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

energy supply. Means and procedures should be in place (in case of possible supply problems) to ensure that the laboratory can continue its activities.

The GPCL Guide contains requirements for all critical aspects of laboratory activities, for example:

- qualification of equipment and validation of analytical procedures,
- risk analysis for measurement quality,
- quality management system (QMS),
- staff competency etc.

The main risk factors for the quality of laboratory measurement results are: personnel, premises, equipment, instruments and other devices, materials, reagents, reference substances and reference materials, calibration, verification of performance and qualification of equipment, instruments and other devices, working procedures, incoming samples, analytical worksheet, validation of analytical procedures, testing, evaluation of test results, certificate of analysis, retained samples and some other.

All these risks need to be systematically identified, assessed and eliminated or minimized with the help of an effective quality system.

The quality management system is aimed not only at ensuring the stable functioning of all processes, but also at continuous improvement due to the systematic analysis and improvement of processes affecting the quality of testing. The QMS should cover planning, risk assessment, auditing, corrective and preventive actions, etc. The QMS is aimed not only at ensuring the stable functioning of all processes, but also at continuous improvement by systematic analysis and improvement of processes that affect on tests. The QMS should cover planning, risk assessment, auditing, corrective and preventive actions (CAPA), etc.

Aim: Development of a set of proposals for the formation of QMS at the domestic laboratories for medicines quality control.

Materials and methods. To carry out our research, we carried out studies on the provisions of GPCL, ISO 9001 and ISO 17025 as part of an overall management system based on the quality risk analysis approach needed to create, implement, operate, monitor, review, maintain and improve of QMS.

Results and discussion. In our work the general algorithm implementation of the system was proposed and developed some sample documents: Quality manual; some standard operating procedures; forms of required entries. We also formulated proposals for the compilation of the basic documentation of the laboratory QMS, proposed are standard job descriptions of personnel involved in the functioning of the laboratory's quality system, and corresponding documented procedures.

Conclusions. Expected changes in the implementation of QMS: operational regulation of activity (system flexibility); minimizing losses of time and resources; improving team discipline; reducing the number of errors and inconsistencies at all levels of the laboratory; improvement of the workflow system; clearer distribution of responsibility; increase employee motivation etc.

DETERMINATION OF RISKS OF PROCESSES OF THE QUALITY SYSTEM OF DISTRIBUTOR OF MEDICINAL PRODUCTS

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Introduction. A pharmaceutical distributor must have a fully developed and properly functioning pharmaceutical quality system, including good manufacturing practices and risk management for quality. This system must be fully documented, and its effectiveness is controlled.

Risk management for the quality of medicinal products is an activity that can not be just a formal fulfillment of the Licensing Terms. It is an integral and very important component of the pharmaceutical quality system. Quality risk management is a systematic process for the overall assessment, control, reporting and review of risks to the quality of the medicinal product during its life cycle.