A methodology for evaluating the quality of documented QMS procedures has also been developed (using the SOP example).

The technique allows to evaluate on a 4-point scale the quality of documented procedures developed from the user's point of view by the following parameters:

- Convenience of application of procedure (clarity, comprehensibility of text and illustrations).
- Correctness of the SOP structure (compliance of the SOP content with the established general requirements).
- Description of the procedure algorithm (completeness and correctness of instructions, requirements).
- The style of presentation of the procedure text (lexical and spelling quality of the document).

When using the technique by the expert(s), it is necessary to fill in the questionnaires.

Recommendations have been made on the preparation of reports on the verification and assessment of the quality of workflow. Reports can be prepared either during scheduled internal audits or during an unscheduled audit of the records management process.

Conclusions. The application of the proposed methods will not only improve the quality of the documented procedures at the research facility, but also improve the entire system of workflow of the organization. Based on the generalization of approaches and methods of document evaluation, an algorithm for auditing the process of document management of QMS has been developed and proposed, which can serve as a typical example for many organizations. As part of the work, an approximate list of questions that auditors should be asked when reviewing the "Document Management" process is formulated. The form of a questionnaire of the auditor is offered. The form of the report on the results of the evaluation of the "Document Management" process for compliance with the requirements of ISO 9001 is proposed. Typical nonconformities most commonly encountered by organizations in document audits are identified and summarized. The method of document flow estimation is developed. Questionnaire forms are developed to evaluate the quality of the document, which can be applied within any process of QMS. All the achievements, completed in the framework of the master's work, are proposed for implementation in the pharmaceutical company LLC "PRO.MED.CS Praha a.s.".

ANALYSIS OF THE FUNCTIONALITY OF THE QUALITY RISK MANAGEMENT PROCESS AT THE PHARMACEUTICAL DISTRIBUTION ENTERPRISES

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Introduction. One of the effective measures to increase the competitiveness of any modern organization is the implementation and continuous development and improving of the Quality Management System (QMS), for example, according to the ISO 9001 standard model, strengthening their competitive position.

The implementation of a Quality Management Systems has become a rule in many industries.

At the present stage of management development, much attention is paid to a risk-based approach. For example, all important decisions in management systems should be made taking into account the identified risks and opportunities for the organization. Risks always exist in all spheres of human activity. They appear when any uncertainty takes place. Risks are also inherent in situations where there is a multi-variance of events. In addition, you need to pay attention to the presence of both negative and positive results of the implementation of risks, i.e. emergency situations.

For example, any organization has a risk when expanding its range of products or services. However, such actions can have positive consequences for the organization.

All actions associated with risks in various fields are now called Risk Management. Risk Management is an integral and important part of modern management.

In Pharmacy Risk Management is the overall process of minimizing risks to the quality of medicines throughout the life cycle to optimize operations and balance risks / benefit for pharmaceutical company.

Risk Management is an integrated, structured, inclusive, dynamic, systematic process of risk assessment, risk impact, risk monitoring and verification, and the exchange of risk information for the quality of medicinal products.

Risk Management supports science-based and practical solutions when integrating into Quality Management Systems. Moreover, the QMS (or Pharmaceutical Quality System – PQS) include validation, quality defects - investigation, audit, verification, documentation, training of personnel and more.

Risk management for the quality of medicines is an integral and very important factor in improving the pharmaceutical quality system, because it is the systematic identification, analysis, evaluation of risks within all systematic processes, with appropriate precautions taken to eliminate the causes of potential discrepancies or reduce the risks to an acceptable level ensures proper functioning and continuous improvement.

In the current National Guideline «Medicines. Quality Risk Management», harmonized with ICH Q9, presents principles and examples of risk management tools for quality that can be applied to various aspects of quality in the operations of pharmaceutical businesses. International Standard ISO 31000: 2018 contains principles and conceptual guidelines for risk management and recommends that certain methods be applied on a case-by-case basis.

Guidelines «Medicines. Good Manufacturing Practice» (GMP) provide for mandatory risk management and do not exclude the use of the risk management model described in ISO 9000 series standards Yes, the GMP Guidelines require distributors to have risk management techniques in place. Quality risk management is a process that facilitates the adoption of scientifically sound and practical decisions when integrating them into quality systems. Effective quality risk management can help to make better and more informed decisions, which will give regulators greater assurance about the company's ability to deal with potential risks, and may affect the scale and level of direct oversight by the regulator. In addition, quality risk management can facilitate the better use of resources by all parties.

National pharmaceutical companies often manage the risk fairly formally, mainly to meet oversight requirements. As a consequence, it may adversely affect the ability of enterprises to consistently supply products that fully meet all established requirements. Scientifically sound approaches to quality risk management allow us to determine the list of undesirable situations, to assess the likelihood of their occurrence and the severity of the consequences, and to develop and take measures to eliminate or minimize the causes of the risks.

Aim. The aim of the work is to analyze the state of functioning of the process of quality risk management at national pharmaceutical enterprises distributors.

Materials and methods. The following methods of research were used: the review of literature data and generalization of the material, methods of analysis and synthesis, marketing, system, logical-structural and comparative analysis, forecasting and programming.

Results and discussion. During 2018-2019, a marketing survey was conducted among distributor pharmaceutical companies on the functioning of the quality risk management process. Questionnaires were sent to 45 enterprises, and 18 respondents received answers, accounting for 40% of their total number. The representativeness of this sample can be considered acceptable. Respondents included representatives of all major pharmaceutical companies in Ukraine's distributors, which are among the top ten in terms of sales of drugs to pharmacies. The enterprises are located in 10 regions of Ukraine; organizations were of different ownerships, sales volumes of medicines, all interviewees indicated that they had valid certificates of Good Distribution Practice.

The survey showed that 78% of participants in the risk management process at pharmaceutical companies in Ukraine's distributors are specialists in the quality department, employees of all departments of distributors conduct 17% of the process and only 5% of respondents mentioned the joint work of the quality department and employees of all departments.

More than 70% of respondents to the risk management process faced the problem of lack of information on methodology and practical aspects of risk management for quality in drug distribution, consultants. 16% of respondents find useful information on risk management in textbooks, guidelines and 11% of respondents in periodicals.

According to the respondents, the greatest difficulties in implementing and operating the risk management process at enterprises were related to the training of risk managers (55%).

Regarding the question of the relevance of risk management results to management expectations, the majority of respondents (88%) said that management is generally skeptical about risk management, perceiving risk management only as a regulatory process.

55% of respondents consider it critical to develop methodological recommendations; 28% of respondents agreed that such recommendations would be useful.

Conclusions. The main problems with the effectiveness of quality management are related to the lack of competence of risk managers, the lack of staff time required to train risk managers, the process itself, the analysis of the results obtained, and the lack of experts involved.

Many businesses most urgently need to improve elements of the risk management process, such as choosing a methodology, documenting the process, enhancing the competence of risk managers, monitoring the implementation of risk mitigation decisions, and more.

According to the data we receive, we plan to formulate a set of proposals on optimal organization of risk management at the pharmaceutical companies of distributors, to substantiate the set of competencies of risk managers, the composition of the team of risk managers, to define scientific and methodological approaches to regulation and documentation of risk management activities.