Conclusions. The analysis of modern principles of the development of the pharmaceutical quality system based on, in particular, the risk-orientated approach to conducting basic business processes is carried out.

Participated in a development of a risk-oriented approach to external audits implemented at Valaritin Pharma LLC.

Based on the application of the risk-oriented approach, the relevant standard operating procedures and forms of documentation introduced by the PQS of the enterprise have been developed.

The application of the risk-oriented approach to external audits has made it possible to optimize the use of human and financial resources of the company in support of this process.

EXECUTION OF EXTERNAL QUALITY CONTROL IN MEDICAL LABORATORIES OF BACTERIOLOGICAL PROFILE

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Introduction. External quality control of laboratory research is one of the methods for ensuring the proper functioning of clinical and diagnostic bacteriological laboratories. The result of determining the sensitivity of microorganisms to antibiotics depends on many factors, the arbitrary change of any of which can lead to biased and false results of the study.

Aim. The purpose of our research was to identify systematic and random errors in the development of the disk diffusion method and to achieve comparative results obtained by laboratories participating in interlaboratory quality control.

Materials and methods. Determination of microorganism's sensitivity and interpretation of the results were carried out in accordance with the order of the Ministry of Health of Ukraine No. 167 of April 5, 2007 "On Approval of Methodological Instructions" Determination of Sensitivity of Microorganisms to Antibacterial Drugs ".

Control strains of Staphylococcus aureus ATCC 25923 (F-49), Escherichia coli ATCC 25922 (F-50), Pseudomonas aeruginosa ATCC 27853 (F-51). The cultures for everyday use were weeded on beetroot meat peptone agar and kept in a refrigerator at a temperature from +2 to +4 0 C.

For sowing, daily cultures were used for the test- state. We used standard industrial drives with different kinds of antibiotics.

Determination of the sensitivity control strains to antibiotics was performed for 10 consecutive days. Test results for each individual strain to carry the protocol.

Process control is one of the key elements of the quality management system and is a control over the actions taken during the handling of samples and in the research process in order to ensure correct and reliable results. Quality control checks the actions related to the study period.

The purpose of quality control is to identify, evaluate and correct errors that occur due to problems with the analytical system, due to working conditions or unlawful actions of employees, before a report will be issued with the results of patient analysis.

Quality control is part of quality management, which aims to meet quality requirements (ISO 9001). The goal of quality control is to check the accuracy and reproduction of laboratory tests to release reports with the results of patient analysis.

The source of the problems should be identified and eliminated before the patient's analysis results are published. Laboratories should strive to use high-precision methods and always follow standard operating procedures. To resolve issues related to quality control, it is useful to establish rules and procedures for corrective action. Consider the following possible causes:

- damage to nutrients, reagents, antibiotic disks, damage to control material (strains of microorganisms), employee mistake;
- non-compliance with the manufacturer's instructions;

- problems with the equipment. In many bacteriological studies, quality control is not as easy as in other laboratory studies.

Therefore, in addition to traditional methods of quality control, the perfect implementation of other processes in the quality system becomes of particular importance. Below are some important general principles of quality: sample testing is an important aspect for all laboratory tests.

For studies that depend on the presence of living organisms in samples, it requires:

- more precise control and better interaction with the laboratory staff, motivated by skilled personnel who understands that compliance with the quality control principles is a merit of quality;
- thermostats, refrigerators, microscopes, steam sterilizers and more. equipment must be carefully serviced and carefully monitored;
- positional and negative controls should be used to check the effectiveness of those analyzes using special strains h reagents;
- reagents should be kept in accordance with the manufacturer's instructions, indicated by the date they were opened and started to be used and should be written off after the expiration date;
- for the continuous improvement of the quality system in the bacteriological laboratory, it is necessary to keep records of all processes of quality control and corrective actions, in case of problems, find and eliminate their source, and then repeat the analysis.

Conclusions. The laboratory should put in place a quality control program for all analyzes. To enter this program, set the rules. Train employees, share responsibilities, and provide staff with all necessary resources for this.

Ensure that the quality control data is complete and that these data are reviewed by the quality officer and the laboratory manager.

CONFORMITY ASSESSMENT OF THE PHARMACEUTICAL COMPANY'S DOCUMENTATION IN ACCORDANCE WITH THE ISO 9001 REQUIREMENTS

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Introduction. The urgency of good documentation of all activities at a pharmaceutical company is the following:

- necessity of formulation and transfer of goals and objectives from management to all levels of the organization;
- ensuring coherence among participants in all processes of a company;
- providing objective evidence of the proper implementation of processes and the conformity of products (services) to the established requirements;
- creating a real basis for making managerial decisions based on a factual data and continuous improvement of activities.

Correctness of the material in the document depends on the correctness of the action. Clarity, conciseness, visibility and uniqueness are characteristics that determine the perception of documents by their users. There are quite a lot of regulatory requirements for the content and structure of Quality Management System (QMS) documents, but they are very common.

Aim. The aim of our research is review of requirements for the document management process within the framework of the quality management system of the organization on the model of the standard ISO 9001 and development of methods for assessing the quality of internal documentation.

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 QMS of pharmaceutical companies.