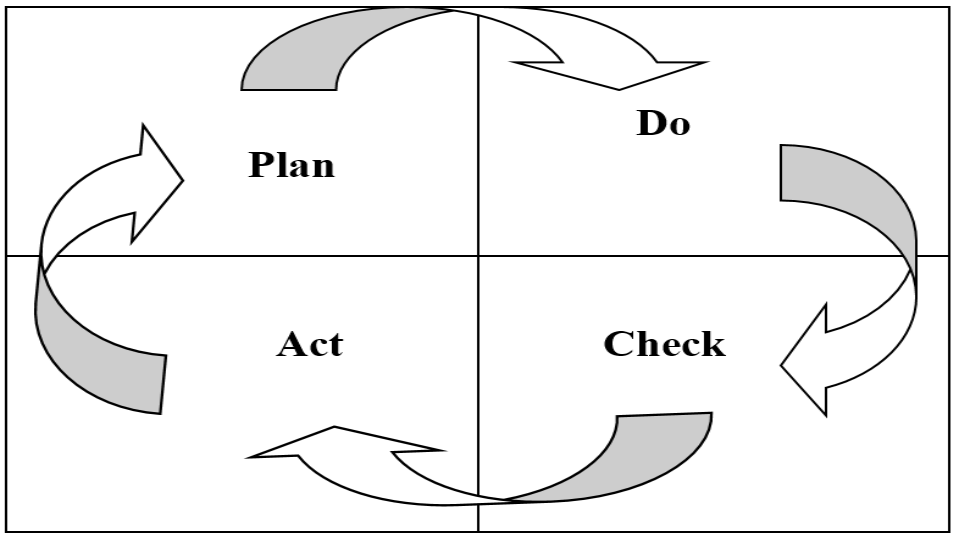

Figure 1. Graphic Interpretation of the Deming-Shewhart Cycle (PDCA).

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In turn, W. Edwards Deming, a disciple of Shewhart, proposed reinterpreting the traditional Shewhart Cycle in the early 1950s as a four-phase sequential process: planning the process, executing the planned actions, comprehensive assessment of the outcomes, and taking actions to improve the process (Deming, 2014) (Figure 1).

The fundamental idea behind the PDCA cycle is the execution of iterative cycles between planning and control actions during the implementation of a specific activity (process) with the aim of discrete improvement along the directions set by the organization. Therefore, the repetition of the PDCA cycle can contribute to achieving the goal of the pharmaceutical complex organization by gathering information regarding the effectiveness of each individual business process and the overall effectiveness of production activities, substantiating the need (when necessary) to modify these goals and the paths to their achievement by influencing business processes that do not meet the required and documented performance indicators.

Moreover, this transformation will occur without the implementation of additional specifically designed processes, but solely through the mechanism of self-improvement established within the organization and embedded within procedures that regulate the process and are appropriately documented.

It is also important to emphasize that the PDCA methodology is applicable to virtually all types of processes where feedback control can be established. In other words, it can be used wherever it is possible to determine the extent to which the completed work conforms to established norms, standards, or regulations (Shcherbakov, 2014). Confirmation of this can be seen in the inclusion of recommendations for the application of the PDCA cycle in the ISO 9001 standard, which can be utilized by organizations of any profile, including pharmaceutical companies (International Standard ISO 9001:2015).

The presence of mechanisms for managing systemic processes based on continuous feedback is assumed within a quality management system structured according to the ISO 9001 model. It is precisely to implement this concept that the ISO 9001 standard suggests applying the PDCA cycle at the level of the entire quality management system and each of its processes (International Standard ISO 9001:2015).

In fact, similar recommendations are provided by the ICH Q10 document (Pharmaceutical Quality System), which establishes requirements for the quality

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management system in the pharmaceutical industry, often referred to as the "pharmaceutical quality system" (Knop, 2019).

However, despite the widespread recognition of the PDCA methodology globally, its practical application on domestic enterprises, including those in the pharmaceutical sector, has encountered significant challenges for quite some time. Often, these challenges can be attributed to a misconception of the very essence of feedback-based management and, consequently, the somewhat formal implementation of the quality management system (Shvets, 2017).

