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TOPICAL ISSUES OF NEW MEDICINES DEVELOPMENT

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Topical issues of new medicines development: матеріали XXVI Міжнародної науково-практичної конференції молодих учених та студентів (10-12 квіт. 2019 р., м. Харків). – Харків: НФаУ, 2019. – 504 с.

Збірка містить матеріали науково-практичної конференції молодих учених та студентів «Topical issues of new medicines development», які 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 й обігу лікарських засобів; інформаційних технологій у фармації та медицині; основ педагогіки та психології; суспільствознавства; філології.

Для широкого кола наукових і практичних працівників фармації та медицини.

Book of Abstracts includes materials of Scientific and Practical Conference of Young Scientists and Students «Topical issues of new medicines development». Materials are groupped according to the main directions of scientific, research and educational work of the National University of Pharmacy. Theoretical and practical aspects of the synthesis of biologically active compounds and development of medicinal substances on their basis; standardization of drugs, pharmaceutical and chemical-technological analysis, the study of raw materials and herbal remedies development, modern drug technology and extemporal recipe; biotechnology in pharmacy, modern advances in pharmaceutical microbiology and immunology, clinical trials of new drugs, pharmaceutical care for prescription and OTC-drugs, evidence-based medicine, modern pharmacotherapy, socio-economic studies in pharmacy, marketing management and pharmacoeconomics during the development, implementation and use of drugs, quality management in development, production and traffi cking of drugs; information technologies in pharmacy and medicine; basics of pedagogy and psychology; social science; philology are presented.

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

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Dear colleagues!

National University of Pharmacy is well-known educational and scientific center in Ukraine and abroad. Nowadays we are proud of our traditions that have been formed for nearly 100 years already. Development and support of students' scientific researches is one of the most important and valuable among them.

More than 1000 students and 280 young scientists are deeply involved in various investigations at our departments. For many of them they signify the first step in further successful scientific career. One day our youth will certainly become professors and academicians, but now the worthy representation of their first obtained scientific results is essential. That is why we are traditionally holding 26th International Scientific and Practical Conference for the students and young scientists "Topical Issues of New Drugs Development".

This year the book of abstracts contains 524 scientific works of the talented researchers from Ukraine, Lithuania, Belarus, Kazakhstan, Uzbekistan and Poland. As usual we welcome young scientists from different universities, research institutes and countries to share their accomplishments in pharmaceutical sciences: from the development of new medicines to the personified pharmaceutical care.

The program of the Conference includes 250 scientific reports at the plenary, poster and 25 key areas sessions. The incredible amount of novel ideas and interesting investigations is waiting for all the participants and guests of this traditional scientific feast. And I am pleased to note that year by year the number of the latter is significantly increasing, confirming the necessity and advisability of the Conference organization.

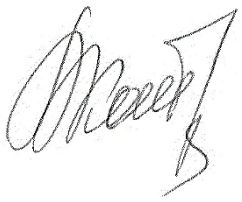
On behalf of the academic community of National University of Pharmacy I sincerely congratulate all the participants of the Conference. Let it be fruitful, joyful and informative, and provide everyone with inspiration and desire to move forward to new discoveries!

Yours faithfully,

Rector of National University of Pharmacy,

Honored Worker of Science and Technology of Ukraine,

Doctor of Pharmacy

Professor  A.A. Kotvitska

Section 20.
QUALITY MANAGEMENT IN THE PHARMACEUTICAL SECTOR OF HEALTHCARE

ANALYSIS OF THE NORMATIVE BASE REGISTRATION OF MEDICINES OF THE REPUBLIC OF UZBEKISTAN

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Introduction. The state regulation concept of the medicinal circulation of the Republic of Uzbekistan determines the directions and tasks of the pharmaceutical industry in the healthcare system and it is aimed at establishing an appropriate regulatory framework governing pharmaceutical activities, developing a national policy in the pharmaceutical field in determining social priorities, providing the population with medicines in order to create conditions for affordable and effective pharmacotherapy and disease prevention.

The main purpose of regulatory measures is to ensure the safety, quality and effectiveness of medicines that manufactured and sold to the consumer. To this end, the state establishes the forms and procedures for the state registration of medicines, the implementation of pharmacological supervision and determines the qualification framework for entities engaged in the production and implementation of medicines. The central link in the regulation of the circulation of medicines is registration, which gives the right to their medical use in the country where they are registered. A detailed expert assessment of the documentation characterizing the properties of medicines is carried out for registration of medicines. The most important element in the registration system is the registration requirements for the presentation of materials for medicines.

