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SOME ASPECTS OF ACTIVITY EVALUATION OF INTERNAL AUDITORS OF A PHARMACEUTICAL COMPANIES QUALITY MANAGEMENT SYSTEMS

An effective quality management system is a prerequisite for the effective and successful operation of any modern enterprise, including pharmaceutical companies. It is generally accepted that in such systems, the internal audit process is an important and integral part. The importance of internal audits for the diagnosis and timely adjustment of the pharmaceutical quality system is emphasized in all existing regulations from the proper practices of medicines (in particular, in the GMP and GDP) and in the national licensing conditions for the conduct of economic activities on the production, wholesale and retail sale of medicines. As for all other processes of the pharmaceutical quality system, the effectiveness of internal audits directly depends on the competence of the involved specialists. The level of auditors' training and their personal qualities acquire special significance for auditing activities.

The aim of the study was to develop approaches to assessing the activity of auditors, to determine the criteria for selecting candidates for auditors, and to determine the criteria for the audit process of the pharmaceutical companies' quality management system.

Results. The article substantiates the importance and proposed approaches to assessing the performance of internal auditors of quality management systems of pharmaceutical companies. A list of indicators and a description of the methodology for assessing the performance of internal auditors, as well as for assessing the effectiveness of the internal audit process, has been developed.

Conclusions. The proposed evaluation approaches provide an opportunity to measure the effectiveness of internal audits, identify trends in its changes, and apply corrective or preventive actions to improve the audit process.

Key words: internal audit; auditor; quality management system; pharmaceutical quality system; ISO 9001; pharmaceutical company; performance evaluation

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ДЕЯКІ АСПЕКТИ ОЦІНКИ ДІЯЛЬНОСТІ ВНУТРІШНІХ АУДИТОРІВ СИСТЕМ УПРАВЛІННЯ ЯКІСТЮ ФАРМАЦЕВТИЧНИХ ПІДПРИЄМСТВ

Дієва система управління якістю є необхідною умовою результативної та успішної діяльності будь-якого сучасного підприємства, у тому числі підприємств фармацевтичного профілю. Прийнято вважати, що в таких системах процес внутрішнього аудиту є важливою і невід'ємною складовою. Важливість внутрішніх аудитів для діагностики і своєчасного коригування фармацевтичної системи якості підкреслюється у всіх чинних настановах з належних практик лікарських засобів (зокрема, у настановах з GMP та GDP), а також у національних ліцензійних умовах провадження господарської діяльності з виробництва, оптової і роздрібною реалізації лікарських засобів. Як і для всіх інших процесів фармацевтичної системи якості, ефективність внутрішніх аудитів напряму залежить від компетентності задіяних фахівців, при цьому для аудиторської діяльності рівень підготовки кадрів, а також їх особистісні якості набувають особливого значення.

Метою дослідження стали розробка підходів до оцінювання діяльності аудиторів, визначення критеріїв відбору кандидатів в аудитори та визначення критеріїв результативності процесу аудиту системи управління якістю фармацевтичних підприємств.

Результати. У статті обґрунтовується важливість та пропонуються підходи до оцінювання діяльності внутрішніх аудиторів систем управління якістю фармацевтичних підприємств. Розроблено перелік показників та описано методіку оцінювання діяльності внутрішніх аудиторів для оцінювання результативності процесу внутрішнього аудиту.

Висновки. Запропонована методика оцінювання надає можливість вимірно характеризувати результативність внутрішніх аудитів, визначати тенденції її змін, вживати коригувальні чи запобіжні дії для вдосконалення процесу аудиту.

Ключові слова: внутрішній аудит; аудитор; система управління якістю; фармацевтична система якості; ISO 9001; фармацевтичне підприємство; оцінка результативності

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НЕКОТОРЫЕ АСПЕКТЫ ОЦЕНКИ ДЕЯТЕЛЬНОСТИ ВНУТРЕННИХ АУДИТОРОВ СИСТЕМ МЕНЕДЖМЕНТА КАЧЕСТВА ФАРМАЦЕВТИЧЕСКИХ ПРЕДПРИЯТИЙ

Эффективная система управления качеством является необходимым условием результативной и успешной деятельности любого современного предприятия, в том числе предприятий фармацевтического профиля. Принято считать, что в таких системах процесс внутреннего аудита является важной и неотъемлемой составляющей. Важность внутренних аудитов для диагностики и своевременного корректирования фармацевтической системы качества подчеркивается во всех действующих установках надлежащих практик лекарственных средств (в частности, в руководствах по GMP и GDP), а также в национальных лицензионных условиях осуществления хозяйственной деятельности по производству, оптовой и розничной реализации лекарственных средств. Как и для всех остальных процессов фармацевтической системы качества, эффективность внутренних аудитов напрямую зависит от компетентности задействованных специалистов, при этом для аудиторской деятельности уровень подготовки кадров, а также их личностные качества приобретают особое значение.