In this context, it is important to note that a quality management system within any organization, particularly within the realm of pharmaceutical enterprises, constitutes a complex mechanism that is significantly regulated by industry norms. These regulatory requirements in the pharmaceutical sector encompass Good Manufacturing Practices (GMP), industry standards, norms, and rules developed within the framework of pharmaceutical company activities. All of these, in one way or another, address aspects of pharmaceutical enterprise operations critical to product quality. However, these standards and requirements overlook methods, tools, and approaches for planning, evaluating, and analyzing the performance of quality management system processes. Moreover, they lack mechanisms for optimizing operations, which could be implemented within organizations to achieve continuous quality improvement.

Simultaneously, an analysis of the situation in the pharmaceutical sector in Russia underscores that the implementation of an effective Quality Management System (QMS), oriented towards continuous process improvement, is a highly pertinent matter for almost every pharmaceutical enterprise today. The driving forces behind this urgency, as mentioned earlier, include heightened competition in both domestic and international markets, coupled with escalating demands for the quality of pharmaceutical products imposed by regulatory bodies (International Standard ISO 9001:2015; Process Approach to Management, 2013; Guidance on the Concept and Use of the Process Approach for Management Systems, 2004).

External background: The literature, often found in foreign publications, delves into the core conceptual significance of the PDCA cycle, elucidating the rationale for employing this methodology in the establishment of a quality management system following the ISO 9001 model (Hoyle D. ISO 9000 Quality Systems Hand-book; Neave, 2000).

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However, the concept of creating a pharmaceutical quality system entails crafting a distinct management framework that guides and monitors the activities of a pharmaceutical enterprise in the realm of quality, tailored to the unique characteristics of this industry (Knop, 2019). Such quality systems for pharmaceutical companies can be developed in accordance with various standards, as long as they are aligned with GMP requirements. Nevertheless, on a global scale, the universally recognized standard is ISO 9001, and interestingly, the ISO 9001 standard itself mandates the creation of a process-based system employing the PDCA methodology.

Nonetheless, the ISO 9001 standard lacks detailed recommendations for the practical application of PDCA. Rather, these documents merely underline the relevance and significance of establishing feedback loops at different organizational levels to ensure the continual improvement of its operations.

The following issues remain problematic:

Determining the appropriate levels at which to implement PDCA (organizational goals, different process levels, operations within processes, or others).

Establishing rational approaches to regulating activities using the PDCA methodology.

Defining practical foundations for documenting PDCA procedures.

Moreover, questions related to the integration of the PDCA cycle into the operations of enterprises come with corresponding recommendations and some normative documents (International Standard ISO 9001:2015; Guidance on the Concept and Use of the Process Approach for Management Systems). However, these sources primarily address approaches to implementing the PDCA cycle at the organizational level, with few examples of its application within specific individual processes. Furthermore, such examples tend to be more theoretical and therefore offer limited practical utility for the operations of pharmaceutical enterprises.

Furthermore, we have not found works that address the issues of using the PDCA methodology within the quality management system of pharmaceutical enterprises, which undoubtedly possess specific characteristics. Thus, it can be concluded that literature dedicated to practical implementation of the PDCA methodology within the framework of forming quality management systems for pharmaceutical companies, developed in accordance with ISO 9001 requirements and the specifics of pharmaceutical production, is extremely limited and does not delve into the applied

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aspects of this problem.

The absence of scientific-practical substantiation for the possibilities of integrating the PDCA methodology into the quality management system of pharmaceutical companies is a major factor contributing to the low effectiveness of organizational structures that oversee quality management at the level of individual business units and production cycles. This is despite the fact that the quality management systems themselves often have a formal, "showcase" character.

In this context, it is advisable to consider issues related to the implementation of a continuous improvement cycle within the quality management system of pharmaceutical industry enterprises.

3 ANALYZING THE RESULTS

One of the first questions that arises when establishing a quality management system in a pharmaceutical company is the identification of processes necessary for its functioning. At this stage, the need arises to determine the types and scope of logically distinct material and informational transformations that the enterprise deems necessary to include in the quality management system as corresponding processes.