Aim. Analyzing the regulatory framework for the registration of medicines of the Republic of Uzbekistan.

Materials and methods. Theoretical analysis of regulatory documentation for the registration of medicines of the Republic of Uzbekistan.

Discussion and results. Registration of medicines in the Republic of Uzbekistan is determined by the Law of the Republic of Uzbekistan «On Medicinal Products and Pharmaceutical Activities», Decree of the Cabinet of Ministers of the Republic of Uzbekistan No. 352 dated December 22th, 2014 «On Approval of the Regulation on the Procedure for Registration of Medicines, Medicinal Products and Issue of Registration Certificate».

The State Unitary Enterprise «Center for Expertise and Standardization of Medicinal Products, Medical Products and Medical Equipment» of the Agency for the Development of the Pharmaceutical Industry under the Ministry of Health of the Republic of Uzbekistan organizes and implements state quality control, registration with simultaneous authorization of medicines, medical products and medical equipment in medicine in the Republic of Uzbekistan, coordinates the activities and management of institutions and organizations carrying out examining, standardization, certification of pharmaceutical and medical products, conducts the examination and approval of regulatory documentation, laboratory and clinical trials.

The registration dossier of the Republic of Uzbekistan differs from the format of a common technical document (CTD) adopted by the International Council on Harmonization as a uniform form of filing documents for registration. A GMP certificate is required only when filing a package of registration documents by foreign manufacturers.

Mandatory certification for compliance with the requirements of the standard of good manufacturing practice (GMP) is planned to be introduced from January 1st, 2023 at the pharmaceutical enterprises of Uzbekistan. Only 9 of the 150 pharmaceutical enterprises in the country are GMP certified.

In 2018, the regulatory framework for the registration of medicines in the Republic of Uzbekistan has changed. The Decree of the President of the Republic of Uzbekistan No. PP-3948 of September 24th, 2018 "On Additional Measures to Improve the Procedure for State Registration and Circulation of Medicines" approved a list of countries and international organizations, the results of which are registered in the Republic of Uzbekistan since 1st November 2018. This list includes: Australia, Belgium, Great Britain, Germany, Denmark, Israel, Ireland, Spain, Italy, Canada, South Korea, Netherlands, Norway, Slovenia, USA, Finland, France, Switzerland, Sweden, Japan, and the European Medicines Agency (EMA).

Recognition provides for the inclusion of the results of state registration and the record of recognition in the State Register of extradition to applicants, in accordance with their request, extracts from this registry. The recognition results are included in the form of records of the State Register for a period of five years. Upon the expiration of the first recognition period, upon the applicant's request, the recognition results may be included in the State Register without limitation of their validity.

Also from November 1st, the requirement to issue a registration certificate (its duplicate) of a medicinal product will be canceled by issuing, at the request of the applicant, an extract from the State Register of Medicinal Products, Medical Products and Medical Equipment.

Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No. 862 dated 10.24.2018 «On approval of the Regulation on the procedure for recognizing the results of registration of medicines carried out outside the Republic of Uzbekistan» provides for the obligatory certificate of a pharmaceutical product (SRR) issued by a foreign authorized agency regulating foreign or interstate pharmaceutical products or copies certified in the prescribed manner.

Conclusion. In the Republic of Uzbekistan, the pharmaceutical industry keeps up with the time, working to harmonize requirements with international norms and rules. However, today a lot of questions on the circulation of medicines in the Republic of Uzbekistan remain unresolved. Probably, one should first turn to the experience of the European Union, which operates according to the adopted laws and rules in the field of regulating the circulation of medicines. Speaking about the issues of admission of new medicines into circulation, it represents such aspects as the format of the registration dossier and the general scheme of consideration of applications, features of preparation and consideration of applications for certain categories of medicines, a report on the evaluation of the medicine, as well as the role of GMP inspectors in the registration system.

EVALUATION RISKS WHEN OPERATING PERSONNEL IN QUALITY CONTROL DEPARTMENT

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Introduction. When considering issues of product quality one of the fundamental concepts is the concept of reliability. Reliability – the degree of risk of occurrence of deviation from the specified product or process characteristics. One of the main purposes of any of the quality management system is to increase nadezhnostivseh processes, quality assurance of products, ie. reduction in the degree of different risks.

