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.

Unfortunately, domestic pharmaceutical companies often carry out risk management formally, mainly to meet the requirements of supervisors. As a result, it can negatively affect the ability of the company to supply products that are fully consistent with all established requirements.

Aim. The aim of our research is analysis of the state of functioning of the risk management process at domestic pharmaceutical distribution companies.

Materials and methods. We used methods of empirical research and comparative analysis. We have worked out the sources of published information, as well as developed and applied the methodology of sociological research through a questionnaire survey of managers and specialists of the relevant units of domestic pharmaceutical distribution companies.

Results and discussion. A sociological survey was carried out among business entities that had a license for the wholesale trade of medicinal products.

The methodology of sociological research envisaged the use of questionnaires with questions on the functioning of risk management process at a particular company. In particular, the questions concerned the competence of involved personnel, the approaches to risk management applied in enterprise, methodical provision of this activity, the most common problems in this process, etc.

Questionnaires were sent to 45 enterprises, including the Top 10 in terms of sales of medicines in the pharmacy network of Ukraine. The addressees were heads of divisions, whose competence included risk for quality management.

Responses were received from 18 respondents, accounting for 40 % of their total number. Representativeness of this sample can be considered acceptable.

Based on the analysis of the results of a sociological survey, we have found that along with the large-scale development of risk management practices, almost all enterprises have certain elements of this process that cause problems.

The vast majority of respondents noted that the risk management in their company is carried out by specialists only among the employees of the department of quality assurance. Very rarely, employees of other departments and outside experts are involved in risk management.

Although, as you know, risk for quality management activities, as a rule, but not always, should be carried out by multidisciplinary teams. When forming groups, they should include experts in the relevant fields.

Respondents indicated a lack of information for organizing the risk management process. More than 70% of respondents in the organization of this process faced the problem of lack of information on the methodology and practical aspects of risk management.

33% of respondents said that they receive information on risk management at a thematic seminar, trainings and from external experts or consultants.

16 % of respondents find useful information about risks in textbooks and methodological recommendations.

Only 11 % of respondents use periodicals for this purpose. Almost all interviewed experts find little useful information on thematic sites. Often information is presented in the form of general provisions and principles. There are practically no specific case studies on risk management.

We also wanted to identify what was the most difficult aspect of implementation of the risk management process at a pharmaceutical companies.

Most respondents (55 %) had the greatest difficulties with training of risk managers. This was due to the lack of time to study, the lack of funds for participation in seminars and trainings, the organization of consultations of third-party experts, etc.

28 % of respondents encountered difficulties in identifying and assessing risks. In fact, only specialists from the quality assurance department, who were not motivated enough and did not understand the goals of this work, were involved.

16 % of respondents also noted difficulties in regulating and documenting this process. The reason for this was the lack of time for the development of regulatory documents, lack of information on documenting this process.

Conclusions. In particular, the answers of experts suggest that the most urgent of the above questions is to ensure the competence of risk managers. Therefore, the development of proposals for the organization of a risk-managers training is the objective of our further research.

ACTUALITY OF THE LEAN PRODUCTION CONCEPT IMPLEMENTATION AT PHARMACEUTICAL ENTERPRISES

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Introduction. Lean production is a management concept that involves optimizing business processes with maximum market orientation and taking into account the motivation of each employee. Lean production forms the basis of a new management philosophy and culture. This is a broad management concept aimed at eliminating losses and optimizing business processes: from the stage of product development, production and to interaction with suppliers.

Aim. Lean Manufacturing Techniques are applicable to any area of the organization's activities with a view to a stable increase in competitiveness in a changing market.

Materials and methods. Pharmaceutical enterprises are no exception, since their main task is the efficiency of production, that is directly related to the complexity and duration of the production cycle. The longer this cycle is, the greater is the number of auxiliary and servicing industries in it, the less effective is production in general.

Results and discussion. The Kaizen Institute, which has worked with a large number of pharmaceutical companies around the world, has identified the typical results that a company can achieve when lean manufacturing is applied (Fig. 1).

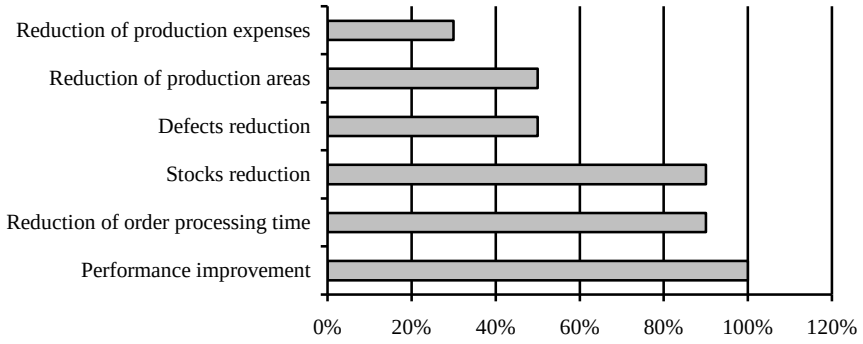

Fig. 1. The effect of the lean production introduction in pharmaceutical companies.

Conclusions. In the pharmaceutical industry, control and reliability processes play a key role. The introduction of lean manufacturing can be used to enhance the competitive advantage of an organization.

The efficiency and payback of this concept are quite high. Its implementation allows companies to gain tangible benefits and competitive advantages, which is especially important in today's competitive environment.

CONTROL OF DATA AND INFORMATION MANAGEMENT AT STATE LABORATORIES FOR THE CONTROL OF MEDICINES

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Introduction. Laboratory control is one of the main regulatory procedures in the system of quality assurance of medicines. State laboratories for quality control of medicines must guarantee and document the correctness of the results obtained, prove their competence not only to their clients, but also to regulatory