During this phase, it is also essential to determine the level of processes at which the PDCA cycle can be regulated. Regarding this matter, we believe that regulating and documenting the PDCA cycle logically makes sense during the initial stages of quality management system development (first-level processes). This involves singling out these processes from the general list of business processes, while disregarding those processes that have minimal impact on product quality (such as advertising activities, public relations, customs logistics, etc.).

Certainly, Figure 2 illustrates the blocks of typical processes within the quality management system, along with an example of decomposed processes, each of which we propose to regulate within the PDCA methodology. In our view, it is important to reflect the cyclic nature of PDCA in the documents describing the systemic processes at each level of pharmaceutical enterprise activity. The policy for implementing the overall PDCA concept at the enterprise level should be outlined in the Quality Manual.

Regulating activities at lower levels (stages, operations, etc.) according to the PDCA cycle in most cases appears to be impractical, as it could lead to a significant increase

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in documentation volume and high-quality assurance costs.

Figure 2. Fragment of the hierarchical architecture of the quality management system of a pharmaceutical enterprise indicating the level of PDCA implementation.

Quality Control System of a Pharmaceutical Company with Depiction of the PDCA Circle Implementation Level

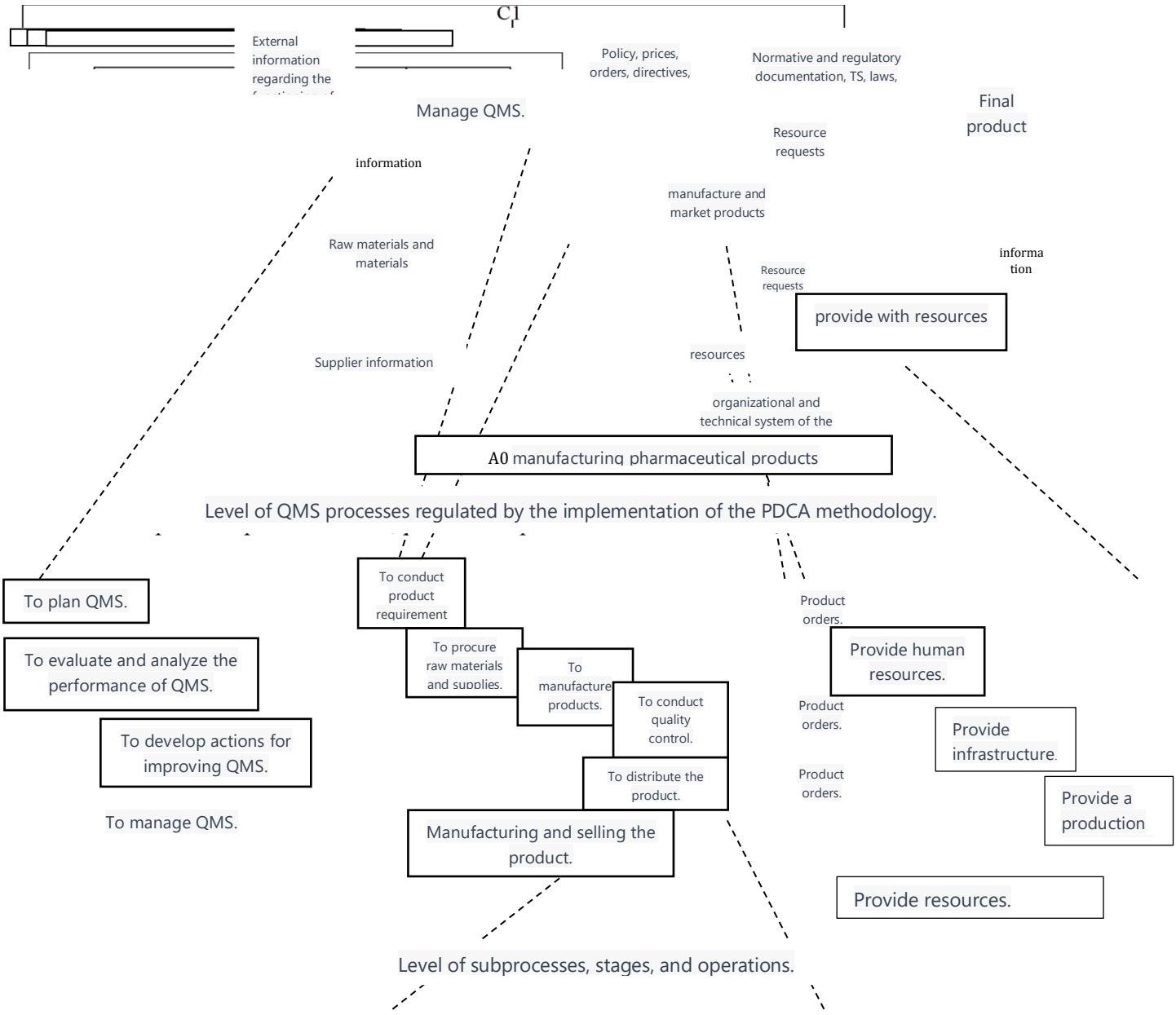

Figure 2. Fragment of the Hierarchical Architecture of the Quality.

In this fragment, it is [illegible] level of the pharmaceutical enterprise, there are numerous external fac[illegible]14) that, in one way or another, impact the process of manufacturing and d[illegible]ucts, as well as

Performing an operation.
Performing an operation.
Performing an operation.
Performing an operation.
Performing an operation.
distributing the products

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their quality.

All other elements in the diagram depict the possibilities of decomposing business processes and establishing "control points" within the quality management system of the pharmaceutical enterprise.

Regarding the reflection of the PDCA cycle in process execution methodologies (PEMs) or other documents that regulate the aforementioned Quality Management System (QMS) processes, it can be affirmed that all of them must contain, at the very least, the following information:

Plan: How the process planning should occur (including considering input data, the current state of the process; promptly defining the goals and tasks of the process; operational distribution of responsibilities and authorities; identifying "checkpoints" for ongoing verification; determining indicators, criteria, and methods for evaluating and monitoring process performance, etc.).

