IMPROVEMENT ELECTRONIC DOCUMENT PROCEDURE AT PHARMACEUTICAL COMPANIES ACCORDING TO THE GOOD MANUFACTURING PRACTICE REQUIREMENTS

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Introduction. Documentation in the pharmaceutical industry is an important part of the quality management and quality control system. The documentation describes the technical characteristics of all materials, methods of manufacture and control. The electronic document procedure of the pharmaceutical company is implemented on web-technologies that use electronic document flow as an instrumental base with a broad set of standard, each company-specific functions with unlimited expansion and integration capabilities, the main objective for which will be the management of the GMP standard.

The introduction of electronic document management in pharmaceutical company greatly optimizes the following areas: time-management (time saving procedures); use of ISO standards; possibility to reduce the risk of delays and completeness of the document (incomplete filling) and the inclusion of non-current documents; clear distribution of responsibility for completing the document.

Aim. The aim of the study is to highlight issues related to use of the electronic document management system in a pharmaceutical company and its regulation in the pharmaceutical quality management system.

Materials and methods. For theoretical understanding of various aspects of the research, methods of analysis and synthesis, modeling and the comparison were used.

Results and discussion. The basic concepts of electronic systems are defined (electronic document, original electronic document, electronic document flow, electronic document flow system (EDS). It analyzes the operating principles of existing systems, that corporate information systems and enterprise management systems, of course, have modules for keeping records, but the possibilities of many of them are very limited. Most document management systems support integration with well-known enterprise management systems.

To improve the existing EDS modules have been described that optimize the work of the pharmaceutical company and bring it in line with the GxP and ALCOA standards. The proposed system makes it easy to work with different types of documents and effectively organize electronic document flow.

Conclusions. The electronic document management system developed in accordance with GMP standards is very useful for a pharmaceutical company. It is a software product that allows you to solve many tasks, improve the electronic document flow of enterprises, plan a variety of internal events, notify about changes to the quality management system documents. The main thing is that the electronic document management system allows to determine the technology of passing internal documents in an organization.

ANALYSIS OF FUNCTIONING OF THE RISK FOR QUALITY MANAGEMENT PROCESS AT PHARMACEUTICAL DISTRIBUTION COMPANIES

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Introduction. Risk for medicines quality management is an integral and very important component of a Pharmaceutical Quality System (PQS). The reasons for this are that the systematic risk identification, risk analysis, risk assessment within all system processes with use of appropriate precautions to eliminate of possible nonconformities causes or reduce risks to an acceptable level ensures the proper functioning and continuous improvement of the company quality system.