

RESEARCHES OF THE INTERNAL AUDIT ORGANISATION AT THE DOMESTIC PHARMACEUTICAL COMPANIES

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Introduction. According to the requirements of GMP for pharmaceutical manufacturing and for distributors to assess the effectiveness and suitability of the pharmaceutical quality system (PQS) must be conducted internal audits (IA) systematically. IA should be used as a tool for searching and analyzing the causes of discrepancies in the work with further correction and and recommendations for improving operations of the company processes. All these data needed for making management decisions.

Aim. In order to analyze the state of IA process at pharmaceutical companies (PC) we have been processed material sources of published information, and conducted a sociological study by a questionnaire of a representatives at domestic PC of production and wholesale trade of medications.

Materials and methods. In the work we have used: system-analytical method, structural and logical modeling, a comparative analysis of peer review, a sociological survey and more. Statistical analysis of the results was performed using the licensed software Microsoft Excel of Microsoft Office 2013.

Results and discussion. Based on analysis of the survey we found that next to the development of large-scale audit practice, there're certain aspects of this process that most PC need to be improved. For example, the survey revealed the problem of auditing methodological support: 44% of respondents expressed the critical need to developed appropriate guidelines, and 43% of respondents agreed with the fact that these recommendations would be useful. Most of the respondents to the question on the reasons of the unsatisfactory efficiency of IA noted a human factor (such as competence of auditors, impartiality and objectivity). Also were mentioned reasons related in the deficiency of hour for planning and conducting audits in reasons that for IA often involved specialists from different business units, which have to leave their main workplace in this short period of time.

Conclusions. We can conclude that the problem with IA efficacy on domestic PC existing and must be solved by reforming the scientifically proven organizational basis for these activity. Therefore, we planned to form a set of proposals for the auditing organization at PC defining scientific and methodological approaches to reglamentation and documentation of the audit process, planning of IA based on risks, implementation of the PDCA methodology to the audit process and other aspects.