processes, as well as production in real time, without presenting to the Quality Control Division of intermediate products.

Real-time production organizations require significant changes in control strategies and control tools. But the use of the process control algorithm based on the feedback loop becomes even more relevant.

Conclusions. In the course of research we have developed recommendations for the improvement of production quality control and operational evaluation of the results: the SOP template "Analysis of samples in the production zone, sampling, procedure, reporting" was developed.

ORGANIZATION OF A RISK-BASED AUDITS AT THE MANUFACTURING PHARMACEUTICAL COMPANY

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Introduction. Production of pharmaceutical products requires compliance with all requirements of Good Manufacturing Practice. Specific requirements relate to the pharmaceutical quality system (PQS). The Pharmaceutical Quality System includes the main business processes (all that is related to the manufacture of medicines) and a number of other processes. These processes include managing processes and processes of providing activities.

One of the PQS's management processes is the process of internal and external audits. Under current requirements, this process should function on the basis of risk management concept.

Aim. The aim of our research is developing of proposals for the optimal organization of the audit process at the research base (LLC "Valartin Pharma") using modern tools and approaches, in particular – the concept of risk-based management.

Materials and methods.

We used methods of empirical research and comparative analysis. The information basis of our study was the materials published in open scientific and professional literature, as well as the regulatory requirements of standards and guidelines for QMS of pharmaceutical companies.

The object of research was a quality management system of the pharmaceutical manufacturing enterprise, built on the requirements of ISO 9001 and GMP.

The subject of the research was the process of internal audit of the pharmaceutical company LLC "Valartin Pharma".

Results and discussion. Taking into account the requirements of Good Manufacturing Practices that came into force in July 2016, we have applied a risk-oriented approach in arranging work on external audits in order to:

- optimizing time and human resources expenses;
- optimization of financial expenses;
- carrying out the risk assessment and establishing the risk category of the company being the subject of the audit;
- establishment of rational periodicity, volume and scale of each audit;
- improvement of planning and conducting of audits process;
- improvement of documented procedures and forms of documents concerning the organization of the process of external audits, etc.

In the study, we used the following documents:

- ICH Q10 Pharmaceutical Quality System.
- ICH Q9 Quality Risk Management.
- EMA/INS/GMP/321252/2012 A. Model for Risk Based Planning for Inspections of Pharmaceutical Manufacturers.
- PIC/S:

- ✓ PI-037. Recommended Model for Risk-based Inspections Planning in the GMP Environment.
- ✓ PS/INF 1/2010/ Quality Risk Management implementation of ICH Q9 in the pharmaceutical field an example of methodology from PIC/S

Main stages of risk-oriented external audits:

I. Definition of the category of the company.

II. Definition of the company's risk category:

- risk assessment / risk analysis;
- establishing a risk category based on a risk assessment.

III. Data processing by the company's risk category:

- definition of audit objects and scale;
- definition of frequency and terms of audits;
- definition of volume (time resource) and number of auditors (human resource).

IV. Periodic review of audit plans and their timely updating.

The procedure for organizing of external risk-oriented audits is presented below.

The definition of the company's risk category was conducted in accordance with the Process Guidelines "Risk for Quality Analysis".

To determine the company's risk category, each company has been evaluated and risk-based analysis of the company, a degree of criticality for product quality has been identified.

Based on the risk assessment of each company, the risk categories of the manufacturers or suppliers, or companies-distributors, or laboratories are identified.

The company's risk category which we were applied:

- Category A – high risk: companies – Active Pharmaceutical Ingredients (APhI) producers / products in bulk / under contract / finished products (FP);
- Category B – average risk:
  - companies - APhI producers / products in bulk / FP / under contract with GMP certificate of PIC/S member country;
  - company suppliers of APhI / products in bulk / FP that do not have a GDP certificate;
  - manufacturers of primary packaging materials for non-sterile and sterile drugs;
  - companies-distributors who do not have a GDP certificate;
  - laboratories for quality control and service provision for studies that have been certified in accordance with the legislation of Ukraine or another country.
- Category C – low risk:
  - companies-manufacturers of secondary packaging materials;
  - companies-manufacturers of printed products;
  - company suppliers of APhI / products in bulk / FP having a certificate of GDP;
  - companies-distributors that have the certificate of GDP.

