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Матеріали

*II Науково-практичної Internet-конференції
з міжнародною участю*

ФАРМАЦЕВТИЧНІ ТЕХНОЛОГІЇ, СТАНДАРТИЗАЦІЯ ТА ЗАБЕЗПЕЧЕННЯ ЯКОСТІ ЛІКАРСЬКИХ ЗАСОБІВ

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STUDY OF APPROACHES TO THE ORGANIZATION OF INTERNAL AUDIT IN PHARMACEUTICAL ENTERPRISES

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Introduction. The pharmaceutical industry plays a leading role in maintaining and strengthening public health, as the quality of medicines is a determining factor in their effectiveness and safety for patients. In today's conditions of globalization, increasing competition and increased regulatory requirements, pharmaceutical companies must ensure that their products and processes comply with international standards and other regulatory acts. One of the key tools to support the effective functioning of a quality management system is internal audit. This process allows you to assess the compliance of all aspects of the enterprise's activities with established standards and regulatory requirements. Internal audit helps to identify risks, identify shortcomings in processes and promptly implement corrective measures, which is critically important for ensuring product quality and its safety for end consumers.

The aim is to study of the approaches to the organization of internal audit in pharmaceutical enterprises.

Methods. The methods of questionnaire, analysis, comparison were used.

Results and discussion. To assess the internal audit procedures of the quality management system at a pharmaceutical company, a survey was conducted among 57 employees of pharmaceutical companies. The distribution of respondents by their positions shows that the largest share is occupied by department heads (30%) and quality managers (28%). Quality engineers make up 14% of the survey participants. It was found that the majority of respondents (47%) have experience in the pharmaceutical industry from 16 to 25 years. It was found that 78% of respondents participated in internal audits of the quality management system. It was found that 59% of respondents are very familiar with the internal audit procedure at a pharmaceutical company, 22% - partially. It was found that 45% of respondents have undergone training in conducting internal audits. It was found that 38% of respondents noted that the roles and responsibilities of internal audit participants are clearly defined for them; 40% of respondents noted that they are partially understood. It was found that the main difficulties that respondents observe during internal audits include: identifying shortcomings - 24% of responses, employee resistance (17%); insufficient training of auditors (15%). It was found that the majority of respondents consider the terms of internal audits to be insufficient to complete all necessary tasks. It was found that 92% of respondents do not experience difficulties in the process of documenting the results of internal audits. 67% of respondents are completely satisfied with the availability of information resources, such as templates, checklists and instructions, for conducting internal audits.

Conclusions. The approaches to the organization of internal audit in pharmaceutical enterprises was analyzed.