Aim. The aim of our study was to analyze the entire complex of tests carried out during the quality control of products manufactured at Ltd "Experimental Plant "GNCLS" for further elimination or mitigation of the consequences of undesirable events.

Materials and methods. In the pharmaceutical industry, the process of quality risk management began in law with the inclusion in 2008 of the GMP EC Guide as part of the 20th Annex. In 2009, a new standard "Medicinal Products. Good Manufacturing Practice" ST-N MOZ 42-4.0:2008 was approved, in which the section "Quality Management" was supplemented with paragraph 1.5 "Quality Risk Management" and Addition No.20 (mandatory) was introduced Quality Risk Management, which is fully consistent with ICH Q9. Thus, quality risk management has become an integral part of an enterprise's quality system.

Results and discussion. We analyzed all the tests of the complex, ongoing quality control of products manufactured by Ltd "Experimental Plant "GNCLS". Test – the experimental determination of quantitative and qualitative characteristics of the product parameters by acting on it or its model of a planned complex of external disturbing risks. Risk management is an important step in the quality assurance. It allows you to set the adverse factors, their causes and consequences, to determine the most effective means and methods to prevent threats. The risk management for quality covers various aspects of the risks of identification and risk assessment analysis to determine its acceptability and, if necessary, measures for risk reduction. Consider the most common potentially dangerous risks due to employees in

the quality control department. Risk assessment carried out by method FMEA (Failure Mode and Effects Analysis). The overall risk of a possible defect or its consequences expressed using quantities MR (Degree of defect in workmanship or priority risk) MR = V * P * K

– V – probability of risk (1 – negligible, 2 – low, 3 – average, 4 – warning, 5 – high);

– P – the severity of the consequences (1 – negligible, 2 – low, 3 – average, 4 – warning, 5 – high);

– K – the probability of defect detection (risk control) (1 – negligible, 2 – low, 3 – average, 4 – warning, 5 – high).

MR – this is a common risk every possible cause of the fault. More MR, the more important is the need to reduce the risk involved. Depending on the calculated value MR defects in the following sections:

MR	Degree of risk
28-125	high
9-27	medium
1-8	low

Risk assessment carried out by method FMEA

Potential risk	The cause of the risk	Effects	Probability of risk	The severity of the risk	Probability of detection	Total risk	Risk Management Plan
			V	P	K	MR = V * P *K	Procedural arrangements for risk management/ Frequency of risk control/ Responsible for overseeing risk
Staff							
Contamination of the product, product mix-ups.	Poor quality of personnel training. Not kvalifikatsirovanny teacher	Release of low-quality products. Harm consumer health.	3	5	2	30 high	Provide training, staff development/ After the training – Teacher/ Daily – Head of division/ When internal audit – Audit Group
Inaccurate test results.	Poor quality of personnel training. Not kvalifikatsirovanny teacher	Release of low-quality products. Harm consumer health.	3	5	2	30 high	Provide training, staff development/ After the training – Teacher/ Daily – Head of division/ When internal audit – Audit Group
Contamination of product, contamination of the test sample.	Failure to comply with hygiene requirements. Not trained staff, the personal qualities of the staff.	Harm consumer health.	3	5	2	30 high	Conduct daily inspection personnel. Treat your hands before handling. MBC control the hands and clothing of personnel. Staff comply with the requirements of personal hygiene/ Daily – Head of division/ When internal audit – Audit Group

Contamination of the product, poor-quality products.	Improper input / output in clean rooms. The lack of a documented procedure. Not trained staff. Not performing official duties.	Harm consumer health.	3	5	2	30 high	Conduct staff training. Observe the changing procedure/ Constantly – Master / foreman/ When internal audit – Audit Group
Contamination of samples, inaccurate QC results.	Poor quality of personnel training. Not kvalifikatsirovanny teacher.	Untimely selection of raw materials, intermediates and finished products.	2	5	2	20 average	Conduct staff training. To carry out sampling strictly according to the approved documents. On each sample immediately after sampling to attach an identification label/ Daily – Head of division/ When internal audit – Audit Group

Conclusions. The work was carried out to improve the quality of products, as a result of which risks of a high and medium degree were identified. For each potential risk, key pre-warning actions are identified, aimed at eliminating or mitigating the consequences of adverse events, ie reducing them.

