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For a wide audience of scientists and pharmaceutaical and medicinal employees.

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Section 19.
QUALITY MANAGEMENT IN THE PHARMACEUTICAL SECTOR OF HEALTHCARE

ANALYSIS OF APPROACHES TO CONDUCTING VALIDATION IN KAZAKHSTAN, UKRAINE AND COUNTRIES OF THE EUROPEAN UNION

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Introduction. Validation is one of the main tools of quality assurance in pharmaceutical manufacturing. Validation is a process of documentary confirmation that equipment, engineering systems, materials, processes lead to established results. Comparison of normative documents of Kazakhstan, Ukraine and the European Union can serve as recommendations in the certification of pharmaceutical industries.

Aim. Study normative documents of the European Union countries, Ukraine, Kazakhstan and to conduct a comparative analysis in the issues of validation.

Materials and methods. The application of good manufacturing practices to the standards of the Republic of Kazakhstan, the Russian Federation, Ukraine, and the standard of good manufacturing practice of the European Union was used for comparative analysis.

Results and discussion. As a result of the analysis it found out that the standards of good manufacturing practices in Kazakhstan and Ukraine are identical, there are differences only in minor formalities. The GMP standard of the European Union gives a more detailed notion of the process of equipment qualification, namely, it refers to such stages as User requirements specification – URS, Factory acceptance testing – FAT, Site acceptance testing – SAT, also there is such concept as "requalification" in the European standard. In the European standard, retrospective validation is not considered an acceptable approach, while in Kazakhstan and Ukraine such a concept still exists. In addition good manufacturing practice of the European Union describes approaches to validating the process: the traditional method of validation, the "quality through development" approach, the combined approach. Also in the good manufacturing practice of the European Union reference is made to ICHQ8, ICHQ9, ICHQ10, ICHQ11. But the principle of carrying out validation measures is the same - it is based on risk assessment.

Conclusions. Thus the analysis of the results showed that Kazakhstan and Ukraine standards and European Union standart are identical, but in the European Union standard some aspects of validation are described in more detail and retrospective validation is considered unacceptable. In general approaches to validation measures are based on risk assessment.

CORRECTING SYSTEM ERRORS AND RESTORATION OF COMPUTERIZED SYSTEMS ON PHARMACEUTICAL ENTERPRISES

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Introduction. In the current GMP guideline, the general requirements for validating computerized systems (CS) are described in Appendix 11, which apply if the CS replaces a manual operation. The requirements for the work on qualification, validation and verification of the CS result in the practical interest of the specialists of the pharmaceutical company (PC) in organizing and conducting such works.

Aim. The aim is to study the requirements of international and national standards regarding the validation tests of the CS on industrial and distribution PC and the development of guidelines for validation work taking into account the national specificity of the PC and the relevant sectoral requirements.

Materials and methods. During the study, information materials on the organization of validation tests on the PC of Ukraine and the world were used. The method of comparing and comparing the requirements of international and regional documents in the field of validation of the CS was applied.

Results and discussion. All requirements for operation, including reliability and recovery, to which the CS must comply, must be specified in the "requirements specification" for this system. The

verification of processes related to the restoration of the CS should include the ability of the system to rectify programming errors (settings), data errors and hardware failures. If the recovery occurs automatically, you should evaluate the re-initialization, the mechanism for verifying the data recovery points and restart. In the procedure for correcting errors and restoring the work of the CS, the following should be taken into account: analysis of errors, composition of commission on restoration works, implementation of additional organizational measures, testing software components, verification of saved data, data recovery, issue of the CS for re-use, instructions and documentation.

Improper use of the CS by users can be fixed by the system owner who implements the training program using the appropriate systems. All cases of interference and misuse must be reported, investigated and evaluated. Any reason for invasion and misuse of the CS must be determined by the subsequent drawing up of a corrective and preventive action plan.

Within the control of CS processes and electronic documents that may affect the quality of products, it is necessary to have documented procedures that are responsible for controlling the development, operation, maintenance and restoration of the CS. In developing this procedure, a risk analysis is required to prove the reliability of the CS, for which at least the following is performed:

- Computer software performs its functions, as provided in the "requirements specification"; - The verification of the CS and electronic documents takes place at appropriate intervals. Software, hardware, and backup procedures are regularly checked to ensure reliability. The data recovery procedure guarantees the integrity of the data. Each set of backups is checked to make sure that there are no errors;

- Critical equipment and interfaces between computers and equipment are periodically or continuously inspected to ensure accuracy and reliability in order to verify compliance status. During a periodic review, you should also check the electronic records that were transmitted to another format or system during the relevant period. The purpose of this review is to confirm that the electronic records have been accurately and reliably transmitted;

- Preservation of appropriate backup or archival systems, such as computer software copies, configuration files and electronic records. All files and saved data must be guaranteed to recover all relevant documentation, if necessary. This also applies to system programs required for data storage and retrieval. For this reason, records should be reserved on a regular and incremental basis, and a backup copy is kept at a remote location to prevent intentional or accidental damage;

- After making changes to the system and backing up, change management should ensure the availability and integrity of backup files and saved data by comparing backup data and original files;

- Changes to the CS (infrastructure and software), infrastructure equipment, configuration files, electronic documents and technological equipment are checked and documented. Changes are made only by authorized employees. All changes must be monitored.

Conclusions. In case of fragmentation and / or disengagement of the CS, the appropriate procedure for restoring the CS to the previous state should be reliable, which is also part of the process of continuity of the process. For critical CS, in the event of an emergency, alternative systems that are available in case of failure of the main system should be considered.

Any CS involved in the GxP processes must ensure the full performance of the required functions and be subjected to validation tests to ensure the consistency of the process that can significantly affect the quality of the drugs.

Carefully organized work on validating the CS provides reliable results that are important for obtaining assurances of quality assurance of medicinal products. Our further research is focused on developing a methodology for validating the CS.

INTRODUCTION OF ELECTRONIC DOCUMENT TURNOVER

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Introduction. Electronic document turnover (EDT) is a system of automated processes for processing electronic documents that implements the concept of paperless workflow. The system allows users to intuitively understand the workflow of all regulating and recording documents (records) by processes, certain GMP requirements. The uniqueness of the system lies in the fact that along with the automation of the stages of the life cycle of documents (design, coding, development, coordination, approval, commissioning, production of controlled copies, change control, archiving), it is able to automate the life cycle of records data, checking, making changes, archiving a record).

Aim. Our goal is to introduce EDT for the effective management of documentation at a pharmaceutical enterprise.

Materials and methods. When implementing EDT, the system should be integrated with other computerized systems installed in the enterprise. The introduction of electronic document management in an organization is not such an easy task. It is not enough simply to develop, purchase, install the program on computers and start work. The success of implementation depends on compliance with several conditions:

- active participation in the automation of office work by the management of the enterprise;
- adherence to the installation stages will allow you to withstand the necessary deadlines and keep within the budget;
- interest of key users. At automation of document circulation it is necessary to consider interests of those employees who will directly work in the program;
- the competent preparation of the project documentation will help to avoid discrepancies between the executor and the customer in the process of system operation;
- validation of computer systems.

In the process of introduction of the EDT system in the enterprise, problems and risks inevitably arise, leading to a violation of the project start-up time, exceeding the budget, incomplete achievement of the goals facing the EDT system or even a complete breakdown of the implementation of the program. The specificity of risks in the implementation of EDT is due to the fact that it is necessary to transfer a significant part of employees to new and unusual methods of work. The main reasons that cause increased risks include the following:

- conservatism of employees;
- insufficient computer literacy of workers;
- lack of documentation for major processes;
- insufficient technical equipment;
- lack of clear project management.

To prevent the emergence of undesirable problems in the organization of EDT, it is necessary to design in detail the operation of the EDT system in the enterprise, organize its phased implementation, train the staff and provide it with operational support in solving problems related to the operation of the EDT system.

Results and discussion. We have identified the main stages of the introduction of EDT in a pharmaceutical company:

- preparation of project documentation;
- identification of key personnel for project management;
- obtaining technical specifications or user requirements specification (URS) from all departments of the enterprise;
- integration of URS into a single project;
- determination of necessary resources;
- retrofitting of units with computer equipment;

- installation and configuration of EDT software;
- identification of key divisions;
- training/recruitment;
- the sequence of EDT implementation;
- validation of EDT.

The compilation of URS for the implementation of the EDT system is a complex process. We decided to start the implementation of the EDT project of one department - Quality Control Department (QCD).

The URS of the QCD were based on paperwork in accordance with the quality control processes. At the moment the following functions are implemented:

1. Electronic database of normative documents (Specifications, Quality control methods, etc.).
2. Electronic database of control results (protocols, analytical sheet, certificates, etc.).
3. Electronic protocols of quality control procedures (methods) are generated.
4. The electronic base of raw materials and auxiliary materials (standards, reagents, etc.) has been formed.

At the moment, an electronic base for the continuous study of stability is being formed.

The next stage is planned to implement the draft procedure - the release of the series in the implementation by the Authorized Person. This procedure is carried out by a separate process.

Conclusions. Based on the implementation of the EDT project in the process of quality control, it is necessary to make a budget for the full implementation of the project and implement the project at the level of the entire organization.

The introduction of EDT will allow:

- to reduce staff costs due to lack of need for "document controllers" (keeping lists of documents and records, making controlled copies of documents, authorized issuing of forms, transfer of project documents for harmonization /approval, etc.);
- exclude paper costs especially for the production of controlled copies, record forms, consumables and maintenance of office equipment, etc.;
- to optimize the working time of personnel employed at various stages of the documentation life cycle.

