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The PDCA cycle implementation at the internal audit process of quality management systems of pharmaceutical companies

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Abstract

At the pharmaceutical industry organizations systematic audits should be conducted. Aimed of the audit is to determining the conformity of the pharmaceutical system with the quality requirements and increasing the effectiveness of the processes.

An analysis of regulatory information sources and our own sociological research was carried out, the results of which can be noted that there are problems associated with the organization of audits. Therefore, the purpose of our study was to develop a set of proposals to increase the effectiveness of the audit process at pharmaceutical companies through the implementation of the PCDA cycle.

The methods used were: systematic-analytical, sociological survey, comparative analysis, structural-logical modeling, etc.

The implementation of the PDCA cycle in the process of internal audit of the quality management system of the pharmaceutical company has been demonstrated.

The approach to practical the PDCA cycle implementation at the organization of internal audits of the quality management system of pharmaceutical companies is proposed. The advantages that can provide this cycle in achieving the goals of continuous improvement of the quality management system effectiveness are considered.

Keywords: Quality management system, pharmaceutical quality system, internal audit, pdca, gmp, gdp, pharmaceutical companies, self-inspection

1. Introduction

Quality Management Systems (QMS) of pharmaceutical industry organizations in the healthcare sector (Pharmaceutical Quality Systems, PQS) involved in the pharmaceutical development, production and marketing of medicinal substances (Active Pharmaceutical Ingredients, API) and finished medical product (MP) have been systematically tested by competent auditors for compliance with all requirements set for such systems and making recommendations for improvement. Such requirements are obligate from the position of national directives of Good Manufacturing Practice (GMP). These requirements do not regulate the methods, means and approaches to planning, evaluation and analysis of the efficiency of PQS processes, as well as mechanisms for optimizing the activities of pharmaceutical companies (PC) ^[1]. Through Internal Audits (IA) (self-inspection), you can assess the degree of compliance with GMP requirements, as well as the degree of achieving goals in the field of quality.

We conducted a sociological survey among 79 Ukrainian PC producing and wholesaling the MP. The respondents were the heads of units, whose responsibilities included the conduct of the IA. 87% of respondents expressed their opinion about the need to develop appropriate methodological support for the organization of audit activity ^[2].

According to the analytical results of regulatory information sources and our own sociological research ^[2, 3], we can state the existence of problems connected with the following aspects of audits:

- training of auditors;
- process-oriented and risk-oriented audits planning;
- application of different audit methods;
- interpretation and classification of situations during the audit;
- introduction of measures to improve the audit process;
- definition of Corrective Actions and Preventive Actions (CAPA);
- Increasing of the auditors' competence.

The position of ISO 9000: 2015 ^[4] does not contradict the GMP requirements of the EU. Built according the model GxP/ISO 9001 QMS of the PC provides availability for mechanisms of managing system processes on the basis of continuously active feedback. To implement this concept, the ISO 9000 standard proposes to apply the PDCA (Plan-Do-Check-Act) cycle at the level of the whole system and each of its processes, including IA ^[5, 6].

In the literature there are publications, the authors of which cover the concept of the PDCA cycle or explain the application of this cycle in the formation of QMS based on the model of ISO 9000, taking into account the specifics of the industry ^[7-10]. They contain capsulized relevant recommendations and some normative and recommended documents ^[4, 6, 11].

Taking into account the urgency of the problem, its theoretical and practical significance, it should be concluded that the problems with the effectiveness of IA in Ukrainian PC exist and need to be solved by scientifically grounded reformation of the organizational principles for the implementation of its activity. Based on this, we carry out the investigations to improve the IA process within the PC, in particular - through the implementation of the PDCA cycle.

2. Material and Methods

The basis for research became the sources of scientific literature of foreign and Ukrainian branch scientists, as well as the results of their own previous studies on the analysis of the IA process implementation in the Ukrainian PC. We used methods of empirical research in our work: system-analytical, sociological survey, comparative analysis, structural-logical modeling, etc.

