

Materials and methods. We have used methods of empirical research and comparative analysis. We analyzed the available published information, and also developed and applied the methodology of previously implemented quality management systems. The informational basis of our research was the materials of open scientific and professional literature, as well as regulatory requirements of standards and guidelines for pharmacy companies in Ukraine and the Republic of Kazakhstan.

Results and discussion. In the process of the study we have carried out a comparative analysis of the requirements of the GPP standard and a number of ISO standards: ISO 9001 of "Quality Management Systems", ISO 14001 of "Environmental Management Systems", ISO 27001 of "Information Security Management Systems", ISO / IEC 20000-1 of "Information technologies. Service Management", ISO 22301 of "Business Continuity Management Systems" and others. It has been done to make possible creating of an optimal model of the management system for a pharmacy organization.

It should be noted that almost all of the above ISO standards in Ukraine and the Republic of Kazakhstan are represented in the form of State Standards (ДСТУ – in Ukraine, ГОСТ – in the Republic of Kazakhstan).

The GPP standard in Ukraine is at the discussion stage. At the time of the research it was not in force yet, though there is an existing Order of the Ministry of Health of Ukraine from 30.05.2013 No. 455 "On Approving the Manual "Good Pharmacy Practices: Quality Standards of Pharmaceutical Services".

In Kazakhstan the GPP standard operates on the basis of the Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 27, 2015 No. 392 "On approval of appropriate pharmaceutical practices".

Having analyzed these documents, we considered the GPP standard as mandatory for implementation in pharmacy organizations. Standards of the ISO series were chosen according to the principle of necessity and the possibility of implementing their provisions in the standard pharmacy organizations of Ukraine and the countries of the CIS. From the listed ISO standards, it was decided to use the ISO 9001 "Quality Management System", ISO 27001 "Information Security Management Systems (ISMS)" standards as the most complementary to the GPP standard.

Conclusions. Thus, for creating the possibility of building an integrated management system and implementing it on the basis of pharmacy organizations in Ukraine and the Republic of Kazakhstan the standards GPP (as mandatory and basic), ISO 9001 of "Quality Management Systems" and ISO 27001 of "Information Security Management Systems" have been chosen.

In the future we plan to develop methodological recommendations for the implementation of these standards in pharmacy organizations as part of an integrated management system.

STAGES OF THE FORMATION OF THE QUALITY MANAGEMENT SYSTEM OF PHARMACEUTICAL COMPANY

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Introduction. Formation of a quality management system (QMS) of a pharmaceutical company is a very important step by which it is possible to confirm reliability, perceptivity and stability of the company's activity.

Development and formation of a QMS will allow the company to gain many advantages: improving the manageability of production processes, improving the quality and competitiveness of manufactured products, reduce production costs, and also make the company oriented to needs of the final consumer.

Quality management system is able to provide a very effective and productive activity of a company, which will undoubtedly affect the quality of products produced. The most effective in shaping the quality system are the rules and requirements defined in the international standard ISO 9001. This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements. The standard 9001 sets out the general requirements for QMS, it

promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach". An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

Aim. The aim of our research was to develop the stages of the quality management system implementation at the pharmaceutical company.

Materials and methods. As materials we used the provisions of the standard ISO 9001:2015 "Quality Management Systems. Requirements".

Results and discussion. All stages in the formation and implementation of QMS can be conditionally divided into 6 stages:

1) Preparatory stage. This stage involves the implementation of the following activities:

a) Issuance of an order on the creation and implementation of QMS.

b) Creation of a working group.

c) Development of a program (work plan) for the creation and implementation of QMS.

2) The second stage - formation of the company Mission, Quality policy, quality objectives.

3) The third stage - definition and construction of the process model of the company's QMS.

The application of the process approach becomes objectively necessary. The process model is a system (network) of interacting processes, each of which affects the functioning of other processes and the system as a whole.

All processes in the organization are divided into 3 groups:

- Basic Processes
- Providing (auxiliary)
- Management Processes

4) The fourth stage – regulating and documenting the QMS.

The structure of the QMS documentation consists of the following levels:

a) "Zero Cycle" forms legal documentation (licensing documents, orders of higher organizations, orders, laws).

b) The "base level" forms the documentation on quality assurance (internal technical documents, internal normative documents, external normative documents, methodological documents, documents on strategic and operational planning, organizational and administrative documents, etc.).

c) Documentation for quality assurance (records).

d) Management documentation (working instructions of performers, documented procedures, quality manual, quality policy and quality objectives).

5) The fifth stage – realization of the QMS documentation at practice.

Implementation of the QMS involves conducting internal audits, as well as realization of risk-oriented thinking implementing corrective and preventive actions that ultimately improve the effectiveness of the processes.

6) The sixth stage - certification of QMS (Voluntary).

Conclusions. Meet the requirements of ISO 9000 series standards - it's not only to work on a new, better-quality level, to make it transparent and to optimize all management processes, but also to significantly improve the quality, increase the efficiency and effectiveness of the activity.