Целью исследования стала разработка подходов к оценке деятельности аудиторов, определение критериев отбора кандидатов в аудиторы, определение критериев результативности процесса аудита системы управления качеством фармацевтических предприятий.

Результаты. В статье обосновывается важность и предлагаются подходы к оценке деятельности внутренних аудиторов систем управления качеством фармацевтических предприятий. Разработан перечень показателей и описана методика оценки деятельности внутренних аудиторов для оценки эффективности процесса внутреннего аудита.

Выводы. Предложенная методика оценки дает возможность измеримо характеризовать результативность внутреннего аудита, определять тенденции его изменений, принимать корректирующие или предупреждающие действия для совершенствования процесса аудита.

Ключевые слова: внутренний аудит; аудитор; система управления качеством; фармацевтическая система качества; ISO 9001; фармацевтическое предприятие; оценка результативности

STATEMENT OF THE PROBLEM

The competence of Quality Management Systems (QMS) auditors, in general, and of the Pharmaceutical Quality Systems (PQS), in particular, consists of certain personal qualities and relevant professional knowledge and skills. The international standard ISO 19011 emphasizes the importance of identification, verification and constant development of auditors' competence. This is also the experience of companies where internal audits carried out [1, 2]. Meanwhile, in Ukraine no higher education institution trains such professionals, either for pharmaceutical field in the health care scope, or other sectors. *Even though* the occupational job title "Quality Systems Auditor" is provided under the National Classification of Ukraine "Occupational Classification" DK 003:2010 (occupation code number 2411.2).

Some universities offer training in an educational-professional program on the "Quality, Standardization and Certification" ("QSC"), which covers subject matters related to organizing the QMS auditing process. For example, at the National University of Pharmacy (Kharkiv, Ukraine), within the specialty "Management", the educational-professional program "QSC" is carried out, and the subject "Quality Management Systems audit" is taught. However, the current demand for such professionals in pharmaceutical industry is far beyond the capacity of educational institutions. In view of this,

companies often provide training and certification for auditors themselves or invite outside experts for skills workshops and other forms of training. It accounts for lack of standardized approaches to the training of auditors and regular methods for competence assessment, which in its turn results in significantly different levels of professionalism of these audits [2].

An audit activity is extremely important for ensure the proper functioning of a pharmaceutical companies (PhC) [3]. At the same time, approaches to the development of training programs and ways of their implementation, methods applied for diagnosing skills and knowledge, identification and evaluation of the essential personal qualities of auditors, and their motivation – all these points require scientific rationale, exact planning and monitoring.

It should be emphasized that besides the internal audit (IA), which is essential for the business development, this activity is envisaged as compulsory from the perspective of the requirements of the current licensing conditions in Ukraine for manufacturing, wholesale and retail of the medicinal products (MP) and appropriate good practices for the MP of the Ministry of Health (in particular, Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) (Decree of Ukraine No. 929, 2016) [4]. All current standards concerning management systems, such as a ISO 9001, ISO 14001, ISO 22000, ISO 13485, etc., also include requirements for statutory the IA [2, 5].

Thus, issues relating to selection, training, periodic certification, regular improvement of competence and motivation of the QMS (PQS) auditors are relevant and important both for national and international pharmaceutical companies, and for companies and organizations of other fields, as well [6].

According to the results of the normative information sources analysis and sociological research conducted by us allowed stating a significant lack of information in the following areas:

- specific requirements for the competence of the staff engaged in the QMS PhC auditing;
- description of the best for the internal auditor personal psychological profile, and methods for its identification and measuring;
- methods and tools for diagnosing knowledge and skills of the PhC QMS auditors [5].

Nowadays each company is forced to develop in-house all the requisite guidance materials and apply them at the own discretion. However, due to the imperfection of the applicable approaches and methods of training and certification of the auditors, many enterprises show inadequate professionalism in auditing, which leads to the low efficiency of the conducted audits. It often results from failed, unreasonably selected candidates for auditors [2, 5].