ORIENTATION TO THE USER IN A PHARMACY

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Introduction. Orientation to the consumer is an effective way of forming loyalty among the end users of pharmacy products. The consumer of drugstore products becomes either a sick visitor or a healthy one, but who wants to purchase preventive drugs.

The manufacturers of medicines have several categories of consumers, namely:

– Direct (visitor) who personally pays the drug.

– Indirect (doctor) who is guided by the symptoms of the client, appoints a specific medication.

One of not a few important stages of consumer orientation is the development of a research plan. This is done by the following methods:

– Internal sources of information (sales statistics, cost statistics, feedback profiles from customers);

– External sources of information: market statistics; results of consumer behavior research; data from manufacturers;

– Observations, surveys conducted by pharmacists or pharmacists, or by visiting research specialists.

Daily work with consumers allows pharmacies to develop effective and right directions of development, necessary to increase their own economic indicators. An important factor in these conditions is skillful attraction of clients, understanding of their needs, quality service, and formation of loyalty among consumers.

According to statistical data in Kharkov, public pharmacies should be slightly more than 50. But not state pharmacies, the number of which "regulates the market" according to the end of 2015 in the Kharkov region – 1300 by almost 3 million people. In this situation, a sharp increase in the level of competitiveness of pharmacy organizations, the guarantee of future success is, first and foremost, the orientation toward the consumer.

Aim. The purpose of our study was to study the methodology of the principle of customer orientation, which underlies the quality management system.

Materials and methods. As methods of research we used – the principle of questioning consumers with subsequent statistical processing of the results.

Results and discussion. A psychological verbal and communicative method was used, based on a specially designed list of questions.

Before the survey begins, the questionnaire should be "run-in" on a small group of people who did not take part in the questionnaire design to check whether the questions are understandable by the alleged questionnaire and whether all the necessary answers to the "quantitative" questions are taken into account.

After the internal "break-in" the questionnaire should be checked on the respondents, that is, to conduct a pilot study or piloting. For this, it is necessary to conduct a survey of about 10 respondents.

During piloting, it is important to pay attention to all questions, the reaction of respondents (clarifications, misunderstandings, comments, objections), as well as suggestions for changing formulations, additions, etc.

Accordingly, based on the results of piloting, it is necessary to adjust the questionnaire. If the design questionnaire is not given enough time to design, that is, did not make it easy to fill, then it can be done on the basis of the results of the pilotage. Even if the questionnaire does not fall into the hands of the respondents, it should be convenient for interviewers.

In our questionnaire, we used the following blocks:

– a cap (this is informing the consumer about the purpose for which the survey is conducted);
– the main part (consists of not a lot of questions that do not incline to any answer).

The first block is focused on the main groups of visitors (80% are female and 40% are male).

The second block is age oriented (the group from 15 to 25 years old is 64%, from 40 to 55 – 15%, from 26 to 40 – 11% and the smallest group from 56 to 10%).

The third block – is focused on the satisfaction of visitors (56% of visitors were satisfied with the assortment, 44% – were not satisfied with the lack of some drugs).

The fourth block is focused on employees (57% of consumers expressed their dissatisfaction with the competence of the staff, 20% expressed dissatisfaction with the queues, 13% were satisfied with everything).

The fifth block is focused on the design of the pharmacy and the location (40% were satisfied with the design, 50% were not happy with the location, 10% were satisfied with the design and location).

Conclusions. The orientation towards the consumer is an important component of the work of every institution in the pharmaceutical industry. Marketing research, professional seminars for pharmacy workers, establishing trust relationships with the consumer contribute to the formation of a positive image of the enterprise, helping to acquire a loyal customer.

According to the questionnaire, we made a conclusion about the need for staff training methods of communication with the client. The increase in the range and some adjustments in merchandising will allow us to attract more consumers to our pharmacy.

ACTUALIZATION OF QUALITY MANAGEMENT SYSTEMS AT STATE LABORATORIES FOR THE CONTROL OF MEDICINES

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Introduction. Effective quality control of medicines is an obligatory component of the national security system of the state. Laboratories for the quality control of pharmaceutical products bear a major responsibility for the results obtained and conclusions made on their basis on the conformity of the tested samples with the requirements of the specifications, because the success of the treatment of patients or even their life depends on the results of such studies. ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*, is the international reference for laboratories carrying out calibration and testing activities around the world. Producing valid results that are widely trusted is at the heart of laboratory activities. ISO/IEC 17025:2017 allows laboratories to implement a sound quality system and demonstrate that they are technically competent and able to produce valid and reliable results.

Aim. The purpose of our work is to analyze the main changes in the new standard ISO/IEC 17025:2017 for determining the methods for updating the work at state laboratories for the control of medicines.

Materials and methods. The theoretical and methodological basis of the work are provisions on the formation of quality management system on the basis of modern concepts of standardization and quality management.

Results and discussion. ISO/IEC 17025 takes into consideration the new ways of working of laboratories today. The most substantive changes are as follows:

- The scope has been revised to cover all laboratory activities, including testing, calibration and the sampling associated with subsequent calibration and testing.
- A new structure has been adopted to align the standard with the other existing ISO/IEC conformity assessment standards such as the ISO/IEC 17000 series on conformity assessment. The process approach now matches that of newer standards such as ISO 9001 (quality management), ISO 15189 (quality of medical laboratories) and the ISO/IEC 17000 series (standards for conformity assessment activities), putting the emphasis on the results of a process instead of the detailed description of its tasks and steps.
- The standard has a stronger focus on information technologies. In recognition of the fact that hard-copy manuals, records and reports are slowly being phased out in favour of electronic versions, it incorporates the use of computer systems, electronic records and the production of electronic results and reports.
- A new section has been added introducing the concept of risk-based thinking and describes the commonalities with the new version of ISO 9001:2015, Quality management systems – Requirements.

Conclusions. The construction of effective quality management system in state laboratories for quality control of medicines will help reduce the number and significance of inconsistencies and errors increase the probability of reliable results, increase the awareness of staff. These measures should definitely be considered progressive both for the national quality control system for medicines and for the entire domestic pharmaceutical market.

DETERMINATION OF AUDIT GROUP MEMBERS' COMPETENCE AT PHARMACEUTICAL ENTERPRISES

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Introduction. The competence of quality management system (QMS) auditors in general and pharmaceutical quality system (PQS) in particular consists of personal qualities and professional knowledge and skills. Given the importance of internal audits (IA) for the pharmaceutical company (PC), which is indicated in the guidelines for good practices in medicines (in particular, GMP, GDP), the issue of selection, training, certification and continuous improvement of the auditor's competence at PC are relevant and important both for domestic ones, and for foreign enterprises.

As a result of the regulatory information sources analysis one can state a certain lack of information concerning specific requirements for the qualification and competence of the personnel involved in the IA. Therefore, in our opinion, it is expedient for the PC to use the provisions of the national standard DSTU ISO 19011: 2012, which contains recommendations for the effective organization and conduction audits of management systems.

ISO 19011 highlights the importance of evaluating the auditors' competence. Such an assessment should take into account the needs of the audit program and its objectives. This provision of the standard should be considered relevant for PC.

Aim. The aim of the study was to determine component of PQS internal auditors' competence to organize scientifically grounded selection of members to the audit team and their further training.

Materials and methods. We used methods of empirical research and comparative analysis. The information basis for the study was the materials published in the open scientific and professional literature, the regulatory requirements of the standards and instructions for QMS and PQM.

Results and discussion. We have argued that the criteria for determining the internal auditors' competence at PC should be determined taking into account the general requirements for the QMS (ISO standards of the 9000 series), the requirements for the audit process (ISO 19011), and the profile requirements for the PQM of the enterprise (GMP guidance, the licensed conditions of the activities on the production and sale of medicines).

In many cases, the audit team includes the group manager (chief auditor), the auditor (s) and expert (s) whose competence was the subject of our study.

Table 1 provides a general list of knowledge and skills of members of the audit team. The "X" mark means that the PC must establish appropriate requirements for each member of the group. More detailed knowledge and skills of group members reviewed further in the text (indicated in the table refer to the relevant paragraphs of text).

