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A Study on Focusing the Increasing Competence of Pharmaceutical Quality Systems' Internal Auditors

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Abstract

The significance of internal audits for the pharmaceutical industry, as stated in the recommendations for excellent pharmacy practises (in particular, GMP, GDP).

The topic of auditor selection, training, grading, certification, and continual development in pharmaceutical firms is relevant and vital for both local and international enterprises. The study's goal was to identify the competency of pharmacy quality system internal auditors and opportunities for growth.

Materials and methods. *The study's focus was on the competency of pharmaceutical quality system internal auditors. Empirical and theoretical research methodologies were employed, most notably the method of comparative analysis of scientific literature in the subject of study, as well as the method of structural and logical modelling. The terms of rules and materials available in open professional scientific literature served as the information foundation.*

Results *The capability of the quality management system Personal attributes, professional knowledge, and abilities are required of auditors in general, and pharmaceutical quality systems in particular. The ISO 19011 standard emphasises the significance of evaluating and continuously developing auditor competence. Such an evaluation should take into consideration the audit*

program's requirements and objectives. The details of industrial activities should decide the areas of growth of auditors' competence. This standard requirement should be deemed significant for pharmaceutical businesses.

Conclusions. *We investigated the requirements for the competency of QMS internal auditors in accordance with international and industry standards. A assessment of the regulatory framework revealed a dearth of information on the research topic of choice. Defined standards for the competency of PQM audits personnel aid in the selection of specialists for the audit team so that the audit team's total competence is sufficient to meet the audit's objectives.*

Keywords*: internal audit, auditor, quality management system, pharmaceutical quality system, ISO 9001, ISO 19011, phar- maceutical company, auditor competence.*

INTRODUCTION

Internal audits (IA) of pharmaceutical quality systems (PQS) are conducted in Ukraine in accordance with a number of regulations, including the Resolution of the Cabinet of Ministers of Ukraine No 929 of November 30, 2016 «On approval of licencing conditions for business activities for the production of medicines, wholesale and retail trade in medicines» (licensing con- ditions, LC) [1], T-H MOH of Ukraine 42-4.0:2020 Guidelines «Medicines. Good Manufacturing Practice» (GMP Guidelines) [2], MOH of Ukraine 42-4.3:2011 Guidelines «Medicines. Pharmaceutical quality system (ICH Q10)» [3].

The availability of competent and qualified employees to carry out all tasks is regulated by GMP Guidelines, LC [1, 2]. Such restrictions, in particular, pertain to the IA process. Given that good IA allows the management of the Pharmaceutical Company (PhC) to examine the operation of a specific process or the PQS as a whole, they are of substantial value [3].

Requirements for required audits are also outlined in ISO 9001:2015 «Quality Management Systems: Requirements» (paragraph 9.2), while general suggestions for management system audits are outlined in ISO 19011:2018 [4, 5].

The professional title «Quality Systems Auditor» is defined in the Ukrainian National Classification «Occupational Classification» SC 003:2010 (here and elsewhere on the text «Classifier», occupation code number 2411.2). The classifier determines a specialist's credentials for performing professional activities. Professional competence is required for qualification [6].

Simultaneously, the term "professional competence" should be understood not only as knowledge of the requirements of relevant guidelines and standards (GxP Guidelines, ICH Q10, ISO 9001, etc.), but also as a specific set of personal qualities and existing skills that enable audits at a high professional level. Competence is defined as the demonstrated ability to use information and skills [6].

Our sociological research at certain Ukrainian PhCs revealed that auditors' lack of expertise is one of the primary causes of issues with IA effectiveness [6, 7].

At the same time, no such experts are trained in Ukrainian educational institutions, including the pharmaceutical sector of health care. Some universities teach auditors in the context of other industrial specialities [8].

Currently, the pharmaceutical industry's need for such professionals greatly outstrips educational institutions' capacity. For these reasons, firms conduct their own auditor training and grading. A company seldom seeks outside specialists for auditor training and education. Such activities result in a lack of consistent ways to auditor training and long-term techniques of measuring their competency. As a result, the audits themselves have drastically varying levels of professionalism.

