

Business criteria – characterize organization, responsibility, initiative, enterprise, etc.

Moral and psychological criteria – outline the characteristics of the employee, such as the ability to self-esteem, honesty, justice, psychological stability.

Integral criteria are characteristics that are obtained on the basis of many other characteristics inherent in the employee and show his authority, health status, general culture, culture of thinking and language, etc.

Certain groups can be conditionally divided into subjective and objective.

Subjective include those criteria that can not be measured in quantitative (monetary) terms using calculations that characterize the change in the quantitative and qualitative performance of the enterprise as a whole.

Objective criteria include those that directly affect the productivity of an employee's work and are measured in direct dependence on changes in the quality of the enterprise as a whole.

Results and discussion. Based on the selected criteria, the following methods are used to assess the employee's performance:

- the method of analytical evaluation, in which the Attestation Commission considers a written description - a review of the employee, and conducts an interview with him;

- the method of the evaluation system, in which the ranking of personnel is carried out, as a result of which the supervisor (attestation commission) is able to compare workers among themselves with consecutive conclusions;

- the method of situational assessment - as a rating scale, a description of the worker's behavior in a specific production situation is used, for which a description of effective and ineffective examples of behavior over time is developed;

- the method for assessing the achievement of goals - focus on the achievement of specific objectives facing the enterprise and the tasks assigned to the employee in accordance with his workplace.

In practice, the most effective methods that do not have subjectivity and directly allow to link the results of an employee's work with changes in the quantitative and qualitative performance of an enterprise are the method of analytical assessment and the method of evaluation for achieving goals (when applying normative tasks). When using the method of analytical evaluation during the certification, the main tasks were:

1. Determination of the employee's compliance with the position held.
2. Identify the prospect of using the potential abilities of the employee and his capabilities.
3. Stimulating the growth of the professional competence of the employee.
4. Identification of the directions of the professional development, vocational training and retraining of the employee.
5. Proposals on the movement of personnel, the release of the employee from the post (dismissal), as well as transfer to more (less) qualified work - depending on the conclusions of the certification.

Conclusions. The methods of the system of assessments and situational evaluation are laborious enough and can be applied: firstly in the non-production sphere, and secondly in small enterprises with a number of up to 50 people.

IMPROVING THE QUALITY OF PHARMACEUTICAL SERVICES

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Introduction. The issue of improving the quality of pharmaceutical services can be achieved through the introduction of modern management systems at enterprises, in particular, the quality management system based on the ISO 9000 quality standards. The ISO 9001:2015 «Quality management systems – Requirements» is based on two methodological aspects: process approach and satisfaction of consumer expectations. The implementation of the process approach and the application of all its principles will allow the organization to further certify its activities in accordance with the provisions of the ISO 9001 standard. This will enable the ineffective links in the enterprise to be identified, improve resource

efficiency, document all activities and establish responsibility for implementation, and most importantly – significantly improve the quality of pharmaceutical services and create a positive image. The process approach is a powerful methodological tool for studying and improving the activities of any organization.

Aim. The purpose of our work was to study the methodology of introducing a process approach to the work of domestic pharmaceutical companies.

Materials and methods. As materials, we used the provisions of the Standard ISO 9001:2015 «Quality management systems – Requirements».

Results and discussion.

The introduction of a process approach for an organization often presents some difficulties because of the lack of experience in interpreting the requirements of ISO 9000:2015 and ISO 9001:2015 and applying them to the specifics of their activities. These requirements cover all aspects of operation and they are universal for use.

The content of the standard' requirements reflects the interests of not only the pharmaceutical services provider, but also the consumer – in order to ensure interaction and mutual benefit to them. Moreover, it is only possible to create an optimal management system in the organization and implement a process approach.

Team work and individual responsibility of each developer of the process approach, has allowed to create a conditions for its successful implementation, focused on the overall result: the provision of quality pharmaceutical services. At the same time, the team was formed to solve certain tasks depending on the goal:

- defining all the functions performed and describing the processes of the organization;
- establishing the relationship between the identified processes;
- development of the mission and objectives of the enterprise;
- determination of the responsibility for each process;
- regulation of defined activities in processes and organization as a whole.

