

DEVELOPMENT OF STANDARD OPERATION PROCEDURES FOR COMPOUNDING PHARMACIES

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In accordance with the modern requirements to the quality assurance (QA) system for compounding preparations development and maintenance of standard operating procedures (SOPs) are obligatory. SOP is a documented set of instructions and step-by-step actions on how to execute a task. It is proved that the development and use of SOPs minimizes variation and promotes quality through consistent implementation of a process or procedure and it helps to ensure quality and minimize the number of errors that occur. There are a lot of advantages of SOPs implementation in compounding pharmacy: assistance in QA; ensuring of consistency; economy of work time; clear lines of accountability; better understanding of the processes; template for the training; additional information for audit.

SOPs in compounding pharmacy should be developed for all daily routine procedures that executed by pharmacists, such as: compounding and quality control of medicines, purchasing, handling of materials, dispensing, cleaning, care for facility and equipment etc. SOPs usually have a clear structure and consist of title, purpose, responsibilities, equipment, materials, procedures, information about the company, implementation, and signatures of authors, reviewer and head of department, information about SOP revisions. In fact, each SOP should contain the answers to the following questions:

- Who participates in the implementation of its requirements?
- What resources are necessary for its implementation?
- Where (In which department) should pharmacist perform SOP?
- When the procedure must be completed?

The most important parts of the SOPs are purpose (areas of work, it should not be over-complex), procedures (a description of the task) and responsibilities (who is responsible for carrying out of the procedure and who ensures that the staff can carry out a procedure). SOPs should be written by the specialist who perform that task and should be annually reviewed by another specialist who involved with the performance of the task and the head of QA department.

Development and implementation of easily readable and clearly specified instructions/SOPs are relevant for practices of compounding pharmacies of Ukraine.