RECOMMENDATIONS REGARDING THE USE OF COMPUTERIZED SYSTEMS IN DISTRIBUTING ACTIVITY OF PHARMACEUTICAL COMPANY

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Introduction. The computerized system (CS) applies to records in electronic form that are used to create, modify, maintain, archive, retrieve or transmit data. Distributor must by ensured confidence in the reliability, quality, and integrity of electronic source data and source documentation.

Distributor should be used only validate CS that contain any data including distribution protocols of drugs and that create source documents (electronic records). Also validate CS applies when source documentation is created in hardcopy and later entered into a CS, recorded by direct entry into a CS, or automatically recorded by a CS.

Aim. Offer a list of recommendations regarding the use of CS in distributing activity of pharmaceutical company.

Materials and methods. In the capacity of research database were used normative documents, which standardize CS functioning and its validation (in particular, GMP/GDP regulations), FDA recommendations, ICH regulations and other information sources. The comparative analysis method, the method of structural and logical modeling expert method were applied during the research.

Results and discussions. Distributor's IT infrastructure must consider all involved CS in distribution processes, which are accompanied by records and protocols created using these systems. Based on risk

management, develop a program for validation and verification of the necessary CS. On the basis of the results of the entire testing, it is necessary to develop rules for the work of staff with CS and to document them.

Documentation and procedures that relate to CS should at least consist of:

- System setup/installation (including the description and specific use of software, hardware, and physical environment and the relationship);
- System operating manual;
- Validation and functionality testing;
- Data collection and handling (including data archiving, audit trails, and risk assessment);
- System maintenance (including system decommissioning);
- System security measures;
- Change control;
- Data backup, recovery, and contingency plans;
- Alternative recording methods (in the case of system unavailability);
- Computer user training;
- Roles and responsibilities of other parties with respect to the use of computerized systems in distributing activity.

Those who use CS must determine that individuals who develop, maintain, or use CS have the education, training and experience necessary to perform their assigned tasks.

Training should be provided to individuals in the specific operations with regard to CS that they are to perform. Training should be conducted by qualified individuals on a continuing basis, as needed, to ensure familiarity with the CS and with any changes to the system during the course of the study.

Should consider the specific functions used by the CS and pay special attention to them:

Direct Entry of Data. Should not use programming features that automatically enter data into a field when the field is bypassed (default entries). However, can use programming features that permit repopulation of information specific to the subject.

To avoid falsification of data, should perform a careful analysis in deciding whether and when to use software programming instructions that permit data fields to be automatically populated.

System Controls. When electronic formats are the only ones used to create and preserve electronic records, sufficient backup and recovery procedures should be designed to protect against data loss. Records should regularly be backed up in a procedure that would prevent a catastrophic loss and ensure the quality and integrity of the data. Records should be stored at a secure location specified in the standard operation procedures (SOP).

Storage should typically be offsite or in a building separate from the original records. It is necessary maintain backup and recovery logs to facilitate an assessment of the nature and scope of data loss resulting from a system failure.

Change Controls. The integrity of the data and the integrity of the protocols should be maintained when making changes to the CS, such as software upgrades, including security and performance patches, equipment, or component replacement, or new instrumentation. The effects of any changes to the system should be evaluated and some should be validated depending on risk.

Changes that exceed previously established operational limits or design specifications should be validated and all changes to the system should be documented.

Limited Access. Access must be limited to authorized individuals. The user should log into that account at the beginning of a data entry session, input information (including changes) on the electronic record, and log out at the completion of data entry session. The system should be designed to limit the number of log-in attempts and to record unauthorized access log-in attempts.

Individuals should work only under their own password or other access key and not share these with others. The system should not allow an individual to log onto the system to provide another person access to the system.

Passwords or other access keys must be changed at established intervals commensurate with a documented risk assessment. When someone leaves a workstation, the person should log off the system. Alternatively, an automatic log off may be appropriate for long idle periods.

Audit Trails. It is important to keep track of all changes made to information in the electronic records that document activities related critical distribution processes. Use of audit trails or other security measures helps to ensure that only authorized additions, deletions, or iterations of information in the electronic record have occurred and allows a means to reconstruct significant details about study conduct and source data collection necessary to verify the quality and integrity of data.

