

ON THE RELEVANCE OF SEARCH FOR THE RATIONAL ASSESSMENT METHODS OF THE PHARMACEUTICAL QUALITY SYSTEM'S EFFECTIVENESS

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The dynamic development of the pharmaceutical market and increasing competition are placing new demands on the organization of pharmaceutical companies' management. In these circumstances, the implementation of quality management systems (QMS) in accordance with the international standards ISO 9000 is a strategically-based solution. In pharmaceutical enterprises, such systems are called pharmaceutical quality systems (PhQS). One of the important aspects of the PhQS is to constantly assess and monitor its effectiveness in order to analyze the causes of discrepancy and reduce risks to quality.

Our research is aimed at studying the approaches, methods and tools used in assessing the PhQS effectiveness. The methodological basis of the study is the statistical and other methods of QMS effectiveness assessment employed at the leading domestic and foreign enterprises. Information base: industry regulatory requirements, published and enterprise data. The study uses comparative, documentation, operational, factor and logical analysis methods. The subject of this study is the PhQS, and the object is the procedures for monitoring and assessment of the PhQS processes.

We have investigated and analyzed the approaches and methods of performance assessment of different management systems' processes. Among modern methods, the following are most commonly used: the method of comparison of the planned and achieved processes output values and characteristics, the calculation of QMS effectiveness based on the expert scores, model of index normalization of effectiveness assessment, enterprise effectiveness and QMS maturity level self-assessment methodology, integrated approaches to quality management self-assessment that include audit, QMS analysis, self-assessment according to the defined criteria, self-assessment according to the criteria of international models of excellence, additional methods – instrumental, registration, computational, sociological. In our view, the calculation of QMS effectiveness based on the expert scores is the most rational method to assess the PhQS effectiveness, which is the subject of our further research.