Table 1

№ by order in the text	**Knowledge and skills**	**Audit group members**		
		Chief Auditor	**Auditor**	**Expert**
1)	Knowledge of the basics of management	X		
2)	Awareness of the products and processes at the PC (enterprises manufacturing / distributing medicine)	X	X	X
3)	Knowledge of the specifics of the object of the specific audit (process / unit of PC)	X	X	X
4)	Knowledge of the PQS' functioning requirements	X	X	
5)	Knowledge and skills of managing the audit process and managing the group of auditors	X		
6)	Knowledge of audit principles, tools and methods	X	X	

7)	Skills for making a programs and audit plans, record keeping and reporting	X	X	
8)	Knowledge of professional terminology	X	X	
9)	Skills of public speaking, communication with the audience, conflict resolution	X		
10)	Surveying skills, interviews	X	X	

1) Knowledge of the basics of management. Relevant knowledge provides an understanding of the organization management principles, taking into account its size, ownership, organizational structure, existing information system, data storage, systems of document circulation, information technologies. It also includes knowledge of legal requirements applicable to PC. There is also a need for awareness of the division of responsibilities and authority, reporting, evaluation of the quality of work performed by the object of audit, etc.
2) Awareness of the products and processes of PC (enterprises producing or distributing medicines). It is assumed that there is knowledge about products and processes in the operation at the PC, sufficient for a full understanding by the group members of applicable criteria of a specific audit (standard, guidelines or other normative document).
3) Knowledge of the specifics of the object of the specific audit (the object is usually a process or unit PC). This information on the type of products or features of a specific PC process is needed for accurately determination of the audit terms, the plan preparation, questionnaires and other accompanying audit documents.
4) Knowledge of the PQS' functioning requirements. Knowledge of Good Practice Guidance (GMP / GDP) requirements and other regulatory documents that PC is govern. Knowledge should be sufficient to determine the state of functioning of the PQM and its compliance with established requirements.
5) Knowledge and skills of managing the audit process and managing the group of auditors. Ability to manage the audit process to achieve the established audit objectives within agreed timeframes. This knowledge is needed for the head of the audit team who should hold meetings professionally, to ensure the effective exchange of information between members of the group and the subject of audit, to assign tasks and to modify them as necessary, to apply moderation principles and to monitor the dynamics of group processes, to be able to effectively resolve disputes, to prove the need for certain decisions of the audit team, to balance the strengths and weaknesses of the individual members of the audit team.
6) Knowledge of the audit principles, appropriate means and methods. Knowledge of the basic principles, practices and techniques of conducting audits in a sufficient amount for the realization and objective assessment of the audit activity.
7) Skills for making a programs and audit plans, record keeping and reporting. Ability to develop supporting documentation, quickly registers information, create records and compile reports on the results and conclusions of the audit.
8) Knowledge of professional terminology. Ability to effectively communicate with employees of different positions at any level of the organization, using appropriate profile terminology, expressions and professional language.
9) Skills of public speaking, communication with the audience, conflict resolution, etc., including the ability to clearly present the results and conclusions of the audit. It is especially important for the head of the audit team to present the relevant audit findings, conclusions and recommendations (for example, at the final meeting).
10) Surveying skills, interviews. Ability to receive relevant information during an interview with representatives of the audit object, asking well-formulated questions, understands and evaluates responses.

The functions of this staff can be performed either by one or a large number of staff members, depending on the specifics of the PC. If it is a small PC, while selecting a candidate in the auditor, you need to focus on the requirements for the competence of the chief auditor.

Conclusions. Clearly defined requirements for the competence of the PQM audits staff assists the selection of specialists to the audit team so that the overall competence of the audit team is sufficient to achieve the objectives of the audit. In the future, we plan to develop an extended list of auditor's competencies, as well as recommendations for their training and certification.

THE PROBLEMS OF STANDARTIZATION OF MEDICINE COSMETICS IN UKRAINE

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Introduction. The problem of standardization of medicinal cosmetic products is important for the development of the cosmetic industry of Ukraine/

The cosmetic industry of Ukraine expresses the presence of the prospects for increasing the competitiveness and ensuring the import substitution, as a result of which the study of modern approaches to the standardization of cosmetic products with a view to their further development in accordance with the requirements of international standards and European directives is an important and topical issue.

Aim. The purpose of the work was to study the question of standardization of medicinal cosmetics in Ukraine and to determine the actual trends and ways of further development of this area of activity.

Materials and methods. The object of research is medicinal cosmetics that are in circulation in the Ukrainian market. The research was carried out by analyzing the legislative and regulatory framework, scientific publications, as well as marketing analysis of the medicinal cosmetic products assortment, which are being implemented in the pharmacy establishments of the city of Kharkiv and the Kharkiv region.

Results of the research. Our research has shown that the cosmetic market in Ukraine is characterized by constant consumer demand and certain growth trends that have been demonstrated in recent years. In the structure of demand in the cosmetic market of Ukraine, the largest share - more than 30% - is occupied by the category of cosmetic products for personal hygiene: foam baths and showers, deodorants, depilators, care products for men and children's skin. Cosmetic hair care products on the domestic market make up more than 19%; for skin care - 18%. The advantage of consumers is the low cost cosmetics, which make up more than 60% of the market; products of the middle price segment is about 30%, premium cosmetics - 9%.

In the domestic market, import cosmetic products, which represent more than 90% of the total volume of cosmetic products, are dominated by almost all the world-famous brands: Avon, Beiersdorf, Colgate-Palmolive, Estee Lauder, L'Oreal, Chanel, Mary Kay, Oriflame, Henkel- Schwarzkopf, Johnson & Johnson, Procter & Gamble, Yves Rocher, etc.

Medical cosmetics make up 1/3 of the range of the pharmaceutical market: it is about 1300 cosmetic brands of about 300 manufacturers. According to the Law of Ukraine "On Medicinal Products" dated 04.04.1996 № 123/96-BP, the means of medical cosmetics are subject to implementation only in the conditions of pharmacies. Research of the range of medicinal cosmetics sold in regional pharmacies showed that the vast majority of this product is intended for the treatment of dermatological diseases of the skin and its appendages - acne, fungal diseases, etc.

In addition to skin pathologies, the object of the influence of medicinal cosmetics is also skin, the various states of which are defined as "cosmetic imperfections" - oily, dry, sensitive, pigmented skin, etc.

Pharmaceutical cosmetics are represented primarily by traditional cream forms of release - up to 60% of the total volume. 20% are liquid forms of release - solutions, lotions. Also today gel forms of release are distributed - 15%, and the smallest share is powder (1,8%).

For medicinal cosmetics, the arsenal and spectrum of which is constantly expanding, the question of standardization is critically relevant. As medicinal products, medicine cosmetics is subject to quality control in accordance with the requirements of the legislation in the field of pharmaceutical activity. However, the current requirements for standardization of do not take into account their features as cosmetic means for the skin. In view of the presence in the medicine cosmetics of specific signs that determine the cosmetic effect and the corresponding consumer characteristics, we consider it appropriate to rate the indicators of cosmetic efficiency. First, it requires the introduction of requirements for pharmaceutical cosmetics to the State Pharmacopoeia of Ukraine. The lack of regulation of the quality indices of such a special category of pharmaceutical products as medicinal cosmetics, the uncertainty of the criteria and methods for assessing their quality, does not allow to properly control the product in circulation. The

problem of standardization is especially topical for the newest forms of medicine cosmetics, whose arsenal and spectrum of action is increasing very dynamically. At the present day cosmetic market, a number of skin preparations of such forms of release are being implemented as bath additives, spit peel, soluble sponge, nail polish, etc., for which there is no appropriate standardization in the State Pharmacopoeia of Ukraine. At the same time, for example, the European Pharmacopoeia contains requirements for the standardization of these forms of drug delivery.

Conclusions: The analysis of the regional market for medicinal cosmetic products demonstrates the availability of stable consumer demand for this category of pharmaceuticals and the dynamic growth of the assortment of their release forms and range of action. The study of the legislative framework regulating the circulation of medicinal cosmetic products has brought the need for legislative harmonization of the relevant terminology and classification, as well as the regulation of the requirements for the quality of medicinal cosmetics in the State Pharmacopoeia of Ukraine.

DEVELOPMENT OF QUESTIONNAIRE FOR CUSTOMERS IN THE PHARMACEUTICAL ENTERPRISES 'LABORATORIES

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Introduction. An important chapter in the management system in accordance with DSTU ISO / IEC 17025: 2006 «General requirements for the competence of testing and calibration laboratories», which is implemented in the laboratories of pharmaceutical companies, is section 4.7 Customer service. This section consists of two divisions. Section 4.7.1 emphasizes that the laboratory should cooperate with customers or their representatives in explaining the customer's request and tracking the work of the laboratory in relation to the work performed, provided that the laboratory provides confidentiality to other customers. Section 4.7.2 states that the laboratory should have feedback from its customers, positive or negative.

Aim. The purpose of our research was to develop questionnaires from clients of the testing laboratory of the pharmaceutical company regarding the satisfaction of our service.

Materials and methods. As materials we used the standards of DSTU ISO / IEC 17025:2006 «General requirements for the competence of testing and calibration laboratories» and DSTU ISO 10004:2013 «Quality management. Satisfaction of customers. Guidelines for monitoring and evaluation».

Results and discussion. We have developed two forms of customer inquiry sheets – shortened and deployed. In a shortened form on a five-point scale, it is necessary to evaluate the quality of the laboratory's work in 4 positions: 1) the organization regarding the confidentiality of information; 2) terms of execution; 3) the quality of the design of the results; 4) the attitude of the staff to work. There are also two questions with the answers: «Are you planning to continue cooperation with us?» and «Do you have any suggestions or suggestions for improving the quality of our service? Which exactly?». In deployed form, respondents are offered nine questions with options for answering: 1) indicate the types of services you received in the Testing Laboratory; 2) Do you satisfy the range of services offered; 3) availability of necessary information and its content; 4) taking samples; 5) competence of the personnel; 6) information provided in the results; 7) the terms of the tests; 8) Overall assessment; 9) comments and wishes.

Conclusions. Practical value of our questionnaires developed by us is to increase the efficiency of communication between customers and testing laboratories of pharmaceutical companies. Feedback with customers, in turn, is analyzed and used to improve the system of management, testing and improving customer service.

FORMATION OF A DOCUMENT MANAGEMENT SYSTEM OF A PHARMACEUTICAL COMPANY

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Introduction. Every year, the average distribution company loses about $ 25,000 per year only because of a non-optimal document flow system (time for searches, restoration, reconciliation, changes, approval, etc.). However, losses due to errors in documents can be much higher.