Formulating a process approach and solving current and strategic tasks to improve the level of service delivery is impossible without creating effective horizontal flows of information. At the heart of the interaction lies not only well-established communication links, but also the exchange of information. Key issues in the process of information exchange are knowledge (descriptive and systematic data), resources, planned and used technology works. Even after the introduction of the process management model, it is not possible to completely eliminate control at individual stages of the process of provision of pharmaceutical services. This is due to various factors: training and involvement of staff, leadership positions, completeness of documenting processes, informal approach to the functioning of the process model and others. There will always be a need to assess the quality level in contractual relations with suppliers, which are required by the current regulatory requirements in the pharmaceutical sector. Training is the most difficult part of the implementation of the program of the process approach, it is necessary to use it in combination with ensuring staff motivation. At the stage of implementation of the process model, it is necessary to conduct training within the framework of staff involvement, taking into account the basic principles of pedagogy and establishing the position of own responsibility for the performance of functions in each of the processes in the organization. Usually using a three-stage system of learning: the first stage – the head and his deputies; second stage – unit managers; the third stage – the staff of the institution.

In order to implement a process approach and meet the requirements of the standard ISO 9001:2015, it is necessary to develop a complex of documents. The organization can use a complex of diverse documents: instructive, methodical, regulating, managers. Regardless of the purpose and category of the data documents, it is necessary to create a general document flow of the enterprise and to classify, mark all developed documents. Only in this case will be able to avoid inconsistency in the accounting and application of documents. In accordance with the ISO 9001 standard, any organization must have the following categories of documents: documented policy provisions and objectives in the field of quality; documented methods and protocols; documents and records required for effective planning, management and control.

Conclusions. Process approach – this is the consideration of the entire company as a network of interacting processes. The peculiarities of the functions of the process approach are that they are not

formulated arbitrarily, but represent a certain system. Therefore, it is very important in the implementation of the consistent pursuit of each of the identified steps and continuously training all the personnel involved in the work.

ORGANIZATION OF THE QUALITY MANAGEMENT SYSTEM REVIEW AT THE PHARMACEUTICAL ENTERPRISE

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Introduction. Quality management systems (QMS) built in accordance with the requirements of the ISO 9001 standard should be systematically monitored, measured and monitored for realization of corrective action and continuous improvement. Without systematic diagnostic QMS cannot function efficiently and provide benefits to the organization, especially for a pharmaceutical company.

Aim. The aim of our research is analysis of the approaches to the expert assessment of the quality management system and the development of a method for determining the effectiveness of the QMS for use on basis of LLC "Pharmaceutical Company "Zdorov'ya", Kharkiv, Ukraine.

Materials and methods. We used methods of empirical research and comparative analysis. The information basis of our study was the materials published in open scientific and professional literature, as well as the regulatory requirements of standards and guidelines for distribution pharmaceutical companies.

The object of research was a quality management system of the pharmaceutical manufacturing company. The subject of the research is the method of expert ball assessment of the QMS effectiveness.

Results and discussion. To evaluate the QMS functioning, we propose to use of the expert ball assessment method. Expert evaluation involves the following actions:

- a set of criteria for the assessment of the QMS is determined;
- the criteria are ranked, each is assigned its own "weight" in points, and the sum of all points defines the final score;
- scores from each criterion may have weight ratios (depending on the criticality of the object being evaluated and determined by expert method);
- experts of QMS assessment is a heads of a structural units or processes.

Advantages of expert evaluation:

- the possibility of using qualitative and quantitative assessments, formalized and non-formalized procedures;
- simple implementation of techniques that does not require complex technologies, a lot of time and involvement of a significant number of employees;
- ability to take into account many aspects of the assessed object, a significant number of variants of development of events;
- do not require long expert training.

In fact, any other diagnostic methods are inadequate for QMS assess.

In many Ukrainian pharmaceutical companies, the assessment of quality system is based simply on a report. Such a report is usually prepared by the Quality Management Division once a quarter, a half-year, or even once a year.

We identified the shortcomings of this approach:

- quantitative evaluation criteria are not applied;
- not all quality system performance criteria are clearly formulated and documented;
- limit values of the QMS performance indicators are not set;
- the findings on the effectiveness of the QMS do not provide grounds for taking corrective or/and preventive action (CAPA) for continually improving of the company's activity.

Many companies now use the quality management system analysis process. However, this process is often not regulated. It is often not provided for a description of the evaluation methods. So, we have