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INTEGRATION OF ISO 9001 AND GMP STANDARDS IN QUALITY MANAGEMENT SYSTEMS OF PHARMACEUTICAL ENTERPRISES

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Introduction. Modern pharmaceutical production requires not only compliance with mandatory regulatory norms of Good Manufacturing Practice (GMP) but also adherence to voluntary international quality standards such as ISO 9001. The topic is particularly relevant in 2025, as European and Ukrainian manufacturers increasingly combine certification according to GMP and ISO 9001.

In the context of globalization of the pharmaceutical market, ensuring the quality of medicinal products is of particular importance. The growing demands for product safety, efficacy, and traceability necessitate the implementation of comprehensive quality management systems capable of integrating regulatory requirements with international standards. The GMP system guarantees compliance with legal norms and pharmaceutical supervision requirements, while ISO 9001:2015 provides a universal model of quality management based on the process approach, continuous improvement, and customer satisfaction.

The aim of this study is to substantiate the feasibility of integrating ISO 9001 and GMP standards into a unified quality management system for pharmaceutical enterprises and to identify its advantages in terms of improved efficiency, process transparency, and competitiveness.

Results and discussion. The analysis revealed a high degree of methodological alignment between ISO 9001:2015 and GMP: customer orientation, risk management, process-based approach, and documentation. Integration of these systems enables the creation of an integrated Quality Management System (QMS), in which ISO ensures systematic and strategic management, while GMP ensures compliance with pharmaceutical safety standards.

The results of integration include the reduction of documentation duplication, optimization of risk management, improvement of personnel qualification, and reduction of audit costs.

Conclusion. The integration of ISO 9001 and GMP enhances the efficiency and effectiveness of the quality management system, promotes the development of a quality-oriented culture, and contributes to international recognition. Further research should focus on developing a model for evaluating the effectiveness of the integrated management system and applying digital technologies in its implementation.

FORMATION OF THE IMAGE OF INTERNET PHARMACIES IN THE WORLD AND IN UKRAINE

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The rapid development of information and communication technologies in the 21st century has led to radical changes in all spheres of social life, including healthcare. The digitalization of medicine has encompassed both the system of electronic medical records and the introduction of tools for remote interaction between the doctor, the patient, and the pharmacy. In this context, online pharmacies (e-pharmacies) have gained special importance as an innovative channel for providing the population with medicines. They combine the advantages of e-commerce with the specific requirements of the pharmaceutical component of the healthcare sector regarding quality, safety, and control. The relevance of the issue is confirmed by the fact that e-pharmacies have become not only

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