ANALYSIS OF APPROACHES TO CONDUCTING VALIDATION IN KAZAKHSTAN, UKRAINE AND COUNTRIES OF THE EUROPEAN UNION

Ayanov A. A.
Scientific supervisor: prof. Ustenova G. O.
Kazakh National Medical University named after Asfendiyarov, Almaty, Kazakhstan
aiaz_19_02@mail.ru

Introduction. Validation is one of the main tools of quality assurance in pharmaceutical manufacturing. Validation is a process of documentary confirmation that equipment, engineering systems, materials, processes lead to established results. Comparison of normative documents of Kazakhstan, Ukraine and the European Union can serve as recommendations in the certification of pharmaceutical industries.

Aim. Study normative documents of the European Union countries, Ukraine, Kazakhstan and to conduct a comparative analysis in the issues of validation.

Materials and methods. The application of good manufacturing practices to the standards of the Republic of Kazakhstan, the Russian Federation, Ukraine, and the standard of good manufacturing practice of the European Union was used for comparative analysis.

Results and discussion. As a result of the analysis it found out that the standards of good manufacturing practices in Kazakhstan and Ukraine are identical, there are differences only in minor formalities. The GMP standard of the European Union gives a more detailed notion of the process of equipment qualification, namely, it refers to such stages as User requirements specification – URS, Factory acceptance testing – FAT, Site acceptance testing – SAT, also there is such concept as "requalification" in the European standard. In the European standard, retrospective validation is not considered an acceptable approach, while in Kazakhstan and Ukraine such a concept still exists. In addition good manufacturing practice of the European Union describes approaches to validating the process: the traditional method of validation, the "quality through development" approach, the combined approach. Also in the good manufacturing practice of the European Union reference is made to ICHQ8, ICHQ9, ICHQ10, ICHQ11. But the principle of carrying out validation measures is the same - it is based on risk assessment.

Conclusions. Thus the analysis of the results showed that Kazakhstan and Ukraine standards and European Union standart are identical, but in the European Union standard some aspects of validation are described in more detail and retrospective validation is considered unacceptable. In general approaches to validation measures are based on risk assessment.

CORRECTING SYSTEM ERRORS AND RESTORATION OF COMPUTERIZED SYSTEMS ON PHARMACEUTICAL ENTERPRISES

Chornyi D. S.
Scientific supervisor: assoc. prof. Lebedynets V. O.
National University of Pharmacy, Kharkiv, Ukraine
quality@nuph.edu.ua

Introduction. In the current GMP guideline, the general requirements for validating computerized systems (CS) are described in Appendix 11, which apply if the CS replaces a manual operation. The requirements for the work on qualification, validation and verification of the CS result in the practical interest of the specialists of the pharmaceutical company (PC) in organizing and conducting such works.

Aim. The aim is to study the requirements of international and national standards regarding the validation tests of the CS on industrial and distribution PC and the development of guidelines for validation work taking into account the national specificity of the PC and the relevant sectoral requirements.

Materials and methods. During the study, information materials on the organization of validation tests on the PC of Ukraine and the world were used. The method of comparing and comparing the requirements of international and regional documents in the field of validation of the CS was applied.

Results and discussion. All requirements for operation, including reliability and recovery, to which the CS must comply, must be specified in the "requirements specification" for this system. The

verification of processes related to the restoration of the CS should include the ability of the system to rectify programming errors (settings), data errors and hardware failures. If the recovery occurs automatically, you should evaluate the re-initialization, the mechanism for verifying the data recovery points and restart. In the procedure for correcting errors and restoring the work of the CS, the following should be taken into account: analysis of errors, composition of commission on restoration works, implementation of additional organizational measures, testing software components, verification of saved data, data recovery, issue of the CS for re-use, instructions and documentation.

Improper use of the CS by users can be fixed by the system owner who implements the training program using the appropriate systems. All cases of interference and misuse must be reported, investigated and evaluated. Any reason for invasion and misuse of the CS must be determined by the subsequent drawing up of a corrective and preventive action plan.

Within the control of CS processes and electronic documents that may affect the quality of products, it is necessary to have documented procedures that are responsible for controlling the development, operation, maintenance and restoration of the CS. In developing this procedure, a risk analysis is required to prove the reliability of the CS, for which at least the following is performed:

- Computer software performs its functions, as provided in the "requirements specification"; - The verification of the CS and electronic documents takes place at appropriate intervals. Software, hardware, and backup procedures are regularly checked to ensure reliability. The data recovery procedure guarantees the integrity of the data. Each set of backups is checked to make sure that there are no errors;

- Critical equipment and interfaces between computers and equipment are periodically or continuously inspected to ensure accuracy and reliability in order to verify compliance status. During a periodic review, you should also check the electronic records that were transmitted to another format or system during the relevant period. The purpose of this review is to confirm that the electronic records have been accurately and reliably transmitted;

- Preservation of appropriate backup or archival systems, such as computer software copies, configuration files and electronic records. All files and saved data must be guaranteed to recover all relevant documentation, if necessary. This also applies to system programs required for data storage and retrieval. For this reason, records should be reserved on a regular and incremental basis, and a backup copy is kept at a remote location to prevent intentional or accidental damage;

- After making changes to the system and backing up, change management should ensure the availability and integrity of backup files and saved data by comparing backup data and original files;

- Changes to the CS (infrastructure and software), infrastructure equipment, configuration files, electronic documents and technological equipment are checked and documented. Changes are made only by authorized employees. All changes must be monitored.

Conclusions. In case of fragmentation and / or disengagement of the CS, the appropriate procedure for restoring the CS to the previous state should be reliable, which is also part of the process of continuity of the process. For critical CS, in the event of an emergency, alternative systems that are available in case of failure of the main system should be considered.

Any CS involved in the GxP processes must ensure the full performance of the required functions and be subjected to validation tests to ensure the consistency of the process that can significantly affect the quality of the drugs.

Carefully organized work on validating the CS provides reliable results that are important for obtaining assurances of quality assurance of medicinal products. Our further research is focused on developing a methodology for validating the CS.