Computer-generated, time-stamped audit trails or other security measures can also capture information related to the creation, modification, or deletion of electronic records and may be useful to ensure compliance with the appropriate regulation.

The need for audit trails should be determined based on a justified and documented risk assessment that takes into consideration circumstances surrounding system use.

Should it be decided that audit trails or other appropriate security measures are needed to ensure electronic record integrity, personnel who create, modify, or delete electronic records should not be able to modify the documents or security measures used to track electronic record changes.

Audit trails or other security methods used to capture electronic record activities should describe when, by whom, and the reason changes were made to the electronic record.

Conclusions. Distributor's IT infrastructure and processes that occur through computerized systems must be integral part of the pharmaceutical quality system, validated, documented and subject to inspections.

All the specific functions of computerized systems should be considered from the point of view of risk management, and users of such systems should be competent and trained by SOPs.

Our further researches are focused on developing methodology of validation CS.

FORMATION OF PHARMACEUTICAL PARTNER TRAINING PROGRAM AT IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEMS

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Introduction. Personnel policy of the organization is a system of views, requirements, norms, and principles, restrictions, defining the main directions, forms and methods of work with personnel. Its purpose is to preserve, strengthen and develop the human potential, to create a highly productive team, to provide favorable economic, social and psychological conditions for its activities. Personnel policy should be harmonized with the goals of the organization and ensure their achievement. This is especially true for the purposes of the quality management system at pharmaceutical companies.

One of the tools for staffing policies is the process of internal staff training. The modern pharmaceutical industry needs a competent and experienced staff who will be fully committed to their work. They must also have the competencies of the quality system itself: its development, implementation and operation support.

The education is conducted with the purpose of consistent expansion and deepening of knowledge, support of a high professional level of employees, improvement of organization and quality management system in general.

Aim. The purpose of our research was to formation a program of internal training of pharmaceutical company’s personnel during the implementation of the quality management system.

Materials and methods. According to the order of the National Agency of Ukraine on Civil Service dated November 4, 2011 No. 49, item 17. Programs of thematic permanent and short-term seminars, trainings, specialized short-term training courses are recommended to be developed in the following structure: I. Explanatory note. II. Tentative thematic plan. III. Contents of educational material. IV. Control of training (for thematic ongoing workshops and specialized short-term training courses). V. Recommended literature. VI. Attachments.

Results and discussion. In the standard ISO 9001, clause 6.2.2. said, "when planning how to achieve its goals in quality, the organization must determine: what to do; what resources will be needed; who will be responsible; when it is completed; how to evaluate the results."

Accordingly, we set the following tasks (fig. 1): to determine the necessary level of competence for personnel involved in work that affects the quality of products; organize training or take other measures to meet these needs; evaluate the effectiveness of the measures taken; Ensure staff awareness of the relevance and importance of their activities and their contribution to the achievement of quality objectives; Record data on education, training, qualifications and experience.