In Europe, the average office employee spends 1-1.5 hours of work per day searching for the necessary documents (both in electronic and paper forms). This indicator in Ukraine is much higher. Based on the results of our research, it was found that employees of a small distribution pharmaceutical company spent an average of 15-25 % of their working time on actions with documents (reconciliation, search in databases, checking the relevance, etc.). At the scale of the all organization (for example, 130 employees) is 83 hours a day or 415 hours a week.

Aim. The aim of our research is sstudy of the document management system and development of proposals for its optimization at the pharmaceutical distribution company "PRANA-PHARM", Kharkiv, Ukraine.

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 distribution pharmaceutical companies.

The object of research was a quality management system of the pharmaceutical distributing company. The subject of our research was the document flow process of the pharmaceutical distributing company.

Results and discussion. There are many nonconformities was identified after analysis of document flow on the basis of our research:

- the document management algorithm is not defined, there is no procedure;
- there is no clear definition of responsibility within the life cycle of the documents (development, agreement, revision, replacement, etc.);
- the documents working out is not planned, at the discretion of the leaders of the directions;
- the distribution of documents is not controlled. Often, departmental staff are not aware of the existence of a particular document;
- there is no procedure for checking documents by a quality specialist;
- the updating of procedures is chaotic, mainly with significant delays;
- not always provided with proper conditions for archiving and storing documentation, etc.

So, the current system of company's document flow requires improvement, in particular:

- procedures for the dissemination of quality policies and quality objectives, Quality Manual;
- document management procedure;
- system of identification of all internal documents;
- requirements for approval of a various documents;
- methodology of checking the "quality" of documents;
- criteria for monitoring and evaluating of effectiveness of the documents flow as a process, etc.

We have developed rules for the implementation of all stages of the life cycle of the company's documents:

- task setting, document development;
- replacement, updating;
- revision, amendment;
- duplication;
- distribution, acquaintance;

- checking, agreement, approval;
- withdraw, archiving, recovery, etc.

We have developed a procedure for managing of the standard operating procedures of the Company ("SOP on SOP"). The management procedure for the Company's SOP includes:

- Basic provisions on the document flow of the company.
- Description of the types and levels of used documents and records.
- Hierarchical system of responsibility distribution for all stages of the life cycle of documents.
- Rules for registration, agreement, approval, amendment, revision, modification, archiving and storage of documents, etc.

Measures for control of document circulation are suggested:

- Single code system (each document and documental form is assigned its own unique code. The system cannot have a document without code).
- At the distribution stage, information is recorded on each document (to whom it is provided, when and in what quantity).
- In the register of registration (e-copy) all the current documents that are available in system are recorded.
- Access to electronic documents or form is allowed only for certain groups of users.

This Provides:

- use only current versions of documents;
- easy and quick access to the required document;
- detailed accounting of all available documents;
- elimination of unauthorized use of documents, etc.

The document management procedure also provides:

- Security of documents: binder pages in folders, numbering of each page, use of persistent paste / ink, control of storage conditions.
- Availability: the introduction of a clear cataloging system and places for storing documents and records.
- Providing information security: instructing staff on the importance of confidentiality, restriction of access to places of storage of documents (safes).
- Ensuring traceability: the "path" of each document is necessarily fixed.

Separately for the electronic documentation system it is provided:

- Ensuring reliability: regular maintenance of computer system, backup of files and storage on different mediaю
- Providing information security: restriction of access to files, privacy mode.
- Ensuring traceability: the "path" of each document is necessarily fixed.

To implement the proposed system of document control it is supposed:

- Approval of the developed procedures for the document flow system.
- Familiarization of all employees with new requirements for document circulation.
- Creation of a register of existing documents and records available in circulation.
- Assignment of standard codes to each document entered in the register.
- Development of new documents and forms of records for new requirements.
- Gradual verification of existing documents for compliance with the quality criteria and making the necessary changes.

The implementation of these measures will significantly reduce the problems with document management at the company.

Conclusions. Expected result of proposal implementation: reduction of the waste of time in search of documents (≈ 30-50%); reducing the number and criticality of errors in the document flow; savings of company funds on paper and supplies.

ON STATE GUARANTEES FOR FREE SUPPLY WITH MEDICINAL PREPARATIONS OF YELLOW CHILDREN ON THE LEGISLATION OF THE RUSSIAN FEDERATION.

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Introduction. This study focuses on the compliance with the legislation of the Russian Federation in pediatric care services. According to paragraph 1 of article 4 of the Federal law "About bases of health protection of citizens in Russian Federation" dated 21 November 2011 No. 323-FZ, determines the state guarantees in the field of children's health. In particular, we consider the preferential provision of medicines children under three years and children from large families of up to six years. Today, many parents face the problem of financial provision of young families, which often puts her over the brink of poverty. In case of illness of a child, many young families are suffering serious financial crisis.

Aim. Therefore, the main purpose – to attempt to solve problems of protection of children's health state, regardless of their social status of their families.

Materials and methods. We studied the documents governing the enforcement and implementation of state guarantees in the field of free provision of children up to three years, and children from large families of up to six years of drugs, conducted a survey among parents, clarifying the rights of their children in this area. In the governing documents clearly defined categories of citizens who are covered by the state guarantee the free provision of medicines, identifies the list of drugs subject to the enterprises of the country-the manufacturer, the average cost, for free software. In addition, the specific features of some regional programs of state guarantees of free rendering to citizens of medical aid and ways of realization of state guarantees through the system of social pharmacy.

Results and discussion. The study of the topic, it became clear that in many regions, especially subsidized, there is the issue of implementation of state guarantees, lack of financial support, although this type of benefit ensures the Federal budget.

As a solution to this problem, we propose to Supplement the Federal legislation in a slightly different way of implementation of state guarantees in the field of provision of medicines, by passing the regional programme, through the mandatory health insurance, without the participation of social pharmacy. In this case, the recipient of the state guarantee will be able to purchase the necessary medicine in any pharmacy, and the system of compulsory health insurance compensates for his costs. In this case, with the purpose of observance of interests of the parties should stipulate the marginal cost of purchased medicines, of necessity, their manufacturer, the deadlines for submission of documents to the compensation, terms of compensation from the date of filing.

Conclusions. Thus, the execution of the state guarantees in the field of provision of medicines of children till three years and children from large families of up to six years for today only possible with adequate funding of this sector in the regions. With the purpose of the mandatory compliance with Federal law is important and possible to find ways to implement it.

DEVELOPMENT OF THE PROGRAM OF PREPARATION OF INTERNAL AUDITORS ON THE PHARMACEUTICAL ENTERPRISE

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Introduction. An important element of any control system is self-diagnostics processes, which are usually called internal audits. Internal audit in today's conditions plays an important role in achieving both strategic and operational goals aimed at increasing the competitiveness and management efficiency. The

internal auditor should act in accordance with the standard DSTU ISO 19011: 2012 and contribute to the achievement of the objectives by using a consistent and systematic approach to the assessment and enhancement of the effectiveness of the control processes, risk management, and corporate governance.

Aim. The purpose of our research was the development of a set of proposals for the establishment of a program for the preparation of internal auditors at the pharmaceutical company.

Materials and methods. As materials, we used the provisions of the Standard ISO 19011: 2012 Guidelines for auditing management systems and the GXP Good Practice Guidance.

Results and discussion. Auditors should have the knowledge and skills necessary to obtain the intended results of audits that they will carry out. All auditors should have both general knowledge and skills as well as specific knowledge and skills that are determined by the nature of the audits conducted and the sectors of the economy in which the organization operates. The head of the audit team should have the additional knowledge and skills necessary to lead the audit team.

We have developed a training program for internal auditors consisting of four blocks: the first one included the question of knowledge of the requirements of ISO standards and sectoral regulatory documents that ensure the quality of manufacturing of medicines; the second block contained topics related to the documentary accompaniment of the audit itself; the third block includes topics in which the rules of conduct and the requirements for the professional and personal qualities of the auditor and the methods of communication during the audit are specified. The fourth unit was practical and contained situational tasks that took place during the audit. Diagnostics of the studied material was carried out for each block and evaluated at 100 points.

Conclusions. The practical value of the proposals we propose is to increase the competence of internal auditors as a guarantee of the successful functioning of the quality management system at the pharmaceutical company.

ESTABLISHMENT OF CRITERIA FOR QUALITY CONTROL OF PERSONNEL IN THE QUALITY MANAGEMENT SYSTEM

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Introduction. Personnel assessment is a tool that allows you to determine the effectiveness of an employee's work, to establish labor indicators in accordance with the requirements of the organization itself. In addition, the evaluation process helps to identify both the individual problems of the employee, and the general, characteristic for the whole team of the enterprise. But most managers have difficulty in assessing their subordinates. This is due to the lack of clear, ambiguous and results-oriented employee evaluation criteria, which leads to the adoption of certain managerial decisions under the influence of personal sympathy, as well as problems associated with the non-working system of incentives and low discipline of employees. To avoid such problems, it is important to determine when evaluating an employee's assessment system based on which criteria the evaluation will be conducted.

Aim. The purpose of our research is to study the methodology for selecting criteria for monitoring the quality of the work of staff to determine the effectiveness and effectiveness of the work of employees of the enterprise.

Materials and methods. When assessing the staff, it is important to correctly establish the criteria and indicators of attestation. It is clear that for all categories of posts can not be applied to unified criteria. The criteria used in modern practice are conventionally divided into 4 groups:

- professional;
- business;
- moral and psychological;
- integral criteria.

Professional criteria are the characteristics of the professional knowledge, skills, skills, professional experience of the employee, his qualifications, effectiveness and efficiency of work.

Business criteria – characterize organization, responsibility, initiative, enterprise, etc.

