

DESIGNING OF MODULAR-COMPETITIVE MODEL FOR SPECIALIST IN ASSURANCE AND QUALITY MANAGEMENT FOR THE PHARMACEUTICAL INDUSTRY

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The problem of acute shortage of personnel, competent in matters of quality assurance (QA) and quality management (QM) for industrial pharmaceutical sector, proved us by analyzing the needs of the modern job market, based on data of monitoring the situation in Ukrainian industrial pharmaceutical companies (IPC), which discussed in several previous publications.

Order to determine functional responsibilities of specialist for QA and QM in pharmacy we analyzed the job regulations and qualifying characteristics of employees of departments of assurance and management quality in leading Ukrainian IPC. To form the list of key competencies analyzed national and international experience of training for QA and QM at the European Organization for Quality and the Ukrainian Association for Quality, and considered the spectrum of basic of knowledge and skills of professionals in the example of Germany and the United States as leaders in developing relevant personnel training. Based on an analysis of the main reasons for lack of effectiveness of quality management systems (QMS) in IPC (Pharmaceutical Quality Systems) we had formulated a set of typical competencies and disciplines for specialist QA and QM in pharmacy, proposed for consideration the leadership of a number of leading national IPC in the form of questionnaires. Based on obtained data were ranked disciplines of professional and practical training and professional competencies.

Results of evaluation the degree of significance of competence demonstrates that clearly necessary for future specialists is competence «planning participation in internal audits (self-inspections)», «working with process model PSQ», «working with documentation PSQ», «planning process indexes of effectiveness PSQ», «management of non-conformities and development of corrective and preventive actions». Most important for the formation of special-professional skills disciplines were identified «Audits QMS», «Regulatory support», «Good manufacturing practice (GMP)», «Good distribution practices (GDP)», «Statistical process management», «The approaches, methods and means QM», «Standardization and certification of pharmacy products», «QM of production processes», «Designing of QMS».

Based on the questionnaire we will develop standards for higher education for the specialties «Quality Assurance in Pharmacy» (bachelor) and «Quality Management in Pharmacy» (MSc).