

DETERMINATION OF AUDIT GROUP MEMBERS' COMPETENCE AT PHARMACEUTICAL ENTERPRISES

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Introduction. The competence of quality management system (QMS) auditors in general and pharmaceutical quality system (PQS) in particular consists of personal qualities and professional knowledge and skills. Given the importance of internal audits (IA) for the pharmaceutical company (PC), which is indicated in the guidelines for good practices in medicines (in particular, GMP, GDP), the issue of selection, training, certification and continuous improvement of the auditor's competence at PC are relevant and important both for domestic ones, and for foreign enterprises.

As a result of the regulatory information sources analysis one can state a certain lack of information concerning specific requirements for the qualification and competence of the personnel involved in the IA. Therefore, in our opinion, it is expedient for the PC to use the provisions of the national standard DSTU ISO 19011: 2012, which contains recommendations for the effective organization and conduction audits of management systems.

ISO 19011 highlights the importance of evaluating the auditors' competence. Such an assessment should take into account the needs of the audit program and its objectives. This provision of the standard should be considered relevant for PC.

Aim. The aim of the study was to determine component of PQS internal auditors' competence to organize scientifically grounded selection of members to the audit team and their further training.

Materials and methods. We used methods of empirical research and comparative analysis. The information basis for the study was the materials published in the open scientific and professional literature, the regulatory requirements of the standards and instructions for QMS and PQM.

Results and discussion. We have argued that the criteria for determining the internal auditors' competence at PC should be determined taking into account the general requirements for the QMS (ISO standards of the 9000 series), the requirements for the audit process (ISO 19011), and the profile requirements for the PQM of the enterprise (GMP guidance, the licensed conditions of the activities on the production and sale of medicines).

In many cases, the audit team includes the group manager (chief auditor), the auditor (s) and expert (s) whose competence was the subject of our study.

Table 1 provides a general list of knowledge and skills of members of the audit team. The "X" mark means that the PC must establish appropriate requirements for each member of the group. More detailed knowledge and skills of group members reviewed further in the text (indicated in the table refer to the relevant paragraphs of text).

Table 1

№ by order in the text	Knowledge and skills	Audit group members		
		Chief Auditor	Auditor	Expert
1)	Knowledge of the basics of management	X		
2)	Awareness of the products and processes at the PC (enterprises manufacturing / distributing medicine)	X	X	X
3)	Knowledge of the specifics of the object of the specific audit (process / unit of PC)	X	X	X
4)	Knowledge of the PQS' functioning requirements	X	X	
5)	Knowledge and skills of managing the audit process and managing the group of auditors	X		
6)	Knowledge of audit principles, tools and methods	X	X	

7)	Skills for making a programs and audit plans, record keeping and reporting	X	X	
8)	Knowledge of professional terminology	X	X	
9)	Skills of public speaking, communication with the audience, conflict resolution	X		
10)	Surveying skills, interviews	X	X	

- 1) Knowledge of the basics of management. Relevant knowledge provides an understanding of the organization management principles, taking into account its size, ownership, organizational structure, existing information system, data storage, systems of document circulation, information technologies. It also includes knowledge of legal requirements applicable to PC. There is also a need for awareness of the division of responsibilities and authority, reporting, evaluation of the quality of work performed by the object of audit, etc.
- 2) Awareness of the products and processes of PC (enterprises producing or distributing medicines). It is assumed that there is knowledge about products and processes in the operation at the PC, sufficient for a full understanding by the group members of applicable criteria of a specific audit (standard, guidelines or other normative document).
- 3) Knowledge of the specifics of the object of the specific audit (the object is usually a process or unit PC). This information on the type of products or features of a specific PC process is needed for accurately determination of the audit terms, the plan preparation, questionnaires and other accompanying audit documents.
- 4) Knowledge of the PQS' functioning requirements. Knowledge of Good Practice Guidance (GMP / GDP) requirements and other regulatory documents that PC is govern. Knowledge should be sufficient to determine the state of functioning of the PQM and its compliance with established requirements.
- 5) Knowledge and skills of managing the audit process and managing the group of auditors. Ability to manage the audit process to achieve the established audit objectives within agreed timeframes. This knowledge is needed for the head of the audit team who should hold meetings professionally, to ensure the effective exchange of information between members of the group and the subject of audit, to assign tasks and to modify them as necessary, to apply moderation principles and to monitor the dynamics of group processes, to be able to effectively resolve disputes, to prove the need for certain decisions of the audit team, to balance the strengths and weaknesses of the individual members of the audit team.
- 6) Knowledge of the audit principles, appropriate means and methods. Knowledge of the basic principles, practices and techniques of conducting audits in a sufficient amount for the realization and objective assessment of the audit activity.
- 7) Skills for making a programs and audit plans, record keeping and reporting. Ability to develop supporting documentation, quickly registers information, create records and compile reports on the results and conclusions of the audit.
- 8) Knowledge of professional terminology. Ability to effectively communicate with employees of different positions at any level of the organization, using appropriate profile terminology, expressions and professional language.
- 9) Skills of public speaking, communication with the audience, conflict resolution, etc., including the ability to clearly present the results and conclusions of the audit. It is especially important for the head of the audit team to present the relevant audit findings, conclusions and recommendations (for example, at the final meeting).
- 10) Surveying skills, interviews. Ability to receive relevant information during an interview with representatives of the audit object, asking well-formulated questions, understands and evaluates responses.

The functions of this staff can be performed either by one or a large number of staff members, depending on the specifics of the PC. If it is a small PC, while selecting a candidate in the auditor, you need to focus on the requirements for the competence of the chief auditor.

Conclusions. Clearly defined requirements for the competence of the PQM audits staff assists the selection of specialists to the audit team so that the overall competence of the audit team is sufficient to achieve the objectives of the audit. In the future, we plan to develop an extended list of auditor's competencies, as well as recommendations for their training and certification.