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

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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

recording the assessment of the results obtained as a set of documentation on the qualification of analytical laboratory equipment (file for each unit equipment).

We established a step-by-step procedure for qualification work, to confirm that the equipment or system is working properly and gives the expected results, in accordance with the requirements of the current GMP rules.

Have described each stage of qualification, which is carried out in four successive stages:

Project Qualification (DQ, Design Qualification)

Installation Qualification (IQ)

Functional Qualification (OQ, Operational Qualification)

Performance or Performance Qualification (PQ, Performance Qualification).

The set of tests for qualification varies depending on the task in each particular case when choosing the object of qualification.

Conclusion. The development of a standard working procedure for qualifying analytical equipment used for analyzing drugs, and applying it to the overall pharmaceutical quality system allowed us to conduct qualification of all performance characteristics (PQ) and some procedures for qualifying functioning (OQ) throughout the life cycle.

Allowed us to confirm the fact that the equipment works correctly when performing routine analyzes.

Thus, we confirm that our equipment is and is constantly maintained in a state of maintenance and calibration that is appropriate for its intended use.

IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEMS AT THE STATE LABORATORIES FOR MEDICINES QUALITY CONTROL

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Introduction. The role of the analytical laboratories at the state medicines quality assurance system is extremely important in view of the importance of the test results to make a decision about the possibility of medicines use.

This predetermines the considerable responsibility of the laboratories and assumes the existence of an effective quality system focused on the accuracy and reliability of the test results.

For the harmonization and standardization of requirements for laboratories at the international level, WHO has developed a «Good Practices for Pharmaceutical Quality Control Laboratories» (WHO Technical Report Series, No. 957, 2010, GPCL). These recommendations are used as the basis of their national rules by many countries of the world to confirm the reliability and accuracy of test results.

These guidelines provide advice on the quality management system within which the analysis of active pharmaceutical ingredients (APIs), excipients and pharmaceutical products should be performed to demonstrate that reliable results are obtained.

These guidelines are applicable to any pharmaceutical quality control laboratory, be it national, commercial or nongovernmental. However, they do not include guidance for those laboratories involved in the testing of biological products, e.g. vaccines and blood products. Separate guidance for such laboratories is available.

These guidelines are consistent with the requirements of the WHO guidelines for good manufacturing practices and with the requirements of the International Standard ISO/IEC 17025.

Compliance with the recommendations provided in these guidelines will help promote international harmonization of laboratory practices and will facilitate cooperation among laboratories and mutual recognition of results. Special attention should be given to ensure the correct and efficient functioning of the laboratory. Planning and future budgets should ensure that the necessary resources are available inter alia for the maintenance of the laboratory, as well as for an appropriate infrastructure and