– insufficient staff motivation pharmacies to involve activities to ensure the quality of customer service and more.

The QMS implementation should be initiated by senior management. This project in general has to constantly underpin management, because leadership and staff motivation are the necessary conditions for ensuring the quality of products of any company.

Conclusions. Thus, it can be argued that the introduction of QMS in any organization, including at the pharmacy, is a rational step towards strengthening the market position and further expansion of the organization.

A properly implemented QMS is able to provide more accurate execution of all activities and minimize risks of any inconsistencies, so you can expect an increase in the quality of service, growing image in the market and increasing economic performance.

RISKS OF PHARMACEUTICAL ACTIVITY AND PROFESSIONAL RESPONSIBILITY OF PHARMACEUTICAL PERSON

Oplavina A. M.
Scientific supervisor: associate professor Zborovskaya T. V.
National University of Pharmacy, Kharkiv, Ukraine
aoplavina@gmail.com

Introduction. The activity of any pharmacy organization is associated with production risks. The economic dictionary considers risk as a «combination of probability and consequences of adverse events». Under adverse events means economic losses and damage to the business reputation of the organization.

The risks of the pharmacy organization consist of the risks inherent in any commercial organization, as well as the specific risks associated with the implementation of pharmaceutical activities. In pharmaceutical activity, distinguish the main processes: the order, acceptance, storage and sale of pharmacy products. Emerging at these stages risks present both to the pharmacy and to the consumer of pharmaceutical services, as the consequence of the risk in most cases is low-quality goods. The leading place in the ranking of reasons for the quality of pharmaceutical activities has related to staffing, namely, «insufficient qualifications of staff» and «unfair attitude of staff to work». It has noted that these risks lead to a decrease in turnover up to 50%. Low liability – a risk that leads to violations in the process of performing individual operations with associated economic losses.

The low level of competence and unfair attitude of the staff towards the work is also a consequence of the lack of responsibility of the pharmaceutical staff. The risks arising from these factors in the implementation of the basic processes of pharmaceutical activity have a significant negative impact, which determines the relevance of their study.

Aim. Study of the risks arising in the implementation of the basic processes of pharmaceutical activity of the pharmacy organization, connected with the lack of responsibility of the pharmaceutical staff.

Materials and methods. In the process of research, the following methods were use: analysis of scientific publications, logical, grouping, comparison, questionnaires, and expert evaluations. The empirical basis for the study was 256 questionnaires of pharmaceutical specialists working in a pharmacy organization; 68 questionnaires of heads of human resources departments, heads of training departments and their managers; expert interview materials of 15 specialists responsible for the pharmaceutical procedure.

Results and discussion. Because of the analysis of current normative documents, the main threats identified for each of the four pharmaceutical processes associated with insufficient employee liability were identify. This became the basis for the development of questionnaires. 20 risks were assigned to the order process, up to the acceptance process – 25; to the processes of storage and implementation – 30 risks. Thus, only 105 risks were assess.

To assess each risk, based on the results of the questionnaire of pharmaceutical specialists, its value was calculate according to the formula:

$$R = v * Q$$

where: R – is the risk value, points, v – the probability of occurrence of risk points, Q – the magnitude of the expected consequences of risk points.

Because of the research, the risks were categorize.

The first category includes the most significant risks (26.7% of all risks), their probability and magnitude of the consequences are maximized. Examples: the inability to order goods due to debts to the supplier, resulting from late payment; wrong order of goods; order of goods is not in accordance with the need, lack of inventory; untimely order of goods; wrong order item; Ordering goods not according to need – creating a poor assortment; lack of information about the structure of the range and running goods; inability to order goods due to the overstocking of the pharmacy; inability to order goods, lack of skills to eliminate errors of work with the program and computer; wrong choice of supplier, high prices; lack of freedom to choose size and delivery interval; inflexible response to changes in demand; order of goods is not in accordance with the need, glut; non-compliance with the procurement interval; no delivery contract; ordering goods from a supplier with a disadvantageous minimum order size; ordering goods from a supplier with a bad reputation; ordering goods from a supplier with unfavorable payment terms; the choice of time-consuming method of ordering goods (by phone) due to incompetence in working with a computer.

The second category (44.7%) includes high-impact risks, but their probability is low. Examples: late acceptance of goods in quality and quantity; acceptance of goods that do not correspond to the invoice by quantity; lack of responsibility for the acceptance of goods; acceptance of goods that do not correspond to the invoice on the shelf life; acceptance of non-order goods; acceptance of goods that do not correspond to the consignment note for the series; acceptance of goods in a damaged shipping container; no selected area of acceptance of goods; theft of goods by staff at the time of acceptance; the absence of the log of receipt of goods; lack of acceptance for quality and quantity; violation of storage of goods during acceptance; acceptance of goods in damaged packaging; Acceptance of goods without information about the documents confirming the quality; late placement of goods in the quarantine zone; acceptance of goods with errors in the accompanying documents; lack of acceptance for quality and quantity; lack of documentation of acceptance; acceptance of the goods by an intangible person in charge.