Many writers [9, 10, 11] have investigated the topic of providing pharmacological expertise at the higher education level. The skills of PhC employees, in particular, were researched and specified in the works [12, 13, 14]. In addition, the functional modular-competence model of the quality assurance expert for PhC was addressed in the works, as well as the curriculum of preparation for such specialists [15].

Most studies show that the importance of competence in all of its meanings and facets most accurately reflects the industry's present situation. Introduction of distant technologies for market interaction,

the usage of which is now quickly increasing in all European nations and Ukraine. The provision of competence by PhC professionals, as well as their ongoing development, enables firms to compete.

Although the researchers emphasised the problem of the PhC staff's competency, we were unable to locate any works dedicated to establishing the competence of the PhC's internal auditors.

The study's goal was to identify the QMS internal auditors' competency and areas for advancement.

MATERIALS AND METHODS

The study's focus was on the competency of QMS internal auditors. The technique of comparative study of scientific literature in the field of research, as well as the method of structural and logical modelling, were utilised as empirical and theoretical research approaches. The terms of rules and materials available in open professional scientific literature served as the information foundation.

RESULTS

In prior study, we underlined that IA process performance indicators should describe the value of audit reports to management. First and foremost, such criteria should describe the value of audit reports for management, which is dependent on the company's choice to optimise it. It is related to the critical role of audits in the maintenance and development of QMS [8].

The worth of the reports can be assessed using an expert approach that employs appropriate questionnaires with specific evaluation scales. Such an evaluation should be performed after each auditor, under certain conditions, at the end of the audit programme [8].

We propose to evaluate the effectiveness of IA using questionnaires/evaluation forms, co- vering the following indicators:

- timely information;
- availability of information presentation;
- usefulness of information provided by auditors to senior management;
- existence of evidence of the submitted information and others.

It is the competence of auditors determines the ability to assess the level of functioning of the QMS, certain processes of the PhC or certain products.

In determining the competence of auditors, it is necessary to take into account audit criteria. There is a connection between the ability to apply knowledge and skills to achieve audit objectives. Thus, clearly defined audit criteria will make it possible to appoint appropriate competent specialists for the role of auditors in the audit team, so that the group has all the necessary knowledge and skills for a particular IA. According to ISO 19011, auditors must follow specific criteria that are compatible with the auditors' personal attributes and contribute to the audit being a dependable way of preserving management policy.

Adherence to ethical standards, honesty in the presentation of results, due diligence, confidentiality, independence, and an evidence-based approach are all prerequisites for ensuring reliable and reproducible audit findings, as well as a high probability that auditors working independently of each other will draw similar conclusions under similar circumstances [5, 6, 8].

In previous studies, we proposed to divide the competence of the auditor into three components:

- professional knowledge (general and specialized),
- skills and abilities,
- personal qualities.

The above-mentioned principles are executed in the presence of particular human qualities, which we discussed in depth in previous phases of the research [6].

Professional knowledge and skills are separated into two categories: specialist knowledge of Quality Management (and, in particular, the pharmaceutical business) and general knowledge and abilities in the organisation and conduct of IA.

Specialized knowledge can be defined as the requirements for the auditor qualification.

In practice, qualifications are assessed by indicators:

- basic education,
- practical experience,
- training.

Table 1 Indicators and criteria for the component competence of auditors

Qualification requirements for internal auditors of QMS	
Indicators	**Criteria**
Basic education	Higher pharmaceutical, technical or economic education; education of a specific type and subject area, which contribute to the development of specialized competence.
Practical experience	Experience in the quality field – not less than 3 years
Professional training	Professional education by the educational program «Quality, certification and standardization» (or simi- lar) and training in the training program of QMS auditors

General audit training should ensure the acquisition of up-to-date knowledge of audit practice. In turn, a well-trained auditor must possess and apply the necessary methods, know the principles and have the organizational skills to conduct the IA. In particular, auditors need to know and be able to:

- develop an audit program taking into account the objectives of quality management system;
- analyze and determine the criteria for the audited entity;
- identify and minimize the risks associated with the audit program and the IA process;
- develop a plan on-site audit;
- feed audit issues, make up and keep records in the checklist;
- communicate with employees (site, unit, process) within the audit object;
- analyze and evaluate the characteristics and performance indicators of the audit object, in order to identify evidence and generate audit data;
- objectively assess the information, situations observed during audits;
- formulate non-compliance reports and initiate CAPA development;
- compile protocols and reports by the IA results, etc [3, 5].

