

CLASSIFICATION OF QUESTIONS USED TO OBTAINING INTERNAL AUDIT EVIDENCE FOR PHARMACEUTICAL QUALITY SYSTEMS

Karamavrova T. V.

Scientific supervisor: prof. Lebedynets V. O.
National University of Pharmacy, Kharkiv, Ukraine
karamavrova.qms@gmail.com

Introduction. In accordance with GMP EC requirements, self-inspections (internal audits, IA) should be systematically conducted to evaluate the effectiveness and suitability of the pharmaceutical quality system (PQS) at manufacturing and distribution pharmacist companies (PC).

According to previous studies, it was established the main reason for the low IA effectiveness is found to be the lack of professionalism of the auditors, which is reflected in, for example, the lack of a constant ability to conduct interviews, analytical monitoring of staff work, proper audit evaluation and interpretation of different work situations. Poll-related issues include the focus of such an effective audit method only on finding non-compliance with specific regulatory requirements, but not on determining the functioning of the individual process and PQS as a whole. Often, when auditors conducting the questions, they are of a formal nature and are closed-ended questions. In addition, auditors ask questions not only about the audit object identified in the plan, but also about other activities performed in the unit. At the same time, it is known that the focus of the IA is not on the functioning of the PQS processes, but rather on the activities of the units complicates and slows down the audit procedure and increases the risks of failure to achieve the audit objectives.

Aim. The purpose of the study was to analyze approaches and develop suggestions for interviewing staff in conducting IA to collect the evidence needed to make objective, impartial audit decisions.

Materials and methods. The basis for the study were sources of scientific literature of foreign and domestic scientists, ISO 9000 standards, the regulatory framework of the pharmaceutical field of health care related to the functioning of PQS, as well as the results of own studies on the analysis of the IA process on PC. The methods of empirical research were used in the work: systematic-analytical, sociological questioning, comparative analysis, structural-logical modeling.

Results and discussion. Most often, the following methods are used when conducting audits:

- analyzing of documented information;
- interviewing employees at the audited entity;
- observing the activities of the staff at the audited entity.

Interviewing is the most applicable audit method that, unfortunately, is not given proper attention. Based on the results of our research, we find that it is advisable to conduct the interview at certain stages.

It should be noted that conducting a productive interviews involves a certain order of the questions. The process-oriented questions allow you to trace the actual implementation of the PDCA methodology within each audited process. During such an audit, it is possible to evaluate the implementation of all phases of the PDCA cycle - from planning to taking action to improve the process.

At the stage of auditing the planning process, it is advisable to address the process manager with a question. The questions should relate to the distribution of responsibilities and powers among the contractors, maintaining the required level of professional training, awareness of the documented procedures, availability of necessary resources and other aspects.

It is known that any questions of the auditors can have a psychological impact on the interlocutor, so the auditor should be tactful and ask questions of a neutral nature. Audit evidences are considered to be objective only if they are supported by the relevant facts. Otherwise, such evidence is subjective and therefore cannot be used by the auditor to make a decision and report.

It is proved that during the audit it is necessary to use the question-request form: "Could you (show, demonstrate, explain, justify)...., please?". In this case, the interlocutor will not feel pressure from the auditor, and the format of the audit will be open and friendly.

We offer a classification of questions that can be used during IA PQS. Therefore, by its focus, the questions can be divided into:

- main - used to find out the subject of communication; focus on specific audit topics;
- additional - used to detail the interlocutor's answer when the answers to the basic questions are too short.

In turn, it is suggested to divide the additional questions into:

- reminders (help to flesh out the answer),
- clarification (help to disseminate information about the subject of the interview),
- control (used to confirm the collected facts).

Control questions are often revealing when auditors identify differences between actual actions and the documented requirements of an audited entity. It is also a good practice to use detailed questions to confirm the collected data and sources of information. The scheme of classification of audit questions is shown in Fig. 1.

The choice of one type of question depends on the specific purpose of the interview and the situation in which it is conducted. In most cases, it is advisable to ask questions that will be answered and provided with explanations (open-ended questions). Questions that require short yes or no answers (closed) are often uninformative, especially during internal audits.

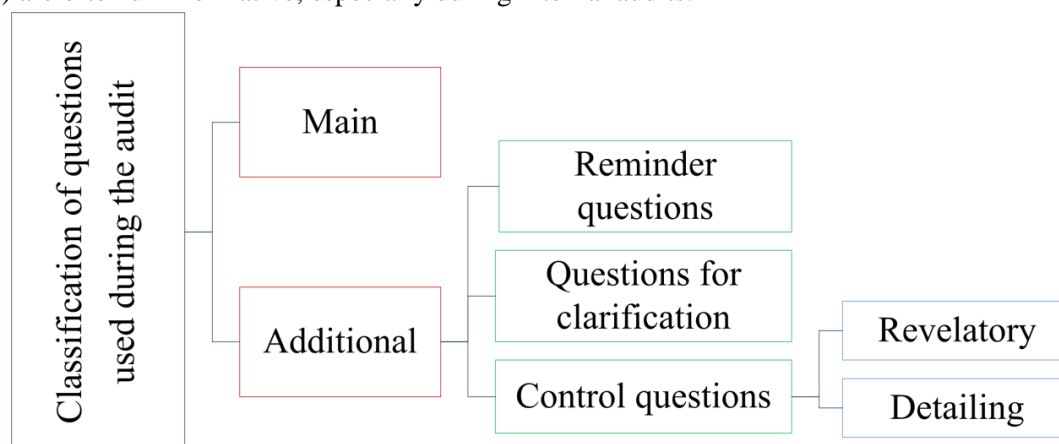


Fig. 1. The classification of questions used during the audit

Choosing the right question formulation is crucial to achieving the goal of the interview.

Conclusions. It is argued that the interview, as a key method of conducting PQS audits, are an important tool for collecting and interpreting audit certificates. In addition, conducting the interview requires careful preparation of appropriate documentation and auditors' competence regarding the audit process and criteria.

It is proven that following the recommendations in practice saves time for preparing and conducting audits; specify the subject matter of the audit and expand the amount and content of the information recorded during the audit; it is better to prepare the auditors and obtain more useful audit results.

In the future, we plan to develop a set of applied recommendations for the organization of audit activities on PC.