

METHODOLOGICAL ASPECTS OF EDUCATIONAL STANDARDS OF TRAINING SPECIALISTS QUALITY MANAGEMENT IN PHARMACY

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Effective pharmaceutical quality system (PQS) is the most important element of achieving competitive domestic pharmaceutical products through unquestioning quality. However, today the acting PQS is ineffective mostly due to the lack of specialized knowledge of quality management (QM) in the heads and specialists of pharmaceutical companies (PC).

In this survey we have analyzed the situation in Ukraine and the world concerning training of QM in general and pharmacy in particular. As a result from the analysis we found that in Ukraine specialty “QM” is not included in the classifier according to Resolution № 787 of the Cabinet of Ministers of Ukraine on August 27, 2010. In Europe at the moment in “QM” trains specialists in 28 countries and more than 90 universities and business schools. In the European Union there is a single coherent system as the European Organization for the preparation, registration and certification of specialists in QM. Therefore, the need for specialized knowledge in professional quality department of the PC is no doubt. This problem can be solved by developing and implementing educational standards of training of QM in pharmacy-based competency approach.

The aim of our work was the detailed study of the functional responsibilities of professionals QM of the PC in the design, implementation and operation PQS based on the experience and mistakes in creating PQS national experts and achievements of foreign scientists. With this experience we have identified and proposed core competencies for future QM specialists. Among them, identified the following: the ability to formulate goals and objectives within PQS processes, develop process model PQS; apply methods and tools for analysis and optimization of processes PQS, to determine appropriate resources to implement and support PQS and others. Also for the effective application of management and skills training programs to professionals QM proposed that such vocational and practical subjects as means and methods of quality management, basic system approach qualimetry, document management, QM processes, TQM, statistical methods in QM, certification and standardization of pharmaceutical products, metrology and measuring equipment and other subjects.

Thus, the formation of the specialty “QM” will allow specialists with the best way to implement quality standard ISO 9000, make PQS useful for PC and workers by embedding it in a system of PC.