Moral and psychological criteria – outline the characteristics of the employee, such as the ability to self-esteem, honesty, justice, psychological stability.

Integral criteria are characteristics that are obtained on the basis of many other characteristics inherent in the employee and show his authority, health status, general culture, culture of thinking and language, etc.

Certain groups can be conditionally divided into subjective and objective.

Subjective include those criteria that can not be measured in quantitative (monetary) terms using calculations that characterize the change in the quantitative and qualitative performance of the enterprise as a whole.

Objective criteria include those that directly affect the productivity of an employee's work and are measured in direct dependence on changes in the quality of the enterprise as a whole.

Results and discussion. Based on the selected criteria, the following methods are used to assess the employee's performance:

– the method of analytical evaluation, in which the Attestation Commission considers a written description - a review of the employee, and conducts an interview with him;

– the method of the evaluation system, in which the ranking of personnel is carried out, as a result of which the supervisor (attestation commission) is able to compare workers among themselves with consecutive conclusions;

– the method of situational assessment - as a rating scale, a description of the worker's behavior in a specific production situation is used, for which a description of effective and ineffective examples of behavior over time is developed;

– the method for assessing the achievement of goals - focus on the achievement of specific objectives facing the enterprise and the tasks assigned to the employee in accordance with his workplace.

In practice, the most effective methods that do not have subjectivity and directly allow to link the results of an employee's work with changes in the quantitative and qualitative performance of an enterprise are the method of analytical assessment and the method of evaluation for achieving goals (when applying normative tasks). When using the method of analytical evaluation during the certification, the main tasks were:

1. Determination of the employee's compliance with the position held.
2. Identify the prospect of using the potential abilities of the employee and his capabilities.
3. Stimulating the growth of the professional competence of the employee.
4. Identification of the directions of the professional development, vocational training and retraining of the employee.
5. Proposals on the movement of personnel, the release of the employee from the post (dismissal), as well as transfer to more (less) qualified work - depending on the conclusions of the certification.

Conclusions. The methods of the system of assessments and situational evaluation are laborious enough and can be applied: firstly in the non-production sphere, and secondly in small enterprises with a number of up to 50 people.

IMPROVING THE QUALITY OF PHARMACEUTICAL SERVICES

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Introduction. The issue of improving the quality of pharmaceutical services can be achieved through the introduction of modern management systems at enterprises, in particular, the quality management system based on the ISO 9000 quality standards. The ISO 9001:2015 «Quality management systems – Requirements» is based on two methodological aspects: process approach and satisfaction of consumer expectations. The implementation of the process approach and the application of all its principles will allow the organization to further certify its activities in accordance with the provisions of the ISO 9001 standard. This will enable the ineffective links in the enterprise to be identified, improve resource

efficiency, document all activities and establish responsibility for implementation, and most importantly – significantly improve the quality of pharmaceutical services and create a positive image. The process approach is a powerful methodological tool for studying and improving the activities of any organization.

Aim. The purpose of our work was to study the methodology of introducing a process approach to the work of domestic pharmaceutical companies.

Materials and methods. As materials, we used the provisions of the Standard ISO 9001:2015 «Quality management systems – Requirements».

Results and discussion.

The introduction of a process approach for an organization often presents some difficulties because of the lack of experience in interpreting the requirements of ISO 9000:2015 and ISO 9001:2015 and applying them to the specifics of their activities. These requirements cover all aspects of operation and they are universal for use.

The content of the standard' requirements reflects the interests of not only the pharmaceutical services provider, but also the consumer – in order to ensure interaction and mutual benefit to them. Moreover, it is only possible to create an optimal management system in the organization and implement a process approach.

Team work and individual responsibility of each developer of the process approach, has allowed to create a conditions for its successful implementation, focused on the overall result: the provision of quality pharmaceutical services. At the same time, the team was formed to solve certain tasks depending on the goal:

- defining all the functions performed and describing the processes of the organization;
- establishing the relationship between the identified processes;
- development of the mission and objectives of the enterprise;
- determination of the responsibility for each process;
- regulation of defined activities in processes and organization as a whole.

Formulating a process approach and solving current and strategic tasks to improve the level of service delivery is impossible without creating effective horizontal flows of information. At the heart of the interaction lies not only well-established communication links, but also the exchange of information. Key issues in the process of information exchange are knowledge (descriptive and systematic data), resources, planned and used technology works. Even after the introduction of the process management model, it is not possible to completely eliminate control at individual stages of the process of provision of pharmaceutical services. This is due to various factors: training and involvement of staff, leadership positions, completeness of documenting processes, informal approach to the functioning of the process model and others. There will always be a need to assess the quality level in contractual relations with suppliers, which are required by the current regulatory requirements in the pharmaceutical sector. Training is the most difficult part of the implementation of the program of the process approach, it is necessary to use it in combination with ensuring staff motivation. At the stage of implementation of the process model, it is necessary to conduct training within the framework of staff involvement, taking into account the basic principles of pedagogy and establishing the position of own responsibility for the performance of functions in each of the processes in the organization. Usually using a three-stage system of learning: the first stage – the head and his deputies; second stage – unit managers; the third stage – the staff of the institution.

In order to implement a process approach and meet the requirements of the standard ISO 9001:2015, it is necessary to develop a complex of documents. The organization can use a complex of diverse documents: instructive, methodical, regulating, managers. Regardless of the purpose and category of the data documents, it is necessary to create a general document flow of the enterprise and to classify, mark all developed documents. Only in this case will be able to avoid inconsistency in the accounting and application of documents. In accordance with the ISO 9001 standard, any organization must have the following categories of documents: documented policy provisions and objectives in the field of quality; documented methods and protocols; documents and records required for effective planning, management and control.

Conclusions. Process approach – this is the consideration of the entire company as a network of interacting processes. The peculiarities of the functions of the process approach are that they are not

formulated arbitrarily, but represent a certain system. Therefore, it is very important in the implementation of the consistent pursuit of each of the identified steps and continuously training all the personnel involved in the work.

ORGANIZATION OF THE QUALITY MANAGEMENT SYSTEM REVIEW AT THE PHARMACEUTICAL ENTERPRISE

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Introduction. Quality management systems (QMS) built in accordance with the requirements of the ISO 9001 standard should be systematically monitored, measured and monitored for realization of corrective action and continuous improvement. Without systematic diagnostic QMS cannot function efficiently and provide benefits to the organization, especially for a pharmaceutical company.

Aim. The aim of our research is analysis of the approaches to the expert assessment of the quality management system and the development of a method for determining the effectiveness of the QMS for use on basis of LLC "Pharmaceutical Company "Zdorov'ya", Kharkiv, Ukraine.

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 distribution pharmaceutical companies.

The object of research was a quality management system of the pharmaceutical manufacturing company. The subject of the research is the method of expert ball assessment of the QMS effectiveness.

Results and discussion. To evaluate the QMS functioning, we propose to use of the expert ball assessment method. Expert evaluation involves the following actions:

- a set of criteria for the assessment of the QMS is determined;
- the criteria are ranked, each is assigned its own "weight" in points, and the sum of all points defines the final score;
- scores from each criterion may have weight ratios (depending on the criticality of the object being evaluated and determined by expert method);
- experts of QMS assessment is a heads of a structural units or processes.

Advantages of expert evaluation:

- the possibility of using qualitative and quantitative assessments, formalized and non-formalized procedures;
- simple implementation of techniques that does not require complex technologies, a lot of time and involvement of a significant number of employees;
- ability to take into account many aspects of the assessed object, a significant number of variants of development of events;
- do not require long expert training.

In fact, any other diagnostic methods are inadequate for QMS assess.

In many Ukrainian pharmaceutical companies, the assessment of quality system is based simply on a report. Such a report is usually prepared by the Quality Management Division once a quarter, a half-year, or even once a year.

We identified the shortcomings of this approach:

- quantitative evaluation criteria are not applied;
- not all quality system performance criteria are clearly formulated and documented;
- limit values of the QMS performance indicators are not set;
- the findings on the effectiveness of the QMS do not provide grounds for taking corrective or/and preventive action (CAPA) for continually improving of the company's activity.

Many companies now use the quality management system analysis process. However, this process is often not regulated. It is often not provided for a description of the evaluation methods. So, we have

developed a scheme for a new process "Analysis of QMS", which specifies inputs, outputs and required resources.

Table 1 presents the criteria developed by us for the assessment of the QMS by the "ball scoring" method.

Table 1. Criteria for QMS assessment

Criteria	Ball
There is a discrepancy that has a significant impact on security, or failure to comply with legislative or critical regulatory requirements. The risk is critical.	**0**
The activities covered by the QMS that affect the conformity of products and / or obligations to the customer are not regulated. The risk can be estimated as critically large.	**1**
In the course of the activities covered by the QMS, the facts revealed non-compliance with the established requirements, which increases the risks to the quality of products / fulfillment of obligations to the customer to an unacceptable level.	**2**
Detected deviations / violations that may affect product compliance and / or fulfillment of obligations to the customer. The risk can be estimated as significant.	**3**
In carrying out activities that may affect the compliance of products with established requirements and / or fulfillment of obligations to the customer, the achievement of the set goals is not ensured.	**4**
The established requirements are fulfilled, but in their implementation only partial achievement of the set goals is ensured. Risk for product quality and for obligations to the customer at an acceptable level.	**5**
Demonstrates the fulfillment of the basic requirements, ensuring the achievement of most of the goals set. Risk for product quality and for obligations to the customer at an acceptable level.	**6**
Provided evidence of a steady performance of requirements and an increase in some performance indicators. The risk for products quality and for obligations to the customer is in an acceptable field.	**7**
The stable fulfillment of all requirements and significant improvement of the activity performance have been demonstrated. The set goals are fully implemented or over fulfilled. The risk for product quality is acceptable and decreases.	**8**
Sustained performance and performance improvements are demonstrated. The process is greatly improved. All set goals are met / over fulfilled. The risk for product quality has decreased significantly.	**9**
Significant increase of efficiency of activity has been demonstrated	**10**

It has been established that the conclusion about the compliance of the QMS with the requirements of ISO 9001/GMP and its effectiveness can be provided under the condition that the general assessment in the first level, as well as all the assessments at levels 2, 3, 4, 5, 6 make at least 6 points out of 10 (not less than 60%).