Depending on the company risk category, the following parameters are set for:

- frequency of audits;
- depth of audits (full, incomplete for certain objects);
- objects of audits (PQS documentation, technical equipment, technological process, quality control, outsourcing activities, logistics, transportation);
- duration of the audits (number of days), which depends on the risk category of the manufacturer or distributor and the criteria of criticality for medicines (time resource);
- required number of auditors (human resource).

We have developed a matrix of risk-oriented approach to external audit. Such matrices contain all information for the organization of risk-based audits.

At the beginning of each year, the Risk-Oriented Approach Matrix is reviewed and updated. On the basis of this Matrix, the Annual Plans of the External Audit Schemes are prepared and the lists of approved manufacturers / suppliers updated.

Conclusions. The analysis of modern principles of the development of the pharmaceutical quality system based on, in particular, the risk-orientated approach to conducting basic business processes is carried out.

Participated in a development of a risk-oriented approach to external audits implemented at Valaritin Pharma LLC.

Based on the application of the risk-oriented approach, the relevant standard operating procedures and forms of documentation introduced by the PQS of the enterprise have been developed.

The application of the risk-oriented approach to external audits has made it possible to optimize the use of human and financial resources of the company in support of this process.

EXECUTION OF EXTERNAL QUALITY CONTROL IN MEDICAL LABORATORIES OF BACTERIOLOGICAL PROFILE

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Introduction. External quality control of laboratory research is one of the methods for ensuring the proper functioning of clinical and diagnostic bacteriological laboratories. The result of determining the sensitivity of microorganisms to antibiotics depends on many factors, the arbitrary change of any of which can lead to biased and false results of the study.

Aim. The purpose of our research was to identify systematic and random errors in the development of the disk diffusion method and to achieve comparative results obtained by laboratories participating in interlaboratory quality control.

Materials and methods. Determination of microorganism's sensitivity and interpretation of the results were carried out in accordance with the order of the Ministry of Health of Ukraine No. 167 of April 5, 2007 "On Approval of Methodological Instructions" Determination of Sensitivity of Microorganisms to Antibacterial Drugs ".

Control strains of Staphylococcus aureus ATCC 25923 (F-49), Escherichia coli ATCC 25922 (F-50), Pseudomonas aeruginosa ATCC 27853 (F-51). The cultures for everyday use were weeded on beetroot meat peptone agar and kept in a refrigerator at a temperature from +2 to +4 0 C.

For sowing, daily cultures were used for the test- state. We used standard industrial drives with different kinds of antibiotics.

Determination of the sensitivity control strains to antibiotics was performed for 10 consecutive days. Test results for each individual strain to carry the protocol.

Process control is one of the key elements of the quality management system and is a control over the actions taken during the handling of samples and in the research process in order to ensure correct and reliable results. Quality control checks the actions related to the study period.

The purpose of quality control is to identify, evaluate and correct errors that occur due to problems with the analytical system, due to working conditions or unlawful actions of employees, before a report will be issued with the results of patient analysis.

Quality control is part of quality management, which aims to meet quality requirements (ISO 9001). The goal of quality control is to check the accuracy and reproduction of laboratory tests to release reports with the results of patient analysis.

The source of the problems should be identified and eliminated before the patient's analysis results are published. Laboratories should strive to use high-precision methods and always follow standard operating procedures. To resolve issues related to quality control, it is useful to establish rules and procedures for corrective action. Consider the following possible causes:

- damage to nutrients, reagents, antibiotic disks, damage to control material (strains of microorganisms), employee mistake;
- non-compliance with the manufacturer's instructions;