# THE PROCESS OF REGULATION INTERNAL AUDIT QUALITY MANAGEMENT SYSTEM

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**Introduction.** Internal Audit (IA) is an integral part of the quality management system (QMS), it allows you to objectively evaluate the operation of the QMS by power, checking the effectiveness of its processes and determines the potential to improve and enhance organizational performance.

Every modern company, including pharmacy companies, which seek to enhance its competitiveness through implementation QMS must adhere to the principles of objective, documented and professional audits, set out in ISO 19011.

**Aim.** The aim of our research was to study the provisions of ISO 19011: 2011, including: principles of VA approaches to management programed IA of IA methods, and assessment of competence of persons involved in the audit process. The study of these provisions would-standard helped us in developing proposals for regulation applied to the IA - on a typical pharmaceutical distributive company.

**Materials and methods.** Typically, domestic enterprises rarely describe the whole process IA in documentary form, leading to numerous violations in the conclusion-no audit, and as a result - to obtain false or incomplete information and incorrect understanding of the continuous improvement process in QMS.

We believe that all activities related to IA necessarily non-necessary to regulate the procedure documented in the cycle PDCA («plan-do-check-act»): This will enable sufficient detail algorithm process - from setting goals and formation program audit steps for its implementation, monitoring, critical analysis ways to continually improve process IA.

**Results and discussion.** We have formed recommendations on program development IA defined process steps, outlined the role of each in achieving the objectives of the audit proposed content documented procedure that includes a description of the following stages: initiation of the audit; IA formation program; of planned audits; preparing reports on IA; assessment of process- IA; taking action to improve the process of IA.

**Conclusions.** We believe that detailed regulation process IA setting clear goals and objectives for internal auditors, which reduces the risk of inconsistencies, but also can be used for training persons involved.