Any rating of less than 6 points requires the fixing of the relevant fact in the record of inconsistencies, followed by an investigation and identifying the reasons for insufficient compliance, as well as the development and adoption of corrective actions.

Conclusions.

1. The importance of continuous QMS analysis is proved. A comparative overview of the main methods for assessing the effectiveness of the QMS was conducted. The actuality of professional application of expert technologies in the evaluation of the QMS is proved. The main aspects of the expert estimation technologies are considered; the comparative analysis of the corresponding methods is carried out.
2. The analysis of typical problems that arise in the process of expert evaluation is carried out. The main disadvantages of expert estimation methods are determined in determining the effectiveness of QMS in domestic companies.

3. The content and conditions for the implementation of the main stages of the QMS expert evaluation are formulated.
4. The method of quantitative determination of the degree of fulfillment of the requirements regulating the QMS processes is proposed. Such an assessment determines the ability of the QMS to ensure the stable fulfillment of all established requirements for activities affecting the quality of products, and also assesses the ability of the QMS to achieve its quality objectives.
5. The measurable values of the QMS, obtained by the methodology of "scoring" through the systematic conduct of audits, make it possible to monitor changes and analyze trends, which ensures conditions for the timely application of corrective and preventive actions, risk reduction.

DEVELOPMENT OF MEASURES FOR MINIMIZATION OF SUBSTANDARD AND FALSIFIED MEDICINAL PRODUCTS SPREADING IN UKRAINE

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Introduction. High-quality drugs are extremely important for human health and are needed in any health care system. The spread of counterfeit and substandard medicines is one of the most pressing issues for the global pharmaceutical market. Low and middle income countries are the most affected by this problem, but it is increasingly threatening and rich countries due to the sale of such drugs via the Internet. Online sales generate a market, most part of which is not regulated and not monitored. The Internet is a major source of counterfeit and low-quality drugs entry.

According to WHO, 1 of 10 drugs are of inappropriate quality or falsified. In recent years, the number of detected counterfeit and substandard drugs has increased by 56%.

There is also a tendency that, with the increase of trainings and education of specialists, the number of detected cases of falsification increases.

It is extremely difficult to estimate the real scale of this problem. It should be understood that when the danger becomes visible, many patients have already suffered harm.

Therefore, the purpose of the work was to search and develop measures to minimize the distribution of counterfeit and substandard drugs in Ukraine.

Aim. Search and development of measures to minimize the distribution of counterfeit and substandard drugs in Ukraine

Materials and methods. Having analyzed the current state of the pharmaceutical market of Ukraine, we can propose the use of complex measures of fighting the problem. They are a necessity to inform the society and specialists, to ensure the reliability of supply chains, and to create a reliable regulatory framework for better control of drugs turnover.

Results and discussion. The first method is to introduce a system of authentication and drug tracking, by applying a unique two-dimensional code for each drug package. This allows controlling the ways of medicines supply, quickly stopping the circulation of a specific batch or packaging, making records. This coding must necessarily be present on prescription drugs. This method is convenient for use by patients who can check the purchased products.

This system is already working in European countries in accordance with Directive 2011-62, which came into force in 2013. Ukraine was planning to implement the system by 2017. Already in October 2017, a pilot project on the implementation of this system has started on the example of the drug "Amixin", which was implemented through the distributor BADM and the retail chain of the Public Enterprises "Pharmacy".

Due to the special danger of low-quality parenteral dosage forms, attention should be paid to the technology that guarantees their quality, called SFERA. This is a technology of non-destructive laser engraving inside transparent materials with a two-dimensional bar code. This technology does not jeopardize the strength and content of a dosage form, guarantees the visual authenticity of medicines.

The next technology called TruTag, allows marking each unit of product, not its packaging. Silicon-based grains are added to the components, which are essentially a chip that can be read by a special portable spectrometer based on an optical reader. Particularly relevant it is in the manufacture of tablets.

Also, in some countries are already used as a protective element RF transponders that allow tracking medications, read them at a distance with a phone or other equipment. The disadvantage is the high cost of equipment.

One of the methods of product protection is a hidden hologram, which is a self-assembled photonic crystal. It is invisible under normal light, and becomes noticeable only with strong directional light of, for example, a lantern.

The presented methods have a place for implementation at such stage of carrying out the input control as an examination of the appearance without opening the package.

The next method is to inform specialists and consumers. For specialists it is relevant to create a special web-portal for quality of drugs with the image of the standard packaging of each registered drug. It is worthwhile conducting seminars, distributing brochures with methods of detecting counterfeit medicines. Consumers can be informed via the media, with the help of special mobile applications, which are now very popular.

Conclusions. In order to minimize the spread of substandard and falsified drugs, it is important to create a reliable system of information, detection and control. The use of serialization of drugs will prevent the entry of poor-quality drugs into the market and become an insurmountable barrier to drug falsifiers.

The implementation of the proposed measures will help increasing control over the circulation of medicines, which will reduce the number of falsified medicines in the market. This requires sufficient funding and implementation of IT, which will greatly facilitate the work of government agencies, manufacturers, wholesalers and pharmacy establishments.

RATIONALE FOR THE CHOICE AND THE POSSIBILITY OF IMPLEMENTATION OF QUALITY STANDARDS IN DRUGSTORE ORGANIZATIONS

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Introduction. The dynamic development of the pharmaceutical industry in all countries of the world almost every year dictates new business conditions at all levels of the life cycle of medicines. Pharmacy organizations are no exception. Thus, over the past decades, the priorities in the activities of pharmaceutical workers have changed somewhat. Earlier the basis of the pharmacy organization's work was the sale of medicines with a focus on the trading process.

Now the emphasis has shifted to the patient and providing them with qualified assistance in choosing the necessary medicines for their rational use.

The pharmacist ceases to be a seller, but becomes a confidant of the patient, an important component of the system of medical care for citizens. In all civilized countries the priorities of the state are aimed at organizing the prevention of diseases and the rational use of medicines. In this regard new concepts are introduced such as pharmaceutical assistance, pharmaceutical provision, self-help, self-prevention, etc.

A process of developing quality standards aimed at pharmacy organizations (for example, Good Pharmacy Practice - GPP) is going on intensively all over the world. According to the generally accepted principles of GPP the activities of pharmacy organizations must be substantially transformed in order to enable the transition to a new level of provision of pharmaceutical services. In connection with this the issues of forming management systems in pharmacy institutions that operate on the basis of modern principles, using modern principles and methods of organizing business processes and monitoring their implementation, become topical.

Aim of the study was to identify a set of quality standards that could be used as a methodological basis for developing an integrated management system in pharmacy organizations of both Ukraine and the Republic of Kazakhstan.

Materials and methods. We have used methods of empirical research and comparative analysis. We analyzed the available published information, and also developed and applied the methodology of previously implemented quality management systems. The informational basis of our research was the materials of open scientific and professional literature, as well as regulatory requirements of standards and guidelines for pharmacy companies in Ukraine and the Republic of Kazakhstan.

Results and discussion. In the process of the study we have carried out a comparative analysis of the requirements of the GPP standard and a number of ISO standards: ISO 9001 of "Quality Management Systems", ISO 14001 of "Environmental Management Systems", ISO 27001 of "Information Security Management Systems", ISO / IEC 20000-1 of "Information technologies. Service Management", ISO 22301 of "Business Continuity Management Systems" and others. It has been done to make possible creating of an optimal model of the management system for a pharmacy organization.

It should be noted that almost all of the above ISO standards in Ukraine and the Republic of Kazakhstan are represented in the form of State Standards (ДСТУ – in Ukraine, ГОСТ – in the Republic of Kazakhstan).

The GPP standard in Ukraine is at the discussion stage. At the time of the research it was not in force yet, though there is an existing Order of the Ministry of Health of Ukraine from 30.05.2013 No. 455 "On Approving the Manual "Good Pharmacy Practices: Quality Standards of Pharmaceutical Services".

In Kazakhstan the GPP standard operates on the basis of the Order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 27, 2015 No. 392 "On approval of appropriate pharmaceutical practices".

Having analyzed these documents, we considered the GPP standard as mandatory for implementation in pharmacy organizations. Standards of the ISO series were chosen according to the principle of necessity and the possibility of implementing their provisions in the standard pharmacy organizations of Ukraine and the countries of the CIS. From the listed ISO standards, it was decided to use the ISO 9001 "Quality Management System", ISO 27001 "Information Security Management Systems (ISMS)" standards as the most complementary to the GPP standard.

Conclusions. Thus, for creating the possibility of building an integrated management system and implementing it on the basis of pharmacy organizations in Ukraine and the Republic of Kazakhstan the standards GPP (as mandatory and basic), ISO 9001 of "Quality Management Systems" and ISO 27001 of "Information Security Management Systems" have been chosen.

