ACTUAL RESEARCHES OF ORGANIZATION OF INTERNAL AUDITS OF PHARMACEUTICAL QUALITY SYSTEMS

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Introduction. For today organization certification in accordance with the requirements of standard ISO 9001 is one of effective events for the increase of competitiveness. For domestic Pharmaceutical Manufacturers such a step makes it possible to consolidate its position not only in domestic but also in foreign markets. Thus the branch requirements of GMP in relation to the pharmaceutical quality system (PQS) do not eliminate application of model of quality management system (QMS), which described in the standards series of ISO 9000.

One of the required elements of QMS is the system of internal diagnostics of company, known as internal audits (IA). At the same time, domestic companies often performed audit formally, mostly just to meet the requirements of supervisory authorities. However, properly organized auditing company management can provide important information about the functioning of the QMS, which can be used for taking corrective and preventive actions in order to improve.

Aim. Our goal at the current stage of researches on organization of audits on pharmaceutical companies (PC) becomes planning assessment of IA at the leading PC by using a sociological survey.

Materials and methods. As information database of research were used laws of Ukraine, which are published in the official sources, and also the resources of Internet network and materials published in scientific and professional literature.

Results and discussion. Since 2011 Ukraine has "Licensing terms for the business of drug manufacturing, wholesale and retail sale of medicines" compliance with this on the base of the pharmaceutical market verifies by the State Administration of Ukraine on Medical Products (SAUMP). Licensing is based on the Law of Ukraine "On Medicines", which provides a PQS at companies that produce a medications. License terms require efficient the PQS, but they do not contain a detailed description of the structure and mechanisms of the PQS. More detailed recommendations on this issue contains at the guidance ICH Q10, which has become a supplement to national guidelines of GMP, however, and this guidance provides only a general description of the PQS and briefly defines place and role of IA.

IA in PC are intended for systematic, independent and documented process of conformity assessment of the PQS as specified internal and external requirements. IA should be directed at identifying of "weak points" (types of activity, where a risk for quality of products and health of patients is unacceptable high), and also on being of

potential of further development of the PQS. Successful IA may contribute to a significant improvement of the PQS, reducing the risks to the quality, increase the productivity of production processes and reduce unproductive expenditures.

The audit of the PQS relating to the types of audits which is not regulated by a state legislation. Accordingly, there are not mandatory legal regulations to determine the order and rules of audit of quality systems, determination of requirements to auditors and the required reporting. Accordingly, there are no mandatory legal regulations to determine the order and rules of the PQS audit, no requirements for auditors, documentary support and more. However, QMS certification for compliance with ISO 9001, it is appropriate to carry out domestic enterprises have to follow all the requirements of the relevant sections of ISO 9001. Methodological assistance to implement these requirements provides standard ISO 19011 "Guidelines for auditing management systems."

In our opinion, the combined compliance guidelines ICH Q10, guidelines on GMP and ISO 9001 and 19011 is a rational approach to effective audit of the company.

We plan to conduct studies to comparative analysis of mentioned standards requirements, and determine the status of audits on domestic enterprises of different ownership, product range, magnitude and complexity of the of production processes. The objects of study in the first phase will serve companies that are certified in accordance with ISO 9001.

For our study, we chose the most acceptable variant to obtain information - a sociological survey to the representatives of company. The respondents, that the heads of quality control department will come forward, will be offered to fill an application form, that will contain questions about the form of audits, the number of involved auditors and their qualifications, frequency of audits, audit complex of documents, applicable auditing methods and so on.

The sociological survey is planned to conduct by using of software products like Google of Form and Survio.

Conclusions. The analysis of existing legal and regulatory requirements to the system found that the regulation of the formation of such systems and their individual processes, in particular - internal audits provided only by general provisions. Is also marked that the certain shortage of methodical literature and scientific publications on these questions. Accordingly, our research aimed at determining the best approaches to the organization of effective audits, as well as the assessment of internal audits proceedings in domestic companies. The results of such analysis will give an opportunity to offer the optimal model of IA organization in accordance with modern requirements and specific of the domestic companies from the production of medical products.