3. Result and Discussion

Despite the widespread acknowledgment of the PDCA cycle in the world for a long time, its application within the Ukrainian enterprises in general and in pharmaceutical companies in particular, is still causing significant methodological problems. On the example of IA processes, these problems are mostly explained as ^[2, 3]:

- a misunderstanding of the fundamental nature of audit activity and a sufficiently formal conduct of the QMS IA within the PC;
- reluctance to work under the "new rules", which implies a constant evaluation of the effectiveness of their activities (Check);
- constant need to develop;
- lack of documented algorithms built on the PDCA concept, etc.

It applies to organizations of any field for which the constant analysis and development of QMS is a normative and vital necessity.

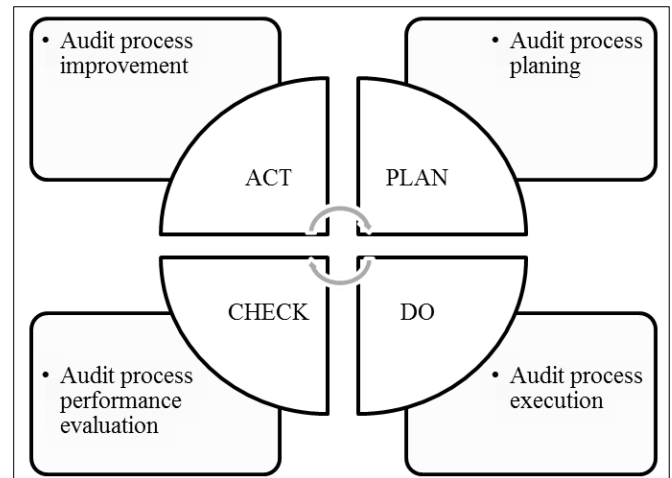
The purpose of IA is to determine the degree of responsibility of the object being tested (process, units) to the requirements, as well as the definition of the perfecting potential.

Certain factors that may cause the risk of failure to achieve the audit goals ^[6] affect the IA process:

- ill-considered planning of audit (incorrect definition of volumes, frequency, criteria and methods of audit);
- incorrect implementation of the audit procedure (inappropriate audit technique, incorrect documentation

filling out, statement of conclusions and preparation of reports);

- insufficient competence of auditors;
- lack of incentives for auditors to find opportunities for improvement;
- Inconsistent monitoring of the process effectiveness, incorrect analysis of the previous audits results, etc.



Source: Created by authors

Fig 1: The general scheme of the internal audit performed by the PDCA cycle

Застосування концепції циклу PDCA у процесі ВА має певні переваги, зокрема: постійна оцінка і робота над поліпшенням. Досягнення переваг циклу досягається завдяки науково обгрунтованим методам оцінки процесу та відповідних САРА^[12].