The international standard ISO 9004:2018 "Quality management – Quality of an organization – Guidance to achieve sustained success" reveals the comprehensive role of IA. So, article 10.5 'Internal audit' of this standard says that: "Internal audits are an effective tool for determining the levels of conformity of the organization's management system to its selected criteria. They provide valuable information for understanding, analysing and improving the organization's performance. Internal audits should assess the implementation, effectiveness and efficiency of the organization's management systems. This can include auditing against more than one management system standard, as well as addressing specific requirements relating to interested parties, products, services, processes or specific issues.

To be effective, internal audits should be conducted in a consistent manner, by competent people, in accordance with the organization's audit planning. Audits should be conducted by people who are not involved in the activity being examined, in order to give an independent view on what is being performed.

Internal auditing is an effective tool for identifying problems, nonconformities, risks and opportunities, as well as for monitoring progress on resolving previously identified problems and nonconformities. Internal auditing can also be focused on the identification of good practices and on improvement opportunities.

The outputs of internal audits provide a useful source of information for:

- a) addressing problems, nonconformities and risks;
- b) identifying opportunities;
- c) promoting good practices within the organization;
- d) increasing understanding of the interactions between processes.

Internal audit reporting usually contains information on conformity to the given criteria, nonconformities and improvement opportunities. Audit reporting is an essential input for management review. Top management should establish a process for reviewing all internal audit results in order to identify trends that can require organization-wide corrective actions and opportunities for improvement" [7].

We think that the goals and objectives of internal audits recommended by the standard, as well as the use of findings from audits, should be formulated taking into account the above-mentioned provisions of the ISO 9004: 2018.

ANALYSIS OF RECENT RESEARCHES AND PUBLICATIONS

O. V. Ivanova, L. L. Dushevin, J. Namešanská proposed generalized methods for assessing QMS auditors [8-10]. The questions of competence of the workers of the pharmaceutical sphere were investigated by L. V. Galiy [11]. V. I. Gorodetska defined the professional competences of experts in quality assurance in pharmacy [12].

Based on the results of sociological research and analysis of the others work, we have determined that often to assess the performance audit is used an indicators, which can not be considered neither complete nor correct [5, 8]. These indicators often include the following:

- full implementation of the program of audits (for a year or another period of time);
- number of identified nonconformities (estimated for each audit);
- correct determination of the audit criteria;
- errors in the audit documents performance;
- correct phrasing of the conclusions (in particular, relevance of the wording of the comments, nonconformities and recommendations for improvement);
- correctness (professionalism) of auditor behavior during the auditing;
- number of violations of the audit plan, etc.

The above mentioned and similar findings, although they somehow characterize the auditing process, provide no answer to the principal question: Does the auditing process achieve its goals (in other words, is it effective)? Of course, for this purpose, it is necessary to start with formulating objectives to be achieved, for which the IA is carried out.

EXAMPLE OF THE EVALUATION FORM FOR INTERNAL AUDITORS

Audit competence profile	Ratings					K _s	Σ
Unit 1. Personal qualities							
1. Tactfulness, diplomacy. Ability to communicate with different people, create an environment of trust	1	2	3	4	5	0,7	
2. Power of observation skills, attention to details	1	2	3	4	5	0,7	
3. Concentration, focus on achievement of the audit purposes	1	2	3	4	5	0,7	
4. Impartiality: readiness to consider alternative points of view	1	2	3	4	5	0,8	
5. Objectivity: conclusions are made on the basis of factual evidence	1	2	3	4	5	0,9	
6. Punctuality. Strict compliance with the established plan of audit						0,6	
Unit 2. Awareness of the requirements, compliance with which is checked during audit							
7. Understanding of the current principles and approaches to quality management	1	2	3	4	5	1,0	
8. Understanding of the role and conditions of the QMS processes operation	1	2	3	4	5	1,0	
9. Correct understanding and ability to interpret the requirements of the ISO 9001 standard	1	2	3	4	5	1,0	
10. Correct understanding and the ability to interpret the requirements of obligatory regulatory documents related to the scope of the audit	1	2	3	4	5	1,0	
Unit 3. Occupational skills							
11. Correct application of risk-oriented thinking	1	2	3	4	5	0,8	
12. Correct and proper record keeping during the audit	1	2	3	4	5	0,6	
13. Correct reporting on the audit results	1	2	3	4	5	0,8	
14. Correct phrasing of recommendations for improvement	1	2	3	4	5	0,8	
Total score							

IDENTIFICATION OF ASPECTS OF THE PROBLEM UNSOLVED PREVIOUSLY

According to the analysis of literary sources, the lack of coverage of the issue on the specified topic was established. In particular, the literature did not find a methodology for comprehensive assessment of the competence of internal auditors of the PQS.

