QUALIFICATION OF STORAGE AREAS AT PHARMACEUTICAL ENTERPRISES

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Introduction. Ensuring quality during storage is an important part of the life cycle of pharmaceutical products. There are several international standards (GMP, GDP, GSP) which states that the pharmaceutical enterprises must undergo validation / qualification.

Aim. The aim of our work was the development of training measures for of storage facilities to ensure the conditions of storage of medicines.

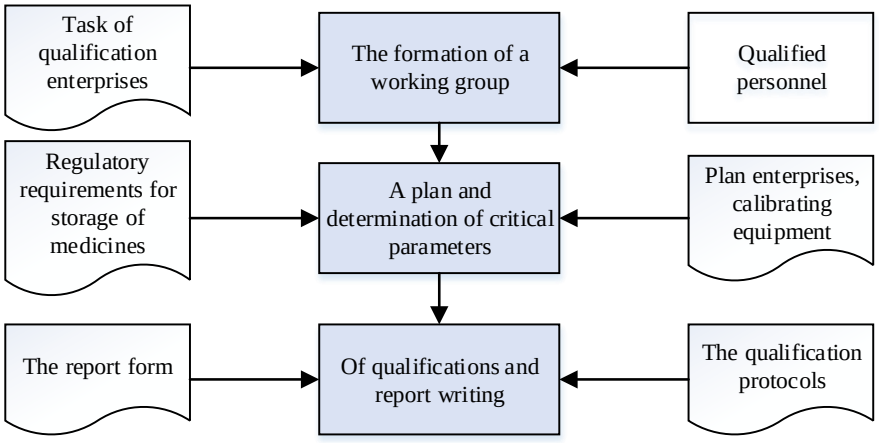
Materials and methods. We used training methods of qualification installation for the work. Work to determine the temperature and humidity were conducted using wireless Datalohheriv.

Results and discussion.

Determine the three stages of validation pharmaceutical enterprises:

- The first step in validation is part of the qualification project. It is performed before construction is to analyze and design documentation.
- Qualification assembly is held for new enterprises or after their reconstruction. At this stage, mainly used methods of visual inspection and comparison with the specification.
- Qualifications operation performed after successful completion of the qualification installation. At this stage, conducted mapping hollow structure using wireless Datalohheriv temperature and humidity.

We have defined pattern of qualification the pharmaceutical enterprises.



Conclusions. We have the place validation / qualification in the system of quality management. Developed and proposed training plan, report and statement of qualifications.