

One of the important stages of the study is the analytical stage. In its course, a generalization and analysis of the final results takes place.

The formation of conclusions and recommendations occurs in the following areas:

1. Does the organization (unit) have sufficient social and psychological resources to change and achieve its goals?
2. What are the limitations and potential for effective individual and group activities of the team as a whole?
3. What socio-psychological factors affect the increase (decrease) in personnel efficiency?
4. Under what conditions will the collective potential be realized to the maximum extent?
5. How and in what areas is it necessary to develop a system of managerial influences to optimize the activities of the enterprise (unit)?

At the final stage, they summarize the diagnosis and research.

Conclusions. A favorable socio-psychological climate is a condition for increasing labor productivity, satisfaction of workers, work and the team. Socio-psychological climate arises spontaneously. But a good climate is not a simple consequence of the proclaimed mottos and efforts of individual leaders. This is the result of systematic educational work with team members, the implementation of special events aimed at organizing relations between managers and subordinates. The formation and improvement of the socio-psychological climate is a constant practical task for managers of any rank. Creating a favorable climate is not only responsible, but also creative, requiring knowledge of its nature and means of regulation, the ability to provide a reliable situation in the team's relationship.

DEVELOPMENT OF MEASURES TO INCREASE THE COMPETENCE OF INTERNAL AUDITORS OF PHARMACEUTICAL QUALITY SYSTEMS

Fedotov A. S.

Scientific supervisor: prof. Pidpruzhnikov Y. V.
National University of Pharmacy, Kharkiv, Ukraine
quality@nuph.edu.ua

Introduction. In addition to expanding product range and technical modernization, many pharmaceutical companies' management aims to improve the quality management system (QMS). One of the important processes of QMS is internal audit, the development of which is given considerable attention. Audit directly affects the quality of the implementation of all processes of the organization, as a consequence - the quality of products. The competence of the auditors depends on the value of the audit results, as well as the attitude to the quality issues by the staff. Audit confidence depends on the auditors' competence. The auditors should demonstrate:

- proper personal qualities;
- ability to apply professionally knowledge, skills and experience in conducting the audit;
- depending on the audit program, the organization must always determine the required level of competence of all internal auditors.

So, components of the auditor's competence are the professional knowledge, personal qualities required, experience and skills.

Aim: to substantiate the relevance, to analyze and to offer a rational approach to training of internal auditors of the quality management system based on a pharmaceutical company.

Research objectives:

- an overview of the ISO 9001 and 19011 standards;
- defining the necessary knowledge, skills and personal qualities that quality auditors should possess;

- identifying effective approaches, methods and tools for the training of the internal auditors;
- development of a set of proposals for training and control of competence of the internal auditors of a pharmaceutical company.

Object of research: quality management system of a manufacturing pharmaceutical enterprise.

Subject of research: the process of internal audits training.

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.

Professional auditor's knowledge and skills:

- knowledge, understanding and ability to interpret ISO 9001 and all industry requirements;
- knowledge and ability to audit in accordance with the provisions of international standard ISO 19011;
- ability to generate ideas to improve and optimize organization and product processes.

Our auditor selection conditions are:

- profile education (e.g. "Quality, Standardization and Certification")
- internship (minimum 2 internship audits);
- experience (at least 2 years in quality);
- honesty, openness, sociability, impartiality, diplomacy, receptivity;
- analytical thinking;
- ability to clearly formulate thoughts.

When planning auditor training, we consider it necessary to determine:

- objectives and requirements of the organization for the audits of QMS;
- substantiation of training needs;
- purpose and scope of training;
- target groups of selected applicants;
- learning methods, content of training courses;
- person responsible for training.

Required resources for the implementation of the curriculum:

- training schedule (duration, timing and main stages of training);
- training procedures (for teachers);
- methodical materials, visual aids;
- knowledge diagnostic tools (criteria and methods developed to evaluate the learning outcomes and performance appraisal of auditors).

We have developed the training program for internal auditors, focused on 50 hours of lectures and 40 hours of practical training. The training program contains test assignments on the materials of lectures and practical lessons necessary for the diagnosis of mastering the material.

Conclusions. It is proved that proper training of internal auditors makes the audit process really effective, and a comprehensive analysis of the QMS is truly valuable for senior management. The directions and stages of auditor training are suggested. Recommended topics and types of classes. Examples of tasks and methodology for diagnostics of auditors' competence are developed. The universal training program for internal auditors has been prepared.