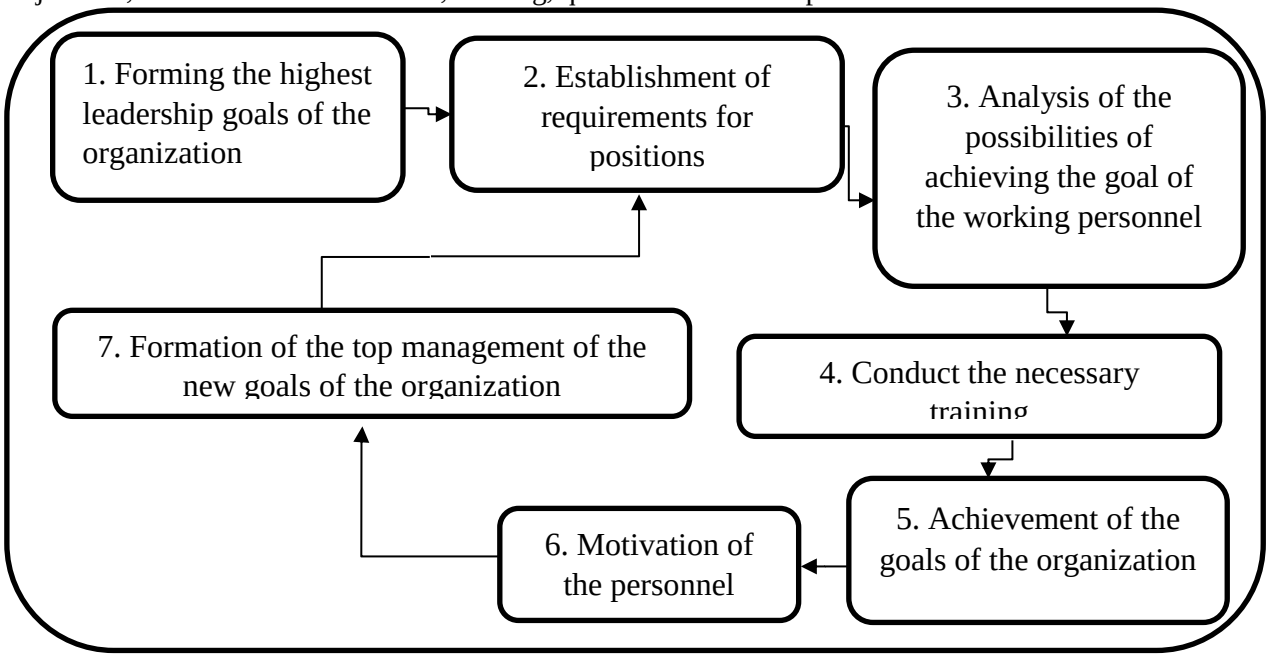

Fig. 1. Elements to be taken into account when implementing the human resources management process.

Particular attention should be paid to the motivation of employees, because this moment is one of the key to developing a training program, because it sets in motion the desire for self-development, improvement and growth, which in turn subconsciously forces the employee to comply with the requirements of the enterprise. The motivational factors include: material encouragement, comfortable working conditions, structured work, relationships and a pleasant circle of communication, recognition of merits, aspiration for achievements, the ability of power, the possibility of change, creativity, self-improvement, and work with interest is interesting.

We offer a course of internal training that will help to better adapt to the staff of the leadership units and their deputies when implementing a quality management system. The training is designed for 20 hours of practical classes and 20 hours of theoretical part.

During the study of the material, the current control over the assimilation of information on the results of tasks and testing.

We have developed three-level test assignments that allow us to differentiate the knowledge gained, depending on the degree of learning and practical skills.

№	Title of topic	Number hours	
		Theoretical part, hour	Practical part, hour
1	Statistical review of the implementation of management systems based on ISO standards. The situation regarding the implementation of QMS in Ukraine and in the world.	1	-
2	Principles of quality management, which are the basis of ISO standards series 9000.	1	1
3	Process approach in enterprise activity. Implementation of the PDCA methodology in the design, regulation and development of the QMS.	1	2

4	Overview of ISO 9000 standards: Structure, Designation and Terms of Application of Standards within the 9000 Series.	2	-
5	General requirements for QMS. Identification of the processes required for QMS. Determining the relationship.	1	3
6	Stages of the formation and implementation of QMS.	1	-
7	Analysis of the requirements of the ISO 9001 standard for document and records management within the quality management system. Hierarchy of documents by the ISO.	2	1
8	Quality policy and goals.	1	2
9	Analysis of the requirements of the ISO 9001 standard regarding the activities of the top management of the organization regarding the maintenance and continuous improvement of the QMS.	2	2
10	Provision of resources. Classification of resources required for the functioning of the QMS.	3	3
11	Analysis of requirements of ISO 9001 to quality control processes. Determination and analysis of the degree of satisfaction of consumer requirements.	2	2
12	Non-compliant product management.	1	1
13	Analysis of the requirements of ISO 9001 to measure and monitor the effectiveness of the QMS processes. Data analysis. Corrective and precautionary measures.	2	3
	Total:	20	20

Conclusions. At this stage, we are finalizing the practical tasks and developing a rating scale for the objective of evaluating results the internal training of the personnel involved in the quality management system.

ACTUALITY OF IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEMS AT DOMESTIC ENTERPRISES FOR THE PRODUCTION OF DRUGS REGULATORS OF COSMETIC MEANS

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Introduction. The introduction of the principles of technical regulation of the circulation of medical cosmetics in Ukraine in accordance with the requirements of international standards and European directives is an important and topical issue. Since CFs are potentially dangerous to consumer health, the issue of their technical regulation is necessary to ensure compliance with the requirements of international standards and the Association Agreement between Ukraine and the EU. Ukraine's cosmetic industry is characterized by high prospects of competitiveness and import substitution, ensuring that compliance with EU standards is a necessary requirement for its effective promotion on the domestic and foreign markets.

