ELECTRONIC SEPARATION OF DRUGS IN THE STATUS OF "QUARANTINE" IN THE PHARMACEUTICAL WAREHOUSE

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Introduction. As stated in the operating license conditions regarding implementation of manufacturing medicines, wholesale and retail trading of drugs, importing drugs (except for active pharmaceutical ingredients), electronic separation of drugs in the status of "quarantine" may be provided on the condition of existence conforming product identification, validation of computerized systems (CS) and upon condition that the system provides equivalent safety. In good distribution practice (GDP), are says that only specifically designated person should perform data entry or changes in the system. In case of system, failure or malfunction should be determined procedures.

Validation of computerized system and program support, that guarantees electronic separation of prohibited for sale drugs from authorized store, is considered extremely important concerning the functioning of the system of quality in modern pharmaceutical distribution companies. Based on validation testing, should be provided determined and documented procedures of process control of behaving with quarantine production and proper actions in case of malfunctioning system.

Validation testing CS and further determination of documented procedures with consideration for validation testing appears to be distributor of drugs matter of interest. In this instance, validation should cover all of the aspects related to CS: starting from system choice and its installation to operation under normal and critical conditions. All of the mentioned aspects are always concerned with risk on quality influence of pharmaceutical production. They have to be determined and estimated during validation process.

Aim. Determination methods of electronic separation of drugs in the status of "quarantine" with the help of relevant CS and PS, in distributing activity of pharmaceutical company.

Materials and methods. In the capacity of research database were used normative documents, which standardize CS functioning and its validation (in particular, GMP/GDP regulations), ISO specialized standards, ICH regulations and other information sources. The comparative analysis method, the method of structural and logical modeling expert method were applied during the research.

Results and discussions. There is properly built and documented process controlling model of quarantine production and the program of CS and program support (PS) validation that provides electronic separation of prohibited for sale drugs with due account for undesirable situations. It allows qualified person of pharmaceutical distributor to guarantee prevention of ingress the quarantine production to permitted for sale store with following statuses:

- Pharmaceutical products that didn`t pass the incoming inspection of quality by qualified person;
- Drugs that are prohibited in accordance with law;
- Drugs that must be utilized (including rejected products);
- Low-quality drugs or those, which under suspicion of quality violation;
- Adulterated drugs or those, which under suspicion of adulteration;
- Drugs that are recalled from the market;
- Returned drugs;
- Drugs that are imported and do not have permission for selling.

When building a functioning system of electronic separation, should be considered, at least, the following:

- The rights for operations performing on quarantine production with the help of CS must be given only to qualified person. Each qualified person should have the necessary access to system authentication and authorization;
- Any operation performed with the help of CS should retain in PS "audit trail" with a history of events and full name of the person, who performed the operation;
- Pre-compiled database a series of drugs that must be blocked by the system in case of such series remains available in authorized selling stock;
- Block activation a series of drugs by program, whose marketing authorization or shelf life soon expires;
- Any returned pharmaceutical production, which is taken on charges and put into the system, must be automatically blocked, until qualified person makes a decision concerned this production;
- Giving an appropriate status for imported drugs, concerning the stages of the formation of the sales permit.

Conclusions. There is properly built and documented process controlling model of quarantine production and the program of CS, whose validation testing is thoroughly organized. In case of malfunctioning, all of the necessary procedures are determined, which are extremely important for obtaining drugs quality guarantee. Our further researches are focused on developing methodology of validation CS.