- 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.

The object of research was a quality management system of the pharmaceutical distributing company, built on the requirements of ISO 9001 and GDP.

The subject of our research was the document flow process of the pharmaceutical distributing company.

Results and discussion. A large number of documentation is used in the pharmaceutical distribution company:

- documented quality policy and quality objectives;
- Quality Manual;
- documented procedures;
- documents, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes, records, etc.

"Document Management" is one of the most important in the group of supporting processes of the Quality Management System functioning of any organization. Each QMS process must be carried out according to the PDCA Cycle:

- **P**lan – process planning;
- **D**o – realization of the process according to the plan;
- **C**heck – evaluation of the process results, analysis of trends, definition of current and potential nonconformities and their causes;
- **A**ct – realization of a corrective and preventive actions to improve.

We have developed the procedure for assessing of compliance of the QMS documentation with the requirements of ISO 9001 (Table 1).

The procedure establishes to define the controls needed:

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled,

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The developed procedure is aimed at checking not individual documented procedures, but in general document systems of a company. A block diagram of the development of the SOP is provided, which involves the stage of application of our procedure. Document checking will detect "bottlenecks" of a document flow system and take appropriate corrective actions to reduce the risk of a nonconformities.

We have also developed a procedure for assessing the quality of the QMS documented procedures (for example, SOPs). The procedure allows to assess the quality of the developed documented procedures on a 4-point scale from the point of view of users by the following parameters:

- Convenience of the procedure (visibility, clarity, clarity of text and figures).
- Correctness of the structure of the SOP (compliance with the content of the SOP set by the general requirements).
- Description of the algorithm for the execution of the procedure (completeness and accuracy of the statement of instructions and requirements).
- Style of the text of the procedure (lexical and orthographic quality of the document).

When using the procedure for an expert (or expert group), it is necessary to fill out special questionnaires that we have developed.

Table 1. Document evaluation protocol

Type of document	Requirements for documents control (4.2.3, ISO 9001)						
	(a)	(b)	(c)	(d)	(e)	(f)	(g)
	to approve documents for adequacy prior to issue	to review and update as necessary and re-approve documents	to ensure that changes and the current revision status of documents are identified	to ensure that relevant versions of applicable documents are available at points of use	to ensure that documents remain legible and readily identifiable	to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled	to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
4.2.1 (a) Documented statements of a quality policy and quality objectives							
4.2.1 (b) A quality manual							
4.2.1 (c) Documented procedures and records required by ISO 9001							
4.2.1 (d) Documents, determined to be necessary to ensure the effective planning, operation and control of its processes							

Note: The dark gray color of the table field indicates that this requirement is not applicable to the corresponding document type. Light gray indicates that this requirement is applicable in part (not applicable to all types of documents).

Conclusions. Application of the developed procedures will allow to improve the quality of the developed documented procedures. It will also improve the entire document management system of the company. The research results proposed for implementation at several pharmaceutical companies.