number of unpainted large (2-10 microns) cells that gemmate (15% or more) – honey ferments, but not heated; Many coloured large cells that gemmate, indicate that the honey fermented and it was heated.

The predominance of small intensively coloured yeast cells with two-contour shells – the honey was stored for more than a year or it was spoiled by overheating. The complete absence of yeast in the drug is the evidence of honey falsification.

Not so long ago, new analytical methods for falsified honey have been developed. At the University of Lyon, using liquid chromatography, it was found that some polysaccharides do not occur in honey. For example, in acacia or polyfloric honey, it is relatively easy to prove even 1% admixture of grain syrups.

Also, it is now possible to prove the presence of foreign enzymes in honey. Samples with added amylase from Aspergillus oryzae were investigated at the Institute of Chemical Technology (Prague) and found that the bee-produced amylase was different from the microbiological enzyme added to counterfeit honey.

Conclusion. So, during our work, we have reviewed the methods for determining the quality of honey and typical problems encountered by research laboratories at both the state and international levels in detecting counterfeit honey.

IMPLEMENTATION OF RISK MANAGEMENT IN PRODUCTION OF INACTIVATED VACCINE AGAINST GOOSE PARVOVIRAL ENTERITIS

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Introduction. Identify internal and external factors impact on the organization is an important step in making the best decisions to achieve the objectives. In carrying out this task in the management of quality using ISO 31000:2018 Risk management – Guidelines, ISO Guide 73:2009 Risk management – Vocabulary and IEC 31010:2009 Risk management – Risk assessment techniques ISO, containing approaches to risk management and terms for adequate interpretation.

The principles of risk management are effectively used in many areas such as finance, construction, automotive and others. Increasingly, risk management approaches are used in pharmaceutical manufacturing and veterinary medicine.

Some companies use several risk management methods. Thus, FTA (Fault Tree Analysis) and HAZOP (Hazard and Operability Study) were used in manufacturing of radiopharmaceutical the drug «Fluorodeoxyl glucose ^{18}F, solution for injections». It also shows the application of a risk management system using several methods in a pharmaceutical company ОАО «ИнтерХим».

Philip Thomas and his colleagues conducted a research showing the risks of applying individual risk management methods and the negative impact on the quality of the process when they are being used, indicating the need to use several methods, taking into account the direction of activity, the features of technological processes, etc.

Aim. The purpose of our work was to conduct a study on identifying and analyzing existing risks using the methods of causation analysis and FMEA (Failure Mode and Effects Analysis) in the production of an inactivated vaccine against goose parvoviral enteritis.

Materials and methods. During the course of work, the analysis of causal relationships was used to identify possible risks by constructing the Ishikawa charts. The FMEA method in order to determine possible consequences and ways to avoid them.

Results and discussion. Risk management consists of the following steps:

- identification,
- analysis,
- a plan of response,
- its implementation,
- further control.

The general scheme of the process of manufacturing an inactivated vaccine against goose parvoviral enteritis consists of several stages:

– the culture of fibroblasts of geese embryos,
– the production of a virus-retaining fluid,
– the inactivation of the virus-retaining fluid,
– the combination of inactivated fluid with adjuvant,
– packaging and labeling of the finished product.

At the first stage of our research, we identified the risks involved in the production of an inactivated vaccine against goose parvoviral enteritis. To do this, a method for analyzing causative relationships was used, which allows identifying possible causes of unwanted problems. To do this, we have constructed a Ishikawa Diagram («fish bone»).

For our research, we used six groups of primary causes: these are premises, personnel, technologies, equipment and infrastructure elements, solutions and reagents, packaging and labeling (Fig. 1). Each of them had several second causes of influence, which we used for a comprehensive risk assessment.

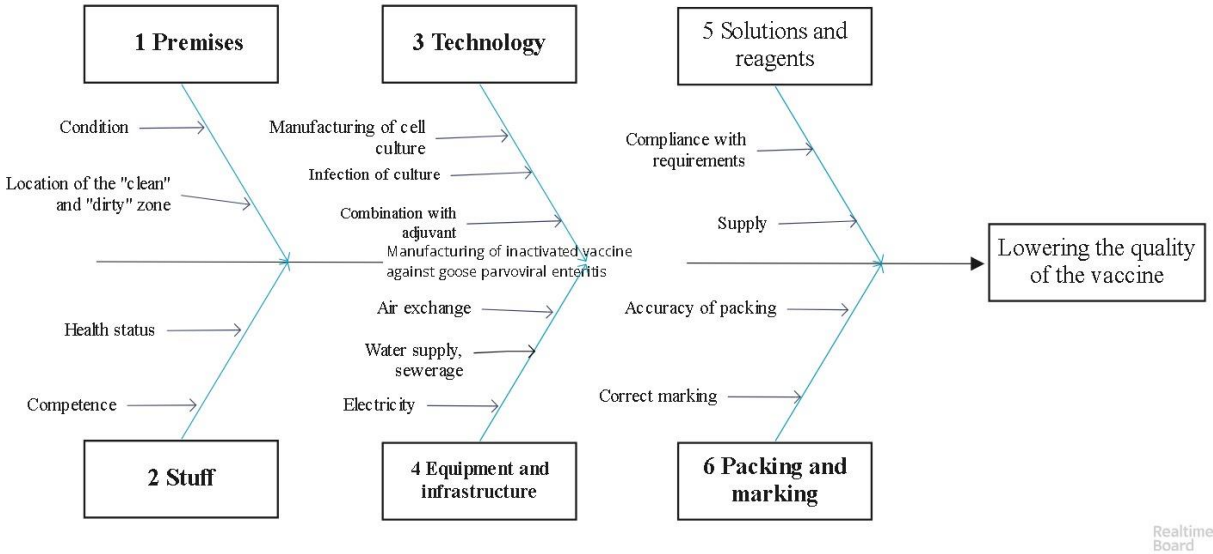

Figure 1. Ishikawa Diagram.

In the next step we have analyzed all the detected unwanted risks. For this purpose, we used the method FMEA. For example, when analyzing the premises defects can be detected in the internal state of the premises and raised in the «clean» and «dirty» areas. The impact on staff quality vaccines due to his state of health and competence of all involved employees. Violation technology of biological product can take place on the stages of preparation of cell culture, the inactivation of the virus-retaining fluid and its association with an adjuvant. Failure of equipment and systems in violation of the exchange of air, water, electricity, sanitation is also a cause lower quality product. Furthermore, it should be noted factors such as quality and timely delivery of reagents and process stability packaging and labeling.

The most influential are the indicators of the violation of the technology of manufacturing inactivated vaccine (preparation of cell culture – 400 and the inactivation of the virus-retaining fluid – 400), the state of health of personnel – 216, failure of the electrical supply – 250, marking and packaging (instability of the packing procedure – 280, violation of requirements to marking – 200). Apparently, the methods of control at these stages are not sufficiently effective.

It is also necessary to take measures to reduce the likelihood of occurrence. Our further planned research is aimed at reducing the causes of inconsistencies and improving control methods. The effectiveness of corrective actions will be checked by repeated FMEA analysis.

Conclusions. The application of the proposed methods (method of causality analysis and FMEA analysis) allowed to identify, classify and rank possible risks in the manufacture of an inactivated vaccine against goose parvoviral enteritis.

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