Do: How process execution should take place (including the algorithm for executing all stages and operations with the necessary level of detail and in a format deemed necessary for the given process; developing measures to ensure process stability and adherence to planned parameters; instructions for applying necessary documents, conducting checks, etc.).

Check: How the evaluation and analysis of process performance should be conducted (including describing actions for recording process performance; comparing them against established criteria; identifying trends in process development; identifying arising discrepancies and potential discrepancies; generating management reports, and so forth).

Act: How actions for improvement and enhancement of the process should be initiated and carried out (including describing actions for analyzing causes of discrepancies, developing and implementing corrective actions and/or measures aimed at preventing possible situations negatively impacting the process and product quality).

The methodological approaches structured in this manner for implementing business processes enable the practical utilization of the PDCA methodology and establish mechanisms for continuous improvement across all quality management processes. The crux in this context lies in defining conditions for the systematic collection of information about process characteristics, its "weak points" (areas of

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heightened risk), as well as setting conditions for timely implementation of corrective and preventive actions aimed at addressing identified discrepancies and reducing the risks of potential issues within the quality management system of pharmaceutical companies.

3 CONCLUSION.

Based on the foregoing, it is evident that significant challenges arise when establishing a quality management system within a pharmaceutical enterprise, particularly in terms of regulating systemic processes through the implementation of the PDCA methodology. The application of a process-oriented approach in quality management system implementation entails employing various process management tools (feedback-based management) for specific processes. This includes the establishment of algorithms and mechanisms for planning, implementation, assessment, analysis, and continuous improvement.

Regrettably, domestic enterprises largely neglect such an approach, leading to the overall ineffectiveness of quality management systems in many pharmaceutical companies and facilities.

Conversely, the experience garnered from using the process-oriented approach in quality management has demonstrated its effectiveness, substantiating the potential for continual, purposeful enhancement of business processes that contribute to pharmaceutical product quality.

In this context, the PDCA methodology, when applied at the process level within the quality management system, stands as a pivotal factor in fostering the effective functioning of a pharmaceutical enterprise. Nevertheless, the positive outcomes of implementing the PDCA methodology are contingent on a correct understanding of the feedback-based management concept and the degree of formalization of all quality management processes.

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