OBJECTIVE STATEMENT OF THE ARTICLE

The purpose of the current stage of our research was to develop approaches to assessing the activity of auditors, and to determine the criteria for selecting candidates for auditors and to determine the criteria for the effectiveness of the audit process of the PhC QMS.

PRESENTATION OF THE MAIN MATERIAL OF THE RESEARCH

Based on the study of the provisions of the ISO 19011 and other information, we can conclude that an evaluation of the competence of candidates in auditors is advisable to apply several methods simultaneously, and the assessment procedure to conduct in at least two stages.

The proposed methodology is expert and has, like all similar methods, a subjective character. The result of this methodology is highly dependent on the expertise of experts. We assume the application of the methodology only with the presence of a compe-

tent chief auditor (CA, head of the audit team) at a company.

The expertise of CA must meet the requirements for auditors of management system certification, and further desirable to match the qualification requirements for the authorized person in the PhC.

First stage – the initial estimation of candidates, which usually involves the following operations:

1. Establishing an evaluation criteria. An evaluation criteria may be quantitative (such as duration of work in the relevant specialty, number and duration of audits performed, number of hours of profile training, etc.) and qualitative (such as evidence of the personal qualities, knowledge and skills demonstrated while preparing for an audit).

2. Identification and documenting the information concerning the competence of auditors which is required to meet the needs of the audit program (information regarding personal qualities, knowledge, skills).

Second stage – the evaluation of the auditors' work effectiveness.

1. The evaluation of the candidate as a trainee provides for diverse methods of assessment of current capabilities candidate auditors during the working process and comparing the results of the evaluation criteria identified in the first stage. Can be used indicators such as: reviewing the check-lists, plans, programs developed by the candidates for

auditors, interviewing, monitoring their performance while preparing for auditing, testing them for audit criteria knowledge, examining the results of the solved situation challenges etc.

2. The systematic monitoring of the auditors activities should be established after the formation of the audit team. To provide comprehensive competence assessment of the auditors, we propose to use a sociological survey by means of questionnaires. This evaluation may hold as managers of proven processes / units and CA. CA is responsible for periodic assessment of each auditor during the entire audit program performance.

On the base of our own experience, studied ISO 19011 standard and reviewed special publications, we have developed a key performance profile list that should be used to evaluate auditors. An example of the questionnaire to evaluate the auditor's competence is given in Table.

Steps to perform the auditor's systematic evaluation.

1. CA has to determine the significance coefficient (K_3) for each competence parameter. In Table, the coefficient K_3 values are given as an example: they must be determined according to the management priorities for each audit program and may vary.

2. CA submits the estimates for the parameters given in the table with a certain periodicity. It is best done after each audit.

3. CA evaluates auditors on a scale from 1 to 5, where 1 is the lowest score, and 5 is the highest

4. Every particular score is multiplied by the K_3 , and then the total score is calculated.

5. For each characteristic unit, the auditor needs to have a score or even exceed the level of the established eligibility criterion.

6. The estimated scores for all auditors are collected in a single database. These scores build the basis for determining the appropriateness of engaging a particular auditor in further audits, and also this information is used to develop corrective and preventive measures to improve education for auditors and increase their motivation.

A necessary condition for effective audits – proper training of auditors. However, it is not sufficient. It is necessary to identify and apply adequate indicators to ensure a stable performance of the audit process, which would have fully characterized of this process. First of all, such criteria should characterize the value of the audit reports for the management, which is based on the decision to optimize the company. It is connected with an important role of audits in maintaining the functioning and development of QMS [3]. The value of the reports can be evaluated by expert method using relevant questionnaires with certain rating scales. Such an assessment should be carried out after each audit or, under certain conditions, at the end of the audit program.

CONCLUSIONS AND PROSPECTS FOR FURTHER RESEARCH

Monitoring the audit process by the “Value of reports for senior management” provides the opportunity to measure the performance of the IA, determine the trends of its changes, and take corrective or preventive actions to improve the audit process.

In the future, we plan to develop an extended portrait of the auditor's competence, as well as recommendations for their training and certification.

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