In the future we plan to develop methodological recommendations for the implementation of these standards in pharmacy organizations as part of an integrated management system.

STAGES OF THE FORMATION OF THE QUALITY MANAGEMENT SYSTEM OF PHARMACEUTICAL COMPANY

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Introduction. Formation of a quality management system (QMS) of a pharmaceutical company is a very important step by which it is possible to confirm reliability, perceptivity and stability of the company's activity.

Development and formation of a QMS will allow the company to gain many advantages: improving the manageability of production processes, improving the quality and competitiveness of manufactured products, reduce production costs, and also make the company oriented to needs of the final consumer.

Quality management system is able to provide a very effective and productive activity of a company, which will undoubtedly affect the quality of products produced. The most effective in shaping the quality system are the rules and requirements defined in the international standard ISO 9001. This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements. The standard 9001 sets out the general requirements for QMS, it

promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach". An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

Aim. The aim of our research was to develop the stages of the quality management system implementation at the pharmaceutical company.

Materials and methods. As materials we used the provisions of the standard ISO 9001:2015 "Quality Management Systems. Requirements".

Results and discussion. All stages in the formation and implementation of QMS can be conditionally divided into 6 stages:

1) Preparatory stage. This stage involves the implementation of the following activities:

a) Issuance of an order on the creation and implementation of QMS.

b) Creation of a working group.

c) Development of a program (work plan) for the creation and implementation of QMS.

2) The second stage - formation of the company Mission, Quality policy, quality objectives.

3) The third stage - definition and construction of the process model of the company's QMS.

The application of the process approach becomes objectively necessary. The process model is a system (network) of interacting processes, each of which affects the functioning of other processes and the system as a whole.

All processes in the organization are divided into 3 groups:

- Basic Processes
- Providing (auxiliary)
- Management Processes

4) The fourth stage – regulating and documenting the QMS.

The structure of the QMS documentation consists of the following levels:

a) "Zero Cycle" forms legal documentation (licensing documents, orders of higher organizations, orders, laws).

b) The "base level" forms the documentation on quality assurance (internal technical documents, internal normative documents, external normative documents, methodological documents, documents on strategic and operational planning, organizational and administrative documents, etc.).

c) Documentation for quality assurance (records).

d) Management documentation (working instructions of performers, documented procedures, quality manual, quality policy and quality objectives).

5) The fifth stage – realization of the QMS documentation at practice.

Implementation of the QMS involves conducting internal audits, as well as realization of risk-oriented thinkingб implementing corrective and preventive actions that ultimately improve the effectiveness of the processes.

6) The sixth stage - certification of QMS (Voluntary).

Conclusions. Meet the requirements of ISO 9000 series standards - it's not only to work on a new, better-quality level, to make it transparent and to optimize all management processes, but also to significantly improve the quality, increase the efficiency and effectiveness of the activity.

ORGANIZATION OF PRODUCTION QUALITY CONTROL IN PHARMACEUTICAL COMPANY

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Introduction. The provision of high-quality, safe and effective medicines to the population is the fulfillment of the requirements of the general international quality standards at each stage of the medicinal product's life cycle. This is especially true of the production process.

The manufacturer of medicinal products should organize production in such a way as to guarantee the conformity of the medicinal product to its intended use without potential risk to consumers due to violation of the conditions of production and quality of the drug.

The pharmaceutical quality system consists in the fact that the quality of the medicinal product (MP) is provided at all stages and for all processes of the introduction of drugs from the pharmaceutical development, through transfer to production. Quality management at an enterprise includes all issues that, individually or, affect the quality of products. Quality system. adopted at work, must ensure that:

- Production can continuously produce products with appropriate quality indicators;
- production provides a controlled state of the production process supported by an effective monitoring and monitoring system in relation to process parameters and product quality;
- conducted all necessary control of products and production process.

We consider it expedient to propose to the pharmaceutical companies to develop SOP "Analysis of samples in the production zone, sampling, procedure, reporting".

Aim. The analysis of the quality management system of the pharmaceutical company and the development of proposals for improving production quality control in the pharmaceutical company

Materials and methods. As an algorithm for actions necessary to describe the sampling procedure and the analysis and reporting procedures, it is expedient to use the proposed algorithm for implementing the principle of QMS "Permanent Improvement" based on the feedback loop with the attachment to it of references to the statistical processing of the data. The basis for the study is the position of the modern pharmaceutical quality system, its theoretical and methodological component. The system approach to the study of processes of production control of medicines in the modern pharmaceutical company was used in this work.

The theoretical basis of the research is the scientific works and publications of domestic and foreign scientists, normative legal documents in the field of pharmaceutical quality system, quality management, etc., which is indicated in the list of literary references.

Results and discussion. When sampling always there are practical problems such as contamination of the point of contact sampler, which can become a problem for the quality of the product. GMP refer to the need to develop a separate procedure designed to prevent the contamination of selected material and other products. The remnants of the materials may be included in the subsequent series, which may adversely affect the profile of AFI impurities. Using a single-use sampler reduces the risk of contamination of the sample but adds recycling issues.

However, in accordance with WHO recommendations, sampler training should be organized directly in the sampling area. In the case of the impossibility of such an organization, clear regulation and adequate control over the transfer of tools from the training zone (for example, in QC laboratories) to the premises where the sampling is carried out is required.

To guarantee the safe use of the purified sampler and to monitor the purification process, we were asked to add a sampler purification report to the SOP.

This approach will allow us to begin work on a new approach to quality control, which is actively being implemented in pharmaceutical manufacturing in the EU countries - production of real-time products (PAT). Its essence lies in the fact that with the help of dynamic control of intermediate products, as well as parameters of the production process in real time, it is possible to provide the quality of the finished product (finished medicinal product), with minimal intermediate control. Thus, there is a continuous verification of

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;

- problems with the equipment. In many bacteriological studies, quality control is not as easy as in other laboratory studies.

Therefore, in addition to traditional methods of quality control, the perfect implementation of other processes in the quality system becomes of particular importance. Below are some important general principles of quality: sample testing is an important aspect for all laboratory tests.

For studies that depend on the presence of living organisms in samples, it requires:

- more precise control and better interaction with the laboratory staff, motivated by skilled personnel who understands that compliance with the quality control principles is a merit of quality;
- thermostats, refrigerators, microscopes, steam sterilizers and more. equipment must be carefully serviced and carefully monitored;
- positional and negative controls should be used to check the effectiveness of those analyzes using special strains h reagents;
- reagents should be kept in accordance with the manufacturer's instructions, indicated by the date they were opened and started to be used and should be written off after the expiration date;
- for the continuous improvement of the quality system in the bacteriological laboratory, it is necessary to keep records of all processes of quality control and corrective actions, in case of problems, find and eliminate their source, and then repeat the analysis.

Conclusions. The laboratory should put in place a quality control program for all analyzes. To enter this program, set the rules. Train employees, share responsibilities, and provide staff with all necessary resources for this.

Ensure that the quality control data is complete and that these data are reviewed by the quality officer and the laboratory manager.

CONFORMITY ASSESSMENT OF THE PHARMACEUTICAL COMPANY'S DOCUMENTATION IN ACCORDANCE WITH THE ISO 9001 REQUIREMENTS

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Introduction. The urgency of good documentation of all activities at a pharmaceutical company is the following:

- necessity of formulation and transfer of goals and objectives from management to all levels of the organization;
- ensuring coherence among participants in all processes of a company;
- providing objective evidence of the proper implementation of processes and the conformity of products (services) to the established requirements;
- creating a real basis for making managerial decisions based on a factual data and continuous improvement of activities.

Correctness of the material in the document depends on the correctness of the action. Clarity, conciseness, visibility and uniqueness are characteristics that determine the perception of documents by their users. There are quite a lot of regulatory requirements for the content and structure of Quality Management System (QMS) documents, but they are very common.

Aim. The aim of our research is review of requirements for the document management process within the framework of the quality management system of the organization on the model of the standard ISO 9001 and development of methods for assessing the quality of internal documentation.

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 distributing company, built on the requirements of ISO 9001 and GDP.

The subject of our research was the document flow process of the pharmaceutical distributing company.

Results and discussion. A large number of documentation is used in the pharmaceutical distribution company:

- documented quality policy and quality objectives;
- Quality Manual;
- documented procedures;
- documents, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes, records, etc.

"Document Management" is one of the most important in the group of supporting processes of the Quality Management System functioning of any organization. Each QMS process must be carried out according to the PDCA Cycle:

- **P**lan – process planning;
- **D**o – realization of the process according to the plan;
- **C**heck – evaluation of the process results, analysis of trends, definition of current and potential nonconformities and their causes;
- **A**ct – realization of a corrective and preventive actions to improve.

We have developed the procedure for assessing of compliance of the QMS documentation with the requirements of ISO 9001 (Table 1).

The procedure establishes to define the controls needed:

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled,

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The developed procedure is aimed at checking not individual documented procedures, but in general document systems of a company. A block diagram of the development of the SOP is provided, which involves the stage of application of our procedure. Document checking will detect "bottlenecks" of a document flow system and take appropriate corrective actions to reduce the risk of a nonconformities.

We have also developed a procedure for assessing the quality of the QMS documented procedures (for example, SOPs). The procedure allows to assess the quality of the developed documented procedures on a 4-point scale from the point of view of users by the following parameters:

- Convenience of the procedure (visibility, clarity, clarity of text and figures).
- Correctness of the structure of the SOP (compliance with the content of the SOP set by the general requirements).
- Description of the algorithm for the execution of the procedure (completeness and accuracy of the statement of instructions and requirements).
- Style of the text of the procedure (lexical and orthographic quality of the document).