Third – the least dangerous risks (18,1%), their probability and the consequences are minimal. Examples: Untimely control of expiration dates, expiration; storage of goods on the floor without pallets; lack of quarantine zone; choose the wrong light mode; choose the wrong temperature mode; joint storage of goods subject to separate storage; the lack of the ability to find goods promptly, the inconvenient systematization of places of storage; violation of the order of storage of medical products.

The fourth category (10.5%) was risky with a high probability of occurrence, but a low magnitude of the consequences. Examples: sales of pharmaceutical products by a staff member who does not have a pharmaceutical education; rudeness with buyers; improper appearance of the employee; improper registration of showcases and trading room; incomplete counseling; lack of log of incorrectly written recipes; excess of leave rules; ignoring buyers; conflicts between employees in the presence of buyers; realization of a product that meets the needs of the buyer; The grading of all risks is based on the probability of occurrence and the magnitude of expected losses. Linguistic risk assessment was conducted according to the table.

The magnitude of the risk in points	**Linguistic evaluation**
from 101 to 121	critical risk
from 76 to 100	significant risk
from 51 to 75	high risk
from 26 to 50	average risk
from 1 to 25	low risk

The analysis of critical and maximal risks shows that most of these risks arise in the process of storing and ordering the product. The risks associated with the acceptance and sale of goods are present among the critical and significant risks, but in a smaller number. This result is explain by the inevitable occurrence of material liability because of the appearance of inappropriate goods.

Controlling organizations pay close attention to the storage of pharmacy goods, and its violation leads to the imposition of a significant fine. The quality of information and consulting support and the product acceptance process are not evaluate by regulatory organizations, but they are important for the reputation of the pharmacy among pharmaceutical service consumers and suppliers.

Conclusions. Risks in the processes of acceptance and storage of goods are most significant. Reducing the risks of the basic processes of pharmaceutical activity will avoid economic losses and losses for the reputation of the pharmacy organization. Increasing the responsibility and competence of pharmaceutical staff, standardizing and controlling the processes of pharmaceutical activity is a priority task in terms of reducing risks.

QUALIFICATION OF ANALYTICAL EQUIPMENT IN THE SYSTEM OF QUALITY MANAGEMENT OF THE ENTERPRISE

Plakhotnaya O.A.
Scientific supervisors: associate professor, Gubin I.I., associate professor, Romelashvili E.S.
National University of Pharmacy, Kharkiv, Ukraine
OlgaPlakhotna@gmail.com

Introduction. Qualification of equipment is a necessary prior step for validating analytical methods. Even if all servicing of equipment is carried out under a contract, it is the responsibility of the laboratory to monitor the condition of the equipment (especially during routine analysis).

Qualification of laboratory equipment is a necessary procedure for any research center. GMP (Good Manufacturing Practice or Good Manufacturing Practice) and GLP (Good Laboratory Practice or Good Laboratory Practice) rules determine the quality control of testing for pharmaceutical companies. During the qualification procedure, the greatest attention is paid to the equipment configuration, since standard equipment is often supplemented with separate test and standardized samples. The quality and effectiveness of subsequent research depends on their compliance with the required indicator. In order to ensure a pharmaceutical quality system, it is important that not only equipment with calibration, but also the method of analysis must pass the qualification.

The process of qualification of analytical equipment in the laboratory is documented in accordance with the requirements of modern WHO documents (World Health Organization), PIC / S (the Pharmaceutical Inspection Co-operation Scheme, convention on cooperation of pharmaceutical inspections), FDA (Food and Drug Administration, Sanitary Inspectorate quality of food and medicine), ISO 17025 (General requirements for the competence of testing and calibration laboratories, General requirements for the competence of testing and calibration laboratories) of leading pharmacopoeias and regulatory documents Tami for specific pieces of equipment available in the laboratory of the enterprise.

Aim. The goal of our work is to develop a standard working methodology for the qualification process of analytical equipment "The order of work on qualification (DQ, Design Qualification, Project Qualification; IQ, Installation Qualification, Installation Qualification; OQ, Operational Qualification, Functional Qualification; PQ, Performance Qualification, Performance Qualification or Performance Qualification)."

Materials and methods. As materials of research and development used the regulatory documentation mentioned above.

As above, the regulatory documentation mentioned above.

The main requirement for all equipment used in specific laboratories is compliance with its intended use. Therefore, the internal qualification process of the equipment must establish that the working specification (what the manufacturer claims) is suitable for the intended application and that the equipment operates in accordance with this specification. The ISO 17025 standard describes in detail the requirements that a laboratory must meet to guarantee its competence from a technical point of view and the ability to produce reliable results.

Results and discussion. In the process of creating a standard working methodology, we considered and identified those responsible for carrying out and the scope of work on qualification, eligibility criteria, thought out experimental studies and tests, determined the type and method of