ELECTRONIC DOCUMENT MANAGEMENT AS AN ELEMENT OF THE QUALITY MANAGEMENT SYSTEM AT PHARMACEUTICAL ENTERPRISE PJSC "PHARMSTANDART-BIOLIK", UKRAINE

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Introduction. In the conditions of the modern world and total information system development, the use of electronic document management systems is topical. According to the GMP (Good Manufacturing Practices) requirements at pharmaceutical companies in the world and in Ukraine in particular the issue of proper workflow regulated and there is separate standard Good Documentation Practice (GDocP). In 2014, the WHO introduced Guidance on good data and record management practices. This document includes the notion of ALCOA (attributable, legible, contemporaneous, original and accurate). The ALCOA concept includes requirements for the documentation design in clinical studies, but for unifying the workflow, it was use in the pharmaceutical industry. According to the requirements of the DSTU ISO 9001:2015, the organization, regardless of its activities, must document its Quality Management System (QMS) ie., describes in the relevant documents all the processes of the system.

Aim. The purpose of the study is to study the interaction between the Electronic Document Management System (EDM) and the Quality Management System (QMS) of the PJSC “PHARMSTANDART-BIOLIK”.

Materials and methods. For the Ukrainian pharmaceutical companies the EDM is relatively new system and in modern conditions, its integration with the QMS is an urgent issue. On the example of PJSC “PHARMSTANDARD-BIOLIK” these two systems separately from each other and their functioning as the uniform mechanism of management in the conditions of one pharmaceutical enterprise have been considered. In the course of the research, the current state of the EDM and QMS and their interaction were analyze, and an analysis of the functioning of these systems in the business units performed.

Results and discussion. The analysis showed that both systems are configured and active in the enterprise, but the absence of an electronic signature system excludes the full and proper functioning of electronic document management and its integration into the QMS.

Conclusions. Taking into account the above, we suggest introducing a local electronic signature system with a corporate server, validating computer systems and integrating the EDM into the QMS.