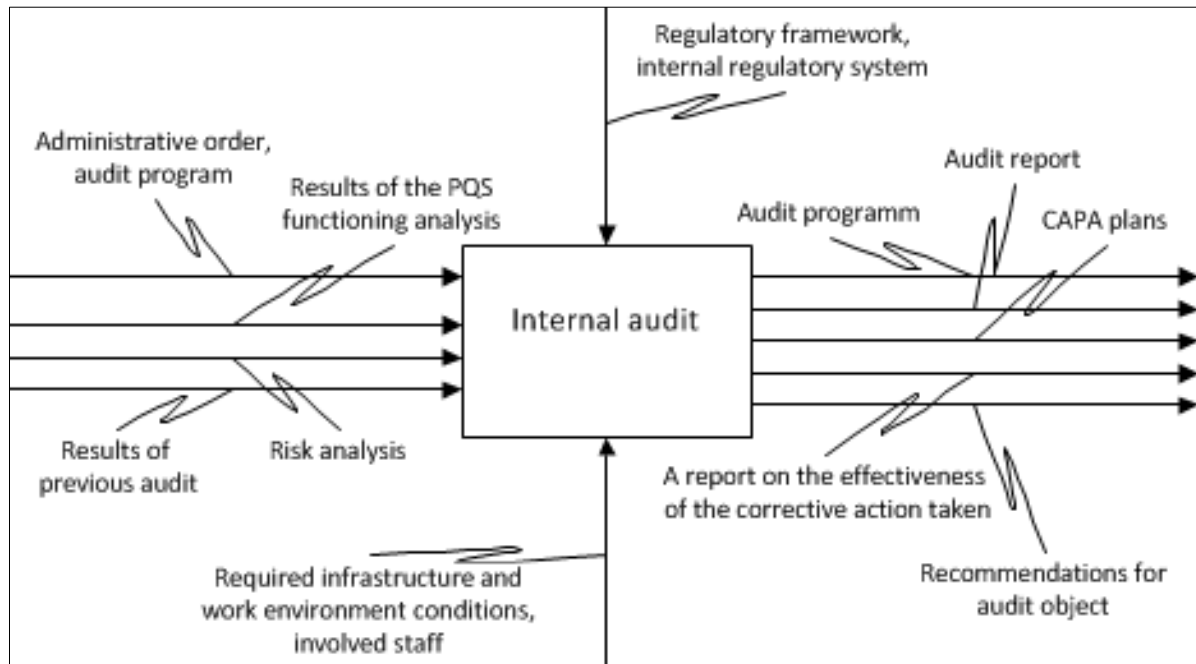
The use of the concept of the PDCA cycle in the IA process has certain benefits, including: constant evaluation and improvement work. Achievement of the cycle benefits is gained through scientifically grounded and corresponding to САРА ^[12] methods for the process assessment.

The PDCA cycle can be applied theoretically, using the various instruments and tools. However, in practice most of them can be reduced to a documented description of the internal audit process implementation for all phases of the PDCA cycle. The specific stages of performing the IA process in the PDCA cycle are shown in fig. 1

The implementation of the PDCA cycle in the documented techniques of the PC QMC is to describe the individual stages of the process. In a separate section it is necessary to provide a graphical model of the process along with the traditional sections of the documented procedure ("Terms, definitions and abbreviations", "Normative references", "Purpose and scope", "Responsibility and authority"). In most cases this model is represented using IDEF0 (fig. 2) with a small text explanation to visualize the connections of the IA process with other processes and specify inputs/outputs.

When regulating the IA process, it becomes very important to describe the stages of planning, performance evaluation and improvement, which are often ignored ^[5, 13].

Consider a practical example of the phases of "fixing" the PDCA cycle and risk-oriented thinking into the procedure of IA QMS within the PC.



Source: Created by authors.

Fig 2: Model of internal audit process by model IDEF0

3.1 The Macro-level

The macro-level of the process involves the development of the Audit Program (AP) and other regulatory documents, the assessment of the audit activities resulting quality and IA process improving actions. This level defines the purpose of the process and the risks which can affect its achievements. Already at this level it is evident that the goals and risks understanding will allow the IA process to move further more consciously. Consequently this level can cover the whole range of audits conducted during the year on all processes of the PC QMS. Corrective actions at this level may include changes: the QMS process model, the macro-level algorithm for IA implementation, the selection and preparation of auditors, and so on.

3.2 The Micro-level

The micro-level of the process is to plan and prepare a specific audit, conduct it at the site, prepare the report, develop CAPA jointly according to the identified inconsistencies (IC), check the effectiveness of their implementation and completion of the audit, evaluate each individual audit and improve the process. This level covers properly each conducted audit of the PC QMS processes. A detailed diagram of the IA process using the IDEF0 model is shown in fig. 3.

3.2.1 The Plan phase (Fig. 3-a)

In the description of the process planning phase, it is necessary to provide an explanation of the procedure for establishing special tasks for members of the audit teams. Tasks are formed on the basis of the current program of audits, management directives and other factors. The description of this phase also includes comments of the documents analysis for compliance with the requirements of which the audit should be conducted, and any norms that belong to the scope of audit, as well as comments on the compilation of questionnaires (check-lists).

