The results of the studies allow us to develop a plan to minimize inconsistencies in the production of the biological product.

The obtained results can be used to introduce risk management in the veterinary vaccine manufacturing companies, which will ensure stable work, reduce costs by increasing the level of organization and improving the quality of the drug.

THE QUALIFICATION PROCESS ON THE EXAMPLE OF THE SECONDARY PACKAGING WAREHOUSE

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Introduction. In the management of the resources of pharmaceutical enterprises, warehouse logistics occupies a special place. The tasks of warehouse logistics are: reception of material resources, their placement, storage, maintenance of necessary storage conditions, carrying out loading and unloading works, etc. In this regard, the necessary component of improving the efficiency of a pharmaceutical company is the optimization of material resources management in warehouses, that is, the calculation of optimal warehouse areas, which, on the one hand, is connected with the need to create and maintain efficient conditions for the storage of material resources and optimize the movement of internally displaced material resources, and, on the other hand, will help to optimize storage costs, reduce the cost of medicines and increase their availability to the population. Also important for pharmaceutical companies is the need to implement the requirements of international GMP rules and GSP recommendations, which is a condition for licensing and certification of warehouses. According to these requirements warehouses for storage should pass the qualification procedure. Warehouse qualification is a process of documentary confirmation that requires storage of products throughout the warehouse area and facility, in each of them, in the places where food is stored.

Aim. The purpose of our research was development of measures for the qualification of warehouses to provide conditions storage of medicinal products.

Materials and methods. As a qualification material, we used the rules Good storage practice – "Medicines. СТ-Н МОЗУ 42-5.1:2011», designed according to «WHO Technical Report Series, No. 908, 2003, Annex 4. Guide to good storage practices for pharmaceuticals». In addition, storage of medicines in Ukraine regulates a number of domestic normative documents in particular an order the Ministry of Health Ukraine dated March 16, 1993, No. 44.

Results and discussion. We have chosen a secondary packaging warehouse as an object of qualification. The ventilation, air conditioning and air purification system should operate according to the set parameters and, if necessary, the air properties, regardless of drying time, day or climatic season, should be stable. Accordingly, the qualification should protect these conditions and conduct, at least for the two most critical climatic seasons, when the temperature is higher and lower than the temperature of the products occurring in the "warm" and "cold" periods of the year.

The storage conditions in the warehouse should be: temperature 10-25^{0}C, air humidity 45-70%. To confirm the storage conditions, we need to determine the optimal position of temperature and air humidity sensors indoors.

To do this, we conducted a research on the optimal location of the sensor for temperature and air humidity. Having placed the recorders of the series HUATO HE173-USB, we recorded the temperature and air humidity for 7 days. So, we have installed an optimum measurement point. At this point, we installed a data logger – a two-task wireless data logger with temperature and air humidity with an LCD. It transmits data up to 600 meters (without interference). Reading interval from 1 reading to 1 second to 1 reading at 24 o'clock. Measurements are made in a stable state of the parameters of ventilation and air conditioning systems. At the same time, the temperature and the relative air humidity of the environment we monitored.

Points are selected depending on the number and structure of racks, the control is carried out at each level of the racks, the sensors are located at a distance of 7-10 m from each other. In the case of

placement of products on pallets – the temperature is monitored at an altitude of 1.5-2 m. To determine the point of constant control point, the maximum "warm" and minimum "cold" temperatures are determined. At points the average annual temperature is determined, the temperature deviation from the temperature limits of storage is calculated (for example, storage at +15 – c+25^{0}C, average temperature at the cold point + 17^{0}C – deviation of 2^{0}C, in warm +24,5^{0C}, deviation of 0,5^{0}C, therefore the heat point is chosen for constant control). In the case when deviations from the normalized limits coincide, the point most convenient for personnel is chosen.

The sampling points are plotted on the premises plan and included in the research and control forms. Test results and their analysis are recorded in the forms of deviations. The deviation sheet contains a description of the rejection and a recommendation for its elimination. After the elimination of the deviation, the result is recorded in the rejected message, and the deviation sheet is closed.

Designed deviation sheets are used as a supplement to the Qualification Protocol. If the deviation letter remains open during the development of the report, the result of the qualification may be unsatisfactory.

Conclusions. As a result, we have definite the necessary characteristics for the qualification of warehouses. The methodology for the qualification of the warehouse gives us an understanding of the principles and approaches to this process. Establish eligibility criteria and plan work on the qualification of warehouses. Studies have allowed us to determine the optimal location of the sensor to collect the necessary information about the temperature and air humidity in the warehouse. As a result of our research, we developed a qualification protocol.