For the chief auditor, in addition to outstanding skills, one of the additional required skills is to evaluate the implementation of the audit program according to pre-established indicators. We have summarized the main indicators of professional knowledge and skills of auditors in 10 main blocks (Fig. 1). These blocks contain indicators related to general knowledge and skills of auditing, specialized knowledge in the field of QMS, and indicators of social and communi- cative abilities.

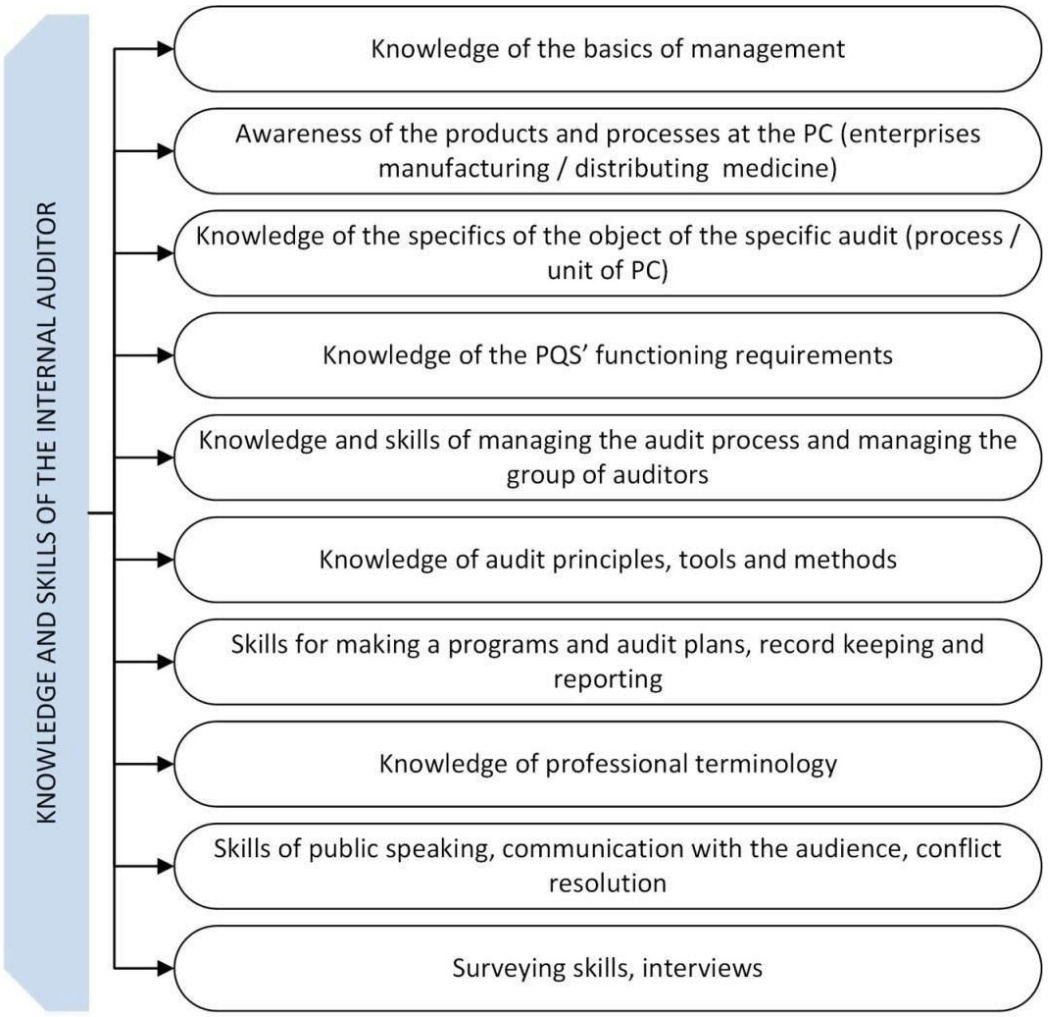

Fig. 1. Categories of knowledge and skills of internal auditors of the pharmaceutical quality system