Usually the basic data for planning each IA is:

- Risk analysis results of the audit object;

- Analytical results of PC QMC functioning processes according to their systematic monitoring and evaluation;
- The results of previous similar audits.

The results of the implementation of the phase Plan are: site audit plan, the specific audit group organization instructions, data on informing members of each auditing group about planned audits, necessary documents preparation instructions, study of audit criteria, checklists and other forms of records.

3.2.2 The Do phase (Fig. 3-b)

IA realization consists of successive steps:

- Holding a preliminary meeting;
- "on-site audit";
- Holding the closing meeting;
- Preparation of the audit finding report;
- Participating in the development of the CAPA (if required);
- Checking the CAPA's performance (adequacy).

According to the results of audit we suggest to involve internal auditors in the development of CAPA, it increases their responsibility in formulating conclusions and motivation to help improving the activity of the verified object.

3.2.3 The Check phase (Fig. 3-c)

It is advisable to complete the process proof cycle after completing each individual audit. This stage provides an assessment:

- The work of the auditors according the pre-established criteria (to assess their ability in achieving their goals and providing the required results);
- Audit process based on established performance indicators.

Questionnaire may be used to assess the work of auditors [12]. Here it is possible to include questions which allow assessing each auditor comprehensively. For example, to evaluate personal qualities (tolerance, sociability, observation, determination, insistence, etc.) [14] ; audit readiness (knowledge of audit criteria, plan, audit methods, etc.), applicable audit technique (demonstrated professional skills,

including the ability to work independently, adherence to the pre-planned audit schedule, correct record keeping during the audit, the correct comments formulation, the presentation of the IC facts, the proposed recommendations)^[3, 12].

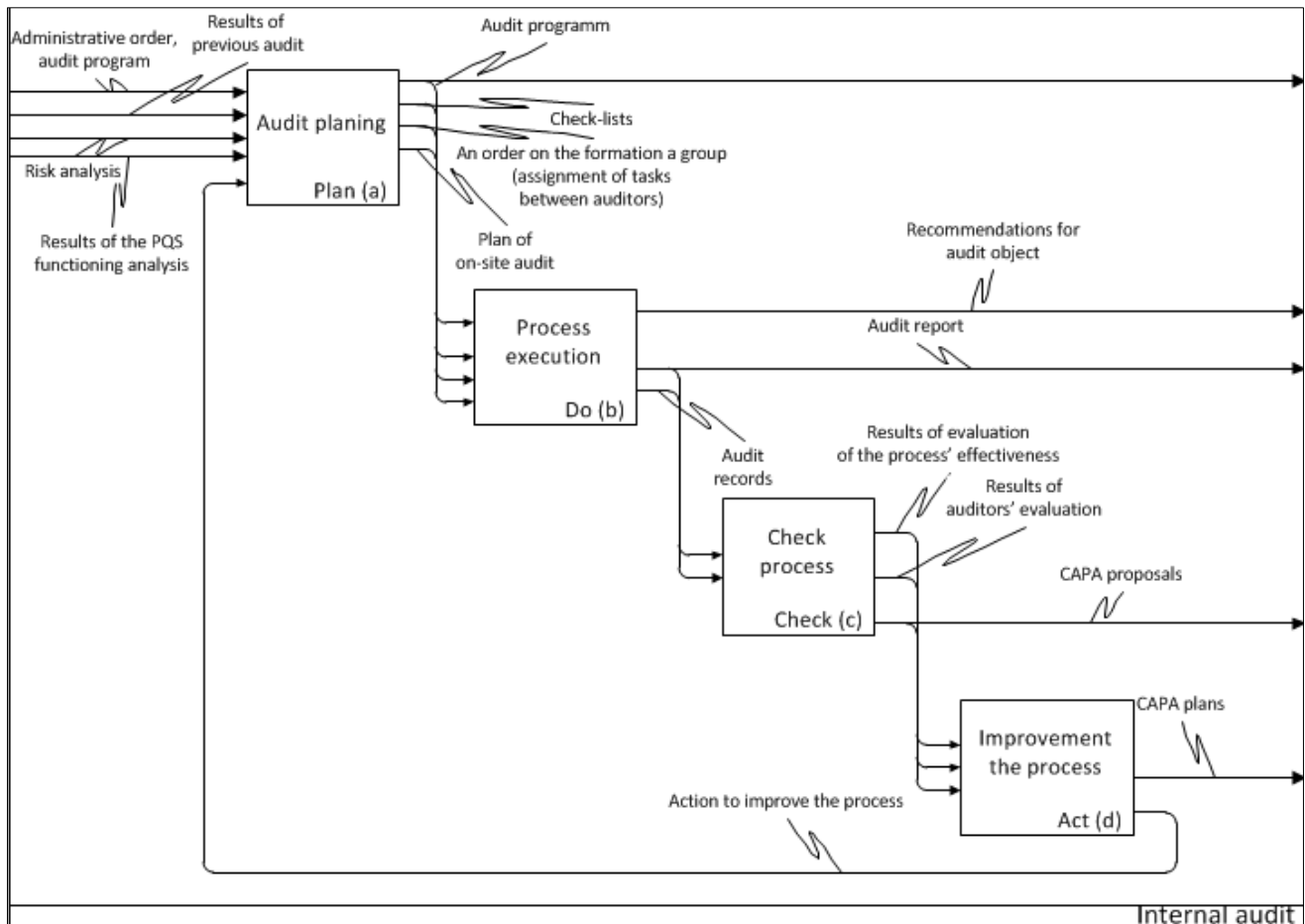
The audit process is evaluated according the established performance indicators, which are particularly characterized by the value of audit reports for management. Such indicators, and especially the corresponding criteria, may vary. In the most cases they are set for the period of the certain audit program implementation^[12].