When using the procedure for an expert (or expert group), it is necessary to fill out special questionnaires that we have developed.

Table 1. Document evaluation protocol

Type of document	Requirements for documents control (4.2.3, ISO 9001)						
	(a)	(b)	(c)	(d)	(e)	(f)	(g)
	to approve documents for adequacy prior to issue	to review and update as necessary and re-approve documents	to ensure that changes and the current revision status of documents are identified	to ensure that relevant versions of applicable documents are available at points of use	to ensure that documents remain legible and readily identifiable	to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled	to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose
1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
4.2.1 (a) Documented statements of a quality policy and quality objectives							
4.2.1 (b) A quality manual							
4.2.1 (c) Documented procedures and records required by ISO 9001							
4.2.1 (d) Documents, determined to be necessary to ensure the effective planning, operation and control of its processes							

Note: The dark gray color of the table field indicates that this requirement is not applicable to the corresponding document type. Light gray indicates that this requirement is applicable in part (not applicable to all types of documents).

Conclusions. Application of the developed procedures will allow to improve the quality of the developed documented procedures. It will also improve the entire document management system of the company. The research results proposed for implementation at several pharmaceutical companies.

IMPROVEMENT ELECTRONIC DOCUMENT PROCEDURE AT PHARMACEUTICAL COMPANIES ACCORDING TO THE GOOD MANUFACTURING PRACTICE REQUIREMENTS

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Introduction. Documentation in the pharmaceutical industry is an important part of the quality management and quality control system. The documentation describes the technical characteristics of all materials, methods of manufacture and control. The electronic document procedure of the pharmaceutical company is implemented on web-technologies that use electronic document flow as an instrumental base with a broad set of standard, each company-specific functions with unlimited expansion and integration capabilities, the main objective for which will be the management of the GMP standard.

The introduction of electronic document management in pharmaceutical company greatly optimizes the following areas: time-management (time saving procedures); use of ISO standards; possibility to reduce the risk of delays and completeness of the document (incomplete filling) and the inclusion of non-current documents; clear distribution of responsibility for completing the document.

Aim. The aim of the study is to highlight issues related to use of the electronic document management system in a pharmaceutical company and its regulation in the pharmaceutical quality management system.

Materials and methods. For theoretical understanding of various aspects of the research, methods of analysis and synthesis, modeling and the comparison were used.

Results and discussion. The basic concepts of electronic systems are defined (electronic document, original electronic document, electronic document flow, electronic document flow system (EDS). It analyzes the operating principles of existing systems, that corporate information systems and enterprise management systems, of course, have modules for keeping records, but the possibilities of many of them are very limited. Most document management systems support integration with well-known enterprise management systems.

To improve the existing EDS modules have been described that optimize the work of the pharmaceutical company and bring it in line with the GxP and ALCOA standards. The proposed system makes it easy to work with different types of documents and effectively organize electronic document flow.

Conclusions. The electronic document management system developed in accordance with GMP standards is very useful for a pharmaceutical company. It is a software product that allows you to solve many tasks, improve the electronic document flow of enterprises, plan a variety of internal events, notify about changes to the quality management system documents. The main thing is that the electronic document management system allows to determine the technology of passing internal documents in an organization.

ANALYSIS OF FUNCTIONING OF THE RISK FOR QUALITY MANAGEMENT PROCESS AT PHARMACEUTICAL DISTRIBUTION COMPANIES

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Introduction. Risk for medicines quality management is an integral and very important component of a Pharmaceutical Quality System (PQS). The reasons for this are that the systematic risk identification, risk analysis, risk assessment within all system processes with use of appropriate precautions to eliminate of possible nonconformities causes or reduce risks to an acceptable level ensures the proper functioning and continuous improvement of the company quality system.

Unfortunately, domestic pharmaceutical companies often carry out risk management formally, mainly to meet the requirements of supervisors. As a result, it can negatively affect the ability of the company to supply products that are fully consistent with all established requirements.

Aim. The aim of our research is analysis of the state of functioning of the risk management process at domestic pharmaceutical distribution companies.

Materials and methods. We used methods of empirical research and comparative analysis. We have worked out the sources of published information, as well as developed and applied the methodology of sociological research through a questionnaire survey of managers and specialists of the relevant units of domestic pharmaceutical distribution companies.

Results and discussion. A sociological survey was carried out among business entities that had a license for the wholesale trade of medicinal products.

The methodology of sociological research envisaged the use of questionnaires with questions on the functioning of risk management process at a particular company. In particular, the questions concerned the competence of involved personnel, the approaches to risk management applied in enterprise, methodical provision of this activity, the most common problems in this process, etc.

Questionnaires were sent to 45 enterprises, including the Top 10 in terms of sales of medicines in the pharmacy network of Ukraine. The addressees were heads of divisions, whose competence included risk for quality management.

Responses were received from 18 respondents, accounting for 40 % of their total number. Representativeness of this sample can be considered acceptable.

Based on the analysis of the results of a sociological survey, we have found that along with the large-scale development of risk management practices, almost all enterprises have certain elements of this process that cause problems.

The vast majority of respondents noted that the risk management in their company is carried out by specialists only among the employees of the department of quality assurance. Very rarely, employees of other departments and outside experts are involved in risk management.

Although, as you know, risk for quality management activities, as a rule, but not always, should be carried out by multidisciplinary teams. When forming groups, they should include experts in the relevant fields.

Respondents indicated a lack of information for organizing the risk management process. More than 70% of respondents in the organization of this process faced the problem of lack of information on the methodology and practical aspects of risk management.

33% of respondents said that they receive information on risk management at a thematic seminar, trainings and from external experts or consultants.

16 % of respondents find useful information about risks in textbooks and methodological recommendations.

Only 11 % of respondents use periodicals for this purpose. Almost all interviewed experts find little useful information on thematic sites. Often information is presented in the form of general provisions and principles. There are practically no specific case studies on risk management.

We also wanted to identify what was the most difficult aspect of implementation of the risk management process at a pharmaceutical companies.

Most respondents (55 %) had the greatest difficulties with training of risk managers. This was due to the lack of time to study, the lack of funds for participation in seminars and trainings, the organization of consultations of third-party experts, etc.

28 % of respondents encountered difficulties in identifying and assessing risks. In fact, only specialists from the quality assurance department, who were not motivated enough and did not understand the goals of this work, were involved.

16 % of respondents also noted difficulties in regulating and documenting this process. The reason for this was the lack of time for the development of regulatory documents, lack of information on documenting this process.

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).

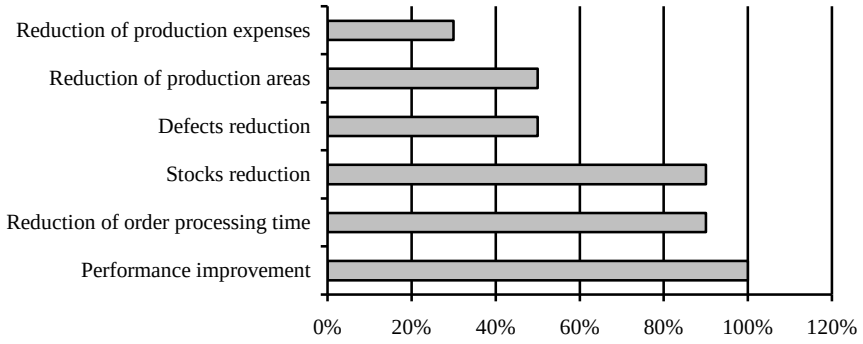

Fig. 1. The effect of the lean production introduction in pharmaceutical companies.

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.

CONTENT

1. SYNTHESIS OF PHYSIOLOGICALLY ACTIVE SUBSTANCES

2. STUDY OF MEDICINAL PLANTS AND CREATION OF HERBAL MEDICINAL PRODUCTS

5. TECHNOLOGY OF PHARMACEUTICAL, PERFUMERY AND COSMETIC PRODUCTS

6. EXTEMPORAL AND MANUFACTURE DRUG TECHNOLOGY SECTION

14. CLINICAL PHARMACY

15. MODERN PHARMACOTHERAPY

Збірка містить матеріали науково-практичної конференції молодих учених та студентів «Актуальні питання створення нових лікарських засобів». Матеріали згруповано за провідними напрямками науково-дослідної та навчальної роботи Національного фармацевтичного університету. Розглянуто теоретичні та практичні аспекти синтезу біологічно-активних сполук і створення на їх основі лікарських субстанцій; стандартизації ліків, фармацевтичного та хіміко-технологічного аналізу; вивчення рослинної сировини та створення фітопрепаратів; сучасної технології ліків та екстемпоральної рецептури; біотехнології у фармації; досягнень сучасної фармацевтичної мікробіології та імунології; доклінічних досліджень нових лікарських засобів; фармацевтичної опіки рецептурних та безрецептурних лікарських препаратів; доказової медицини; сучасної фармакотерапії, соціально-економічних досліджень у фармації, маркетингового менеджменту та фармакоекономіки на етапах створення, реалізації та використання лікарських засобів; управління якістю у галузі створення, виробництва і обігу лікарських засобів; інформаційниих технологій у фармації та медицині; основ педагогіки та психології; суспільствознавства; філології. Також у збірці опубліковані матеріали учасників Всеукраїнського конкурсу студентських наукових робіт зі спеціальності «Фармація, промислова фармація»

Для широкого кола наукових і практичних працівників фармації та медицини.

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