Conclusions. In particular, the answers of experts suggest that the most urgent of the above questions is to ensure the competence of risk managers. Therefore, the development of proposals for the organization of a risk-managers training is the objective of our further research.

ACTUALITY OF THE LEAN PRODUCTION CONCEPT IMPLEMENTATION AT PHARMACEUTICAL ENTERPRISES

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Introduction. Lean production is a management concept that involves optimizing business processes with maximum market orientation and taking into account the motivation of each employee. Lean production forms the basis of a new management philosophy and culture. This is a broad management concept aimed at eliminating losses and optimizing business processes: from the stage of product development, production and to interaction with suppliers.

Aim. Lean Manufacturing Techniques are applicable to any area of the organization's activities with a view to a stable increase in competitiveness in a changing market.

Materials and methods. Pharmaceutical enterprises are no exception, since their main task is the efficiency of production, that is directly related to the complexity and duration of the production cycle. The longer this cycle is, the greater is the number of auxiliary and servicing industries in it, the less effective is production in general.

Results and discussion. The Kaizen Institute, which has worked with a large number of pharmaceutical companies around the world, has identified the typical results that a company can achieve when lean manufacturing is applied (Fig. 1).

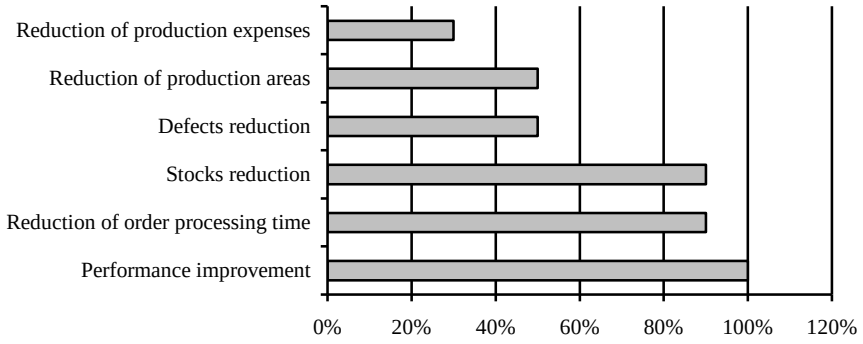

Fig. 1. The effect of the lean production introduction in pharmaceutical companies.

Conclusions. In the pharmaceutical industry, control and reliability processes play a key role. The introduction of lean manufacturing can be used to enhance the competitive advantage of an organization.

The efficiency and payback of this concept are quite high. Its implementation allows companies to gain tangible benefits and competitive advantages, which is especially important in today's competitive environment.

CONTROL OF DATA AND INFORMATION MANAGEMENT AT STATE LABORATORIES FOR THE CONTROL OF MEDICINES

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Introduction. Laboratory control is one of the main regulatory procedures in the system of quality assurance of medicines. State laboratories for quality control of medicines must guarantee and document the correctness of the results obtained, prove their competence not only to their clients, but also to regulatory

bodies. A necessary condition for the proof of the research results is the introduction and constant maintenance of an effective quality assurance system in working order. ISO / IEC 17025: 2017 «General Requirements for the Competence of Testing and Calibration Laboratories» is an updated international standard for quality control laboratories for medicines. In 2017 the ISO / IEC 17025 standard was harmonized with the standard ISO 9001: 2015 «Quality management systems. Requirements» p. 7.11 ISO/IEC 17025:2017 «Control of data and information management» puts forward the requirements for the management of data and information contained in both computerized and non-computerized systems.

Aim. Conduct a preliminary analysis of data and information management in laboratories for quality control of medicines/

Materials and methods. Theoretical analysis of normative documentation on quality assurance of medicines, scientific and educational literature.

Results and discussion. The correctness and reliability of the tests carried out by the laboratory are determined by the following factors:

- human factor;
- facilities and environmental conditions;
- test and calibration procedures, as well as the suitability of the methodologies;
- equipment;
- the ability to trace measurements;
- sampling;
- handling of test and calibration objects.

In order to increase the effectiveness of the functions of laboratories for quality control of medicines, we propose to introduce into the computerized laboratory systems an approximate list of accounting modules that are resources for ensuring the process of monitoring the conduct of research:

- The module «Personnel management» (actual information about the personnel of the laboratory: its competence, work experience and length of service in a particular area, planning of training of laboratory personnel, accounting for training and retraining of employees, monitoring the terms of personnel certification);
- Module «Laboratory logs» (creating a list of journals, assigning access to the journals, changing the form of the journals, performing periodic documentation of monitoring indicators that characterize the state of external conditions in the relevant journals, for example, monitoring the parameters of the environment (temperature, humidity, etc.); tracing the results of studies, measurements and other work carried out by the laboratory in specific conditions);
- Module «Management of normative documents» (formation of the register of normative documents (regulations, standards, standard operating procedures, etc.) with their breakdown into levels, automating the process of updating documents, monitoring the expiration date of regulatory documents, tracking the date of making relevant changes and specific employee who made these changes, keeping expired versions of documents in accordance with the established deadline.
- Module «Accounting of equipment» (identification of laboratory equipment, generation of information on the state of the laboratory instrumentation fleet, maintenance schedules, recording of the results of the equipment maintenance, monitoring the time of verification (calibration) of measuring instruments and testing equipment, adjustments, repairs, etc., to trace the use of certified laboratory equipment in the performance of tests and measurements.
- Module «Test reports» (forms of research and measurement protocols, formation, review and approval of research protocols, etc.)

The introduction of computerized accounting modules to ensure the process of monitoring the work of the laboratory for quality control of medicines will allow implementing the principles of ISO 9001 in the work of laboratories:

1. Customer orientation (analytical control is carried out in accordance with the requirements of the consumer, operational and reporting information on the quality of products is also provided, the reliability of the information of the results of the analysis is ensured, and thereby contributes to the satisfaction of customer requirements).

2. Leadership (delineation of access rights to the objects of accounting modules, responsibility for approving and transferring quality indicators, all processes are monitored by the laboratory manager or persons who have been delegated authority);
3. Involvement of employees (each employee has rights that determine access to directories, journals, control objects, forms of documents, understanding of the measure of responsibility, role in the team).
4. Process approach (modules are processes that are represented as an information sequence of the component of the stage of tests and measurements, include various blocks and functions, reflect all the processes of the analytical laboratory in a single information core).
5. Continual improvement (introduction and adaptation of computerized accounting modules for automation of laboratory processes and improvement of activities based on evaluation criteria on the basis of documented data in modules).
6. Decision-making based on facts (prompt information on the quality of products and automated internal laboratory control allows to minimize the influence of the «human factor», accelerate decision-making and implement actions based on balanced analysis results).
7. Mutually beneficial relations with suppliers (the function of accounting suppliers in terms of supply of quality reagents and materials).

Conclusions. Automation of laboratory processes in a single information space allows to provide full documentation of the entire process, facilitates the implementation of the main functions of laboratories for quality control of medicines and ensures the execution of procedures in accordance with the requirements of regulatory documents.