To date, the problem of ensuring the quality, safety and efficacy of LKZ remains unresolved: in Ukraine there is no legal substantiation and legislative definition of the basic concepts of cosmetology, terminology and classification of CF, the necessary regulatory documents on the above issues have not been introduced, the criteria of quality and safety of modern cosmetic products and methods for its evaluation, etc. The solution of this issue primarily depends on the proper legislative provision of the process of treatment of short-lived products in accordance with the requirements of European standards and the establishment of a national system of technical regulation of the circulation of cosmetic products in general.

Materials and methods. The analysis of the domestic and European legislation was conducted in the sphere of the classification of cosmetic products, in particular, that regulates the question of

unitization and standardization of basic concepts in perfume-cosmetic industry of Ukraine : the National standard of Ukraine ISO 2472: 2006 "Perfume-cosmetic products. Terms and determinations of concepts", corresponding State standards and technical requirements for the certain type of cosmetics. Also used material of Regulation №1223 / 2009 of the European Parliament and of the Council on cosmetic products (Brussels, 30 November 2009), which regulates the requirements for the classification of cosmetic products, operating in the European Union.

Results of the research. The object of the study is the LKZ, which are in circulation in the Ukrainian market. The subject of the study is quality management systems at national pharmaceutical cosmetics manufacturing enterprises. The research was carried out by analyzing the legislative and normative base, the register of drugs, the register of licenses for the production of medicines, scientific specialist publications devoted to this problem.

In accordance with the set tasks, we analyzed the features of the assortment of KZ and LKZ, which are in circulation in the Ukrainian market. According to the results of the analysis of the LR registry, an information base of dermatological preparations has been formed in Ukraine, which consists of 562 trade names. The objects under the Anatomical Therapeutic Chemical classification system were investigated.

The register of existing licenses for the production of medicines was analyzed as of 01.01.2018. It was established that the number of enterprises that have the right to introduce economic activity for the production of medicinal products is 113 units and practically did not change over the last years. According to the results of the analysis of the data of the registration register, 34 enterprises implement economic activities for the production of drugs in the following forms for external use, such as creams, gels, shampoos, powders, solutions, etc.

Creams are produced by 10 Ukrainian enterprises. Most of the cream-like LKZs are manufactured by Health, FC, LLC, Kharkiv (11 preparations), most of which – 20% – preparations with corticosteroids, 5.7% of creams is intended for the treatment of wounds and ulcerative lesions of the skin. Darnitsa, FF, PrAT, Kiev produces 6 LKZ in the form of creams – most of which – 8.5% are presented in the group of drugs with corticosteroids. Five cream products are produced by Farmak, PAO, Kyiv and Kievmedpreparat, PAO, Kyiv – the maximum number of which – 5.7% – is presented in the group of drugs with corticosteroids. Liquid forms of release are produced by 35 Ukrainian enterprises. Liquid forms of release – solutions, lotions for skin application – currently manufactured 88 units. Most liquid LDLs – 5.1% of their total production are manufactured by DKP "Pharmaceutical Factory" Ltd., Zhytomyr, PJSC "Phytopharm", Kyiv, FC "Zdorovya", Kharkiv, LLC "Kwantum Satis" Zaporozhye city. Solutions in the overwhelming majority are typical of a group of antiseptic and disinfectants. 6 Ukrainian manufacturers produce powdered LKZ.

