Conclusions. The having read the regulatory basis for the process of importing medical devices and instructions for their import into the territory of Ukraine, it should be noted that the norms of circulation of medical devices are confirmed by a clear approach of state regulation in this field and revealed a number of inconsistencies in the regulatory framework, which need to be paid attention and introduced with European standards.

OPTIMIZATION OF THE INTERNAL AUDIT PROCEDURES
AT A PHARMACEUTICAL ENTERPRISES
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Introduction. Functioning of the Quality Management Systems (QMS) at any pharmaceutical companies requires mandatory systematic internal audits.

The more effectively the internal audit is performed, the more effective is the quality management system of the organization.

Given the important importance of quality assurance of medicines, the issue of audits for domestic pharmaceutical companies is particularly relevant.

A large number of domestic pharmaceutical companies do not pay due attention to audits, often performing them formally or not taking care of their performance.

Aim: identify the roles and analyze current approaches to conducting internal audits of the quality management systems of drug companies, in compliance with ISO 9001 and GMP requirements, and develop application suggestions for optimizing the audit process of the research object.

Research objectives:
– analyzing of the regulatory requirements for internal audits of QMS;
– studying the experience of audits on the basis of pharmaceutical companies;
– developing of the proposals for optimization of the main stages of the audit process for their implementation on the pharmaceuticals companies.

Object of research: quality management system of a manufacturing pharmaceutical enterprise.
Subject of research: the process of internal audits of QMS.

Materials and methods. To carry out our research, we carried out studies on the provisions of ISO 9001 and ISO 9000 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.
Often, the following are not available at Ukrainian pharmaceutical companies:
– the methodology for evaluating the performance of the audit process and the relevant eligibility criteria;
– rules for asking questions in questionnaires (audit checks);
– rules and criteria for the systematic assessment of the competences of internal auditors and experts involved;
– application of PDCA methodology and others.

Critical audit elements we have identified:
– Audit planning and preparation of audit reports within the PDCA cycle.
– Selection of the audit team.
– Developing questionnaires and maintaining other audit documents.
– Professionalism of auditors.
These elements of the audit process are governed by the Documented Procedure (DP), which is included in the annexes to the master's work.

It is proposed to regulate the audit process in terms of PDCA methodology:

- Development of internal audit programs and procedures, preparation of an audit team (Plan).
- Program Implementation (Do).
- Audit Data Collection and Evaluation (Check).
- Improvement of audit procedures (Act).

Suggested phases of audits:

- planning of the audit program (formation of groups, distribution of responsibilities and authorities, development of audit schedules etc.);
- performing the audit procedures (filling in the forms of meetings, check-lists, protocols for recording of nonconformities (comments, recommendations), drawing up reports, corrective action plans etc.);
- evaluation and analysis of the implementation of the audit program (completion of forms of assessment of auditors, forms of evaluation of audits performance);
- improvement of the audit process by taking corrective and preventive actions in the framework of audit procedures.

The documented procedure for performing the audit process includes:

- description of the inputs and outputs of the audit process;
- description of all phases of the PDCA audit cycle;
- performance indicators of the audit process;
- on-site audit algorithm etc.

Considerable attention is given to the preparation of questionnaires: the value of the audit results depends on the correct formulation of the questions directly.

To motivate the auditors, we have developed a form of assessing the quality of their work by 14 indicators (carried out after each audit). The assessment is carried out by the Chief Auditor or the Deputy Director of Quality.

Conclusions.

Our approaches have already been partially tested in the internal audits. Following the audits, a report was prepared, a discrepancy statement, comments and recommendations were prepared, and a corrective action plan was developed.

DEVELOPMENT OF A SET OF PROPOSALS FOR IMPROVING
OF A SERVICE QUALITY FOR PHARMACY VISITORS
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Introduction. The pharmacy's efficiency implies compliance with current quality management concepts and Good Pharmaceutical Practice (GPP) requirements. At the same time, the quality of pharmaceutical services must meet not only state standards, but also consumer expectations.

Today, competition between pharmacies is very serious, so improving customer service is a necessary and important condition for maintaining business.

Aim. Development of a program for optimizing of a typical pharmacy activity to improve of pharmacy service quality and increase competitiveness. The subject of our research is a pharmacy quality system processes that ensure quality of service and customer satisfaction.