3.2.4 The Act phase (Fig. 3-d)

The perfecting phase is aimed at continuous optimization and

improvement of the IA process in order to increase its resulting character. Such operations may relate to any aspect of IA's improvement:

- Procedures of audit execution within the framework of macro and micro levels;
- Procedures for the selection, evaluation, training, preparation and certification of internal auditors;
- Documents and forms of audit records;
- Audit methods;
- Ways to collect and evaluate audit data;
- Improving the interaction of personnel with processes and units under audit, etc.



Source: Created by authors.

Fig 3: Stages of the internal audit process using the PDCA cycle

As a rule optimization goes down by making changes to the applicable documents in order to improve the procedure for carrying out the IA. Auditors need to maintain continuously their competence by learning or conducting the corresponding training and courses. Upon condition of updating the relevant procedures, there are real grounds for the systematic collection of the information about the PC QMS processes characteristics, the identification of the high risk areas, as well as the reasons for the timely adoption of adequate CAPA, aimed at eliminating the causes of detected IC and reducing the risk of problems. Implemented at the process level PDCA cycle is one of the key conditions for an effective improvement in the performance of the QMS. However, the positive effect of PDCA implementation directly depends on the correct understanding of the management concept on the basis of feedback and the formality degree of its application.

4. Conclusions

The use of the PDCA cycle in the regulation of the IA process stipulates the use of all process control tools. The description of each stage of IA in the phases of the PDCA cycle allows not only establishing the algorithms of the corresponding work, but also to improve the training of performers and minimize other risks of the IC occurrence at the stage of process regulation. Also, during the process evaluation it is possible to select the verification criteria more fully through the use of risk-oriented thinking.

Our proposed approach to the implementation of IA-oriented processes has certain advantages, since it provides a significant increase in the value of audits from viewpoint of identifying and assessing the capacity of the QMS implemented at the enterprise to solve its tasks and achieve its goals.

Such an approach at the sufficient level will significantly improve the QMS efficiency in the pharmaceutical industry and other fields of work.

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