The 10 blocks of QMS auditors' competence may include, but are not limited to:

- Management knowledge. 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 PhC. 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.;

- Awareness of the products and processes of PhC (enterprises producing or distributing medicines). It

is assumed that there is knowledge about products and processes in the operation at the PhC, sufficient for a full understanding by the group members of applicable criteria of a specific audit (standard, guidelines or other normative documents);

- Knowledge of the specifics audit object (the object is usually a process or organization unit of PhC). This information about the type of products or features of a specific PhC process is needed for accurately determination of the audit terms, audit plan preparation, questionnaires (check-lists) and other accompanying audit documents;

- Knowledge of the PQS' functioning requirements. Knowledge of Good Practice Guidance (GMP/GDP) requirements and other regulatory documents that PhC is govern. Knowledge should be sufficient to determine the state of functioning of the PQM and its compliance with established requirements;

- Knowledge and skills of the audit process managing and managing of the auditors group. Ability to manage the audit process to achieve the established audit objectives within agreed time-frames. 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;

- 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 reali- zation and objective assessment of the audit activity;

- Skills for making a programs and audit plans, record keeping and reporting. Ability to de- velop supporting documentation, quickly registers information, create records and compile reports on the results and conclusions of the audit;

- Knowledge of professional terminology. Ability to effectively

communicate with emp- loyees of different positions at any level of the organization, using appropriate profile terminology, expressions and professional language;

- 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);

- 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 [7].

Internal auditors' competency may be obtained and enhanced by reviewing professional trainings and seminars, both in the pharmaceutical and auditing fields. This area of professional growth should also involve obtaining extra education in a certain sector. For example, auditors who review the operation of pharmaceutical laboratories should have a background in pharmacy, clinical pharmacy, biopharmacy, chemistry, and so on.

Given that internal auditor activities are typically undertaken by workers in critical roles, it will be useful to organise auditor groups so that PhC personnel in relevant technical, management, or professional positions may share their knowledge. Self-evaluation, decision-making, planning, delegating, problem-solving, and communication with management, professionals, colleagues, consumers, and other stakeholders are examples of such experiences.

Auditing other management systems is considered best practise. External audits of suppliers and partners are examples of such audits. Invite professionals from other PhC to undertake an internal audit of your organisation. It should be acknowledged in advance that such audits are not undertaken to detect non-conformities in order to harm partners' reputations, but to exchange experiences and identify prospective directions for QMS growth. It is common practise for large PhCs with a high number of branches to move auditors from one branch to another, as each branch may have unique requirements. Such branching is inherent in distributive PhC, with one branch

specialising in medication that requires specialised storage and control requirements, and the other branch specialising in the circulation of medicine for general use and dietary supplements.

Acquiring competence on the basis of "exchange of experience" should be done under the supervision of an auditor with expertise in the same field. As a result, in order to improve the competence of the chief auditor/head of the audit team, responsibilities must be performed under the guidance and supervision of another auditor who has the audit team head's competence.

Additional internships at certifying bodies will also help to the development of general competence, we believe.

Study constraints. The stated research was conducted as one of the steps of a project to develop an educational and methodological package for PhC's internal audit procedure.

Further study will focus on building a PQS training programme, diagnostic tools for their competency, and determining and improving personal attributes.

CONCLUSIONS

The capacity of the IA to fulfil its objectives is dependent on faith in the auditors and their competence. Personnel participating in the design and execution of IA on PhC must have a sufficient degree of knowledge and skills, as well as personal attributes that will aid in the completion of tasks to meet the aim of IA. Furthermore, a suitable degree of established expertise of the auditor allows him or her to solve problems of various types during the audit at the site, to successfully analyse changes, and to foresee likely dangers.

Internal auditors must continually develop their skills. This may be accomplished in a variety of ways, including getting further job experience, training, internships, attending seminars, and so on. When determining the path of competence development, current trends in the pharmaceutical sector development must be considered.

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