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

developed a scheme for a new process "Analysis of QMS", which specifies inputs, outputs and required resources.

Table 1 presents the criteria developed by us for the assessment of the QMS by the "ball scoring" method.

Table 1. Criteria for QMS assessment

Criteria	Ball
There is a discrepancy that has a significant impact on security, or failure to comply with legislative or critical regulatory requirements. The risk is critical.	**0**
The activities covered by the QMS that affect the conformity of products and / or obligations to the customer are not regulated. The risk can be estimated as critically large.	**1**
In the course of the activities covered by the QMS, the facts revealed non-compliance with the established requirements, which increases the risks to the quality of products / fulfillment of obligations to the customer to an unacceptable level.	**2**
Detected deviations / violations that may affect product compliance and / or fulfillment of obligations to the customer. The risk can be estimated as significant.	**3**
In carrying out activities that may affect the compliance of products with established requirements and / or fulfillment of obligations to the customer, the achievement of the set goals is not ensured.	**4**
The established requirements are fulfilled, but in their implementation only partial achievement of the set goals is ensured. Risk for product quality and for obligations to the customer at an acceptable level.	**5**
Demonstrates the fulfillment of the basic requirements, ensuring the achievement of most of the goals set. Risk for product quality and for obligations to the customer at an acceptable level.	**6**
Provided evidence of a steady performance of requirements and an increase in some performance indicators. The risk for products quality and for obligations to the customer is in an acceptable field.	**7**
The stable fulfillment of all requirements and significant improvement of the activity performance have been demonstrated. The set goals are fully implemented or over fulfilled. The risk for product quality is acceptable and decreases.	**8**
Sustained performance and performance improvements are demonstrated. The process is greatly improved. All set goals are met / over fulfilled. The risk for product quality has decreased significantly.	**9**
Significant increase of efficiency of activity has been demonstrated	**10**

It has been established that the conclusion about the compliance of the QMS with the requirements of ISO 9001/GMP and its effectiveness can be provided under the condition that the general assessment in the first level, as well as all the assessments at levels 2, 3, 4, 5, 6 make at least 6 points out of 10 (not less than 60%).

Any rating of less than 6 points requires the fixing of the relevant fact in the record of inconsistencies, followed by an investigation and identifying the reasons for insufficient compliance, as well as the development and adoption of corrective actions.

Conclusions.

1. The importance of continuous QMS analysis is proved. A comparative overview of the main methods for assessing the effectiveness of the QMS was conducted. The actuality of professional application of expert technologies in the evaluation of the QMS is proved. The main aspects of the expert estimation technologies are considered; the comparative analysis of the corresponding methods is carried out.
2. The analysis of typical problems that arise in the process of expert evaluation is carried out. The main disadvantages of expert estimation methods are determined in determining the effectiveness of QMS in domestic companies.

3. The content and conditions for the implementation of the main stages of the QMS expert evaluation are formulated.
4. The method of quantitative determination of the degree of fulfillment of the requirements regulating the QMS processes is proposed. Such an assessment determines the ability of the QMS to ensure the stable fulfillment of all established requirements for activities affecting the quality of products, and also assesses the ability of the QMS to achieve its quality objectives.
5. The measurable values of the QMS, obtained by the methodology of "scoring" through the systematic conduct of audits, make it possible to monitor changes and analyze trends, which ensures conditions for the timely application of corrective and preventive actions, risk reduction.

DEVELOPMENT OF MEASURES FOR MINIMIZATION OF SUBSTANDARD AND FALSIFIED MEDICINAL PRODUCTS SPREADING IN UKRAINE

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Introduction. High-quality drugs are extremely important for human health and are needed in any health care system. The spread of counterfeit and substandard medicines is one of the most pressing issues for the global pharmaceutical market. Low and middle income countries are the most affected by this problem, but it is increasingly threatening and rich countries due to the sale of such drugs via the Internet. Online sales generate a market, most part of which is not regulated and not monitored. The Internet is a major source of counterfeit and low-quality drugs entry.

According to WHO, 1 of 10 drugs are of inappropriate quality or falsified. In recent years, the number of detected counterfeit and substandard drugs has increased by 56%.

There is also a tendency that, with the increase of trainings and education of specialists, the number of detected cases of falsification increases.

It is extremely difficult to estimate the real scale of this problem. It should be understood that when the danger becomes visible, many patients have already suffered harm.

Therefore, the purpose of the work was to search and develop measures to minimize the distribution of counterfeit and substandard drugs in Ukraine.

Aim. Search and development of measures to minimize the distribution of counterfeit and substandard drugs in Ukraine

Materials and methods. Having analyzed the current state of the pharmaceutical market of Ukraine, we can propose the use of complex measures of fighting the problem. They are a necessity to inform the society and specialists, to ensure the reliability of supply chains, and to create a reliable regulatory framework for better control of drugs turnover.

Results and discussion. The first method is to introduce a system of authentication and drug tracking, by applying a unique two-dimensional code for each drug package. This allows controlling the ways of medicines supply, quickly stopping the circulation of a specific batch or packaging, making records. This coding must necessarily be present on prescription drugs. This method is convenient for use by patients who can check the purchased products.

This system is already working in European countries in accordance with Directive 2011-62, which came into force in 2013. Ukraine was planning to implement the system by 2017. Already in October 2017, a pilot project on the implementation of this system has started on the example of the drug "Amixin", which was implemented through the distributor BADM and the retail chain of the Public Enterprises "Pharmacy".

Due to the special danger of low-quality parenteral dosage forms, attention should be paid to the technology that guarantees their quality, called SFERA. This is a technology of non-destructive laser engraving inside transparent materials with a two-dimensional bar code. This technology does not jeopardize the strength and content of a dosage form, guarantees the visual authenticity of medicines.