РОЗДІЛ 2. ТЕОРЕТИЧНІ ПИТАННЯ ТА ПРАКТИЧНІ АСПЕКТИ МЕНЕДЖМЕНТУ В СИСТЕМІ ОХОРОНИ ЗДОРОВ'Я І ДІЯЛЬНОСТІ ОКРЕМИХ ПІДПРИЄМСТВ

METHODICAL APPROACHES TO THE DEVELOPMENT OF DOCUMENTATION FOR THE IMPLEMENTATION OF THE QUALITY SYSTEM IN PHARMACEUTICAL ORGANIZATIONS

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Introduction

Pharmaceutical organizations in Ukraine are in the process of implementing international standards aimed at ensuring the quality of medicines. The main direction of state policy in the pharmaceutical sector in Ukraine is to provide the population with quality, safe and effective drugs. Improving the level of quality of medicines and pharmaceutical services during their distribution is carried out by implementing an effective quality system in the activities of wholesale pharmaceutical companies in accordance with international and domestic quality standards. The implementation of the strategy of quality assurance of medicines in the process of their circulation actualizes the development, implementation and maintenance of a quality system in pharmacies based on the principles of the general theory of quality management and the provisions of good distribution practice (GDP) and good pharmaceutical practice (GPP). Documentation of all processes of the pharmaceutical organizations gives the quality system an official status and determines its construction and effective operation.

Aime of the study is a substantiation of methodical bases and practical approaches to development of the documentation necessary for creation of quality system in pharmaceutical organizations which are engaged in wholesale and retail realization of medicines.

Methods and materials

The materials used in this article are the official websites of the authorized organizations on quality assurance of medicines, regulatory documents and scientific publications on the subject. The study was conducted using the methods of statistical, logical, comparative analysis and generalization of information.

Results

A study of work of pharmaceutical organizations showed that the volume and level of detail of documentation for each organization may be different, due to the number and range of drugs, complexity, nature and interaction of production processes in the organization, as well as the competence of staff performing a particular type of work. The GDP and GPP guidelines do not clearly define the documents required for the establishment and operation of a quality system based on formulated quality criteria. The analysis of scientific publications and quality management practices shows that developing quality system of documents it is advisable to follow the recommendations of the ISO 9001:2008, IDT standard with the priority requirements of GDP and GPP rules.

According to the results of the study of the activities of pharmaceutical organizations engaged in wholesale and retail sales of drugs, adhering to the priority of GDP and GPP rules, taking into account the methodology of ISO 9000 series standards, we determined that for the construction and operation of quality system in pharmaceutical quality, Guidelines for quality, documented procedures for all processes and activities that affect the quality of drugs or services, as well as quality protocols. We have proposed a four-level hierarchy of pharmacy quality system documentation. It is determined that the documents of the first (higher) level include the Quality Policy and the Guidelines for Quality, which are the basic documents in the structure of the quality system and establish the basic principles of its functioning in the pharmacy. They define the approaches and responsibilities of the performers. Level 2 documentation - standard operating procedures (SOP), that describe the interrelated activities and processes of the pharmacy, determine what, who and when performs. SOP's goal is to show workers what to do and when. This allows management to have all the information about the work of staff, to check the correctness and accuracy of the work performed, to track the cause of any non-compliance of the results with the requirements of regulations. In this regard, the use of written SOP is considered one of the most important and effective management mechanisms to control the proper performance of work in the subjects of pharmaceutical activity. The documentation of the third level is intended for concrete divisions of the organization, consists of documents of methodical and instructive character - job descriptions and working instructions of the personnel. The fourth level of documentation includes quality protocols that contain the results or evidence of work.

Conclusion

The studies showed that the pharmaceutical sector of Ukraine is in the process of creating an effective system of drug quality assurance, which is based on international principles, innovative approaches, proper regulatory support and rational application of regulatory functions.According to the results of the study of the activities of pharmacy organizations, the creation of a documentation system that determines the implementation and effective functioning of the quality system in pharmacies is justified, methodological approaches to the development of the structure and content of documents are proposed. Taking into account the regulatory framework of the domestic pharmaceutical sector, a four-level hierarchy of documentation has been developed.

References

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