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STRATEGIC APPROACHES TO IMPROVING RISK MANAGEMENT IN PHARMACEUTICAL ORGANIZATIONS

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Introduction. The effective functioning of pharmaceutical organizations in conditions of high market volatility, regulatory changes and globalization challenges directly depends on the quality of the risk management system. The specificity of the pharmaceutical industry, which is associated with strict requirements for safety, quality (GMP/GDP) and efficacy of medicines, requires the transformation of traditional reactive approaches to risk management into proactive strategic models.

The implementation of integrated risk management allows not only to minimize potential losses at all stages of the product life cycle, but also to ensure the sustainable competitiveness of the enterprise.

The purpose of the study is to develop strategic approaches and scientific and methodological recommendations to improve the effectiveness of the risk management system in pharmaceutical organizations based on the integration of international quality standards and the concept of Enterprise Risk Management.

Research methods. The work used a complex of scientific methods: system-structural and comparative analysis (to study modern risk management models), SWOT analysis (to identify strategic threats to pharmaceutical organizations), as well as methods of expert assessments and process modeling in accordance with the principles of the ICH Q9 standard.

Research results. The results of the analysis of the activities of domestic and foreign pharmaceutical companies prove that the key barriers to effective risk management are the fragmentation of risk assessment and the lack of a unified digital ecosystem for their monitoring.

We have proposed a three-level strategic model for improving risk management, which includes the institutional level (formation of cross-functional teams and integration of risk management into the overall corporate strategy), the process-operational level (standardization of risk identification and assessment procedures at the stages from the development and supply of APIs to the distribution of finished drugs), as well as the technological level, which involves the implementation of specialized digital platforms for automating predictive risk analysis.

Combining the requirements of good practices and ICH Q9 with the matrix approach of the ERM concept has been proven to optimize quality assurance costs and reduce the likelihood of regulatory sanctions.

Conclusions. Long-term stability of the pharmaceutical business requires a transition from local control of deviations to end-to-end strategic risk management. The proposed strategic approaches create the basis for building a flexible risk management system that ensures the continuity of business processes, high quality of medicines, and adaptability of pharmaceutical enterprises to the dynamic conditions of the modern market.