It should be noted separately that the issue of ensuring proper standardization of products is one of the main issues in the quality management system (QMS). In Ukraine, more than 1300 organizations have implemented QMS according to the model of ISO 9001. Nevertheless, it is evident that the level of application of QMS in the activities of the Ukrainian cosmetics industry does not correspond to the world experience of effective management, which is one of the reasons for the imperfection of the standardization system of national cosmetic products. According to our estimates, it is the use of modern models of DMF at all stages of the life of medicinal cosmetic products can be a guarantee of increasing its competitiveness and a catalyst for the further development of the domestic cosmetic industry as a whole. An analysis of the state of implementation of quality management systems at the enterprises of the industry has proved that the issues concerning the formation and implementation of quality management systems at enterprises in accordance with the requirements of the international standard ISO 9001: 2015 have not been sufficiently studied. First of all, it depends on the existence of significant changes in the structure of the new version of the standard. The transition to ISO 9001: 2015 should take place by September 2018. It is revealed that for the management of domestic enterprises, this process is very complicated. This is especially true of those statements of ISO 9001: 2015, which refer to requirements for process planning, which necessarily include risk assessment for each of them. Risk management, risk management is a systemic process for the adoption and implementation of managerial decisions aimed at minimizing the probability of a negative outcome of possible losses associated with its implementation. Senior management of an enterprise must ensure that the requirements of the standard are met and all interested parties are investigated, because the effectiveness of

the implementation of these measures depends on the planning of actions to prevent potential risks. Implementation of quality management systems at enterprises in accordance with the requirements of the international standard ISO 9001: 2015 foresees the purposeful application by the company's management of the policy of organizational development regarding quality.

Conclusions: The results of the conducted research indicate the urgency of the introduction of technical regulation of cosmetic products in Ukraine, which results in solving the problems of competitiveness and import substitution of domestic cosmetic products. The solution of these problems, basically, depends on the level of implementation of the relevant legislative framework and requires the uniting of efforts of all participants of the cosmetic community of Ukraine. The urgency of the implementation of quality management systems at domestic enterprises for the production of medicinal cosmetic products was investigated, important aspects of the formation of quality management systems at enterprises in the context of the requirements of the international standard ISO 9001: 2015 were determined.

ANALYSIS OF MODERN FORMS OF IMPROVING QUALIFICATION OF PHARMACY NETWORK WORKERS

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Introduction. Human resources of any competitive organization is an integral part of the quality management system and one of the most important components of its commercial success.

The need for continuous training dictated pharmacies constant increase in the range of drugs, the advent of new technologies, management approaches and regulatory requirements.

Aim. Analysis of existing approaches to training pharmacies.

Materials and methods. In terms of business, pharmacy today – a retailer in the health system. It performs a social function – providing people with high quality pharmaceutical care and commercial – deserves loyalty, making quality service in turnover and profit pharmacy.

Obviously, effective operation of pharmacy staff is possible only if the knowledge and understanding of advanced retail technologies.

Currently, there are different forms of learning that can be used in pharmacies. PEP, namely lectures (Video lectures), training, travel, conferences and seminars and self-study.

Results and discussion. But each form has its advantages and disadvantages, which we have identified and presented them to the table. 1.

Table 1

Advantages and disadvantages of certain forms of vocational training

Forms of education	Positive aspects	Negative aspects
Lectures	• High-quality and rapid assimilation of theoretical material. • Getting new knowledge. • High informative part of the learning process.	• Students are passive participants in the learning process. • Lack of effective communication between the teacher and the audience.
Training	• Practical skills testing work. • Modeling special situations for the development and consolidation of the necessary skills, the development of new models of behavior, the possible change in attitude to their own experiences and approaches to the work. • During training may apply different techniques and methods.	• Failure to create a continuous training process. • Unwillingness or unsuitability of individual employees to participate. • Inconsistency training classrooms for training.

Study trips	• Improvement and acquire new skills. • Improving staff morale, motivation of staff. • Development of contacts, establishing new relationships. • Improving the image of the company.	• Lack of motivation of the employee. • The potential employee poaching.
Seminars and conferences	• It helps students better understand the content of the material. • Allows you to control the degree of understanding of the students covered material.	• Failure to complete training without prior training
learning	• The worker sets a pace and duration of study, controls the entire process until the implementation of the acquired knowledge in work	• Requires a high level of employee motivation, self-organization and self-control

Conclusion. Based on the foregoing material, we can offer managers pharmacy chains combine different forms of training for better results. For example, when combined lectures and trainings will be provided with feedback from the teacher student that will lead to better learning, while combining training and self-training – the acquired skills will be adjusted and refined.

REGULATION OF MAIN STAGES OF QUALITY MANAGEMENT SYSTEMS FORMATION IN DISTRIBUTION ENTERPRISES OF MEDICINAL PRODUCTS

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Introduction. According to the results of the first half of 2018, the total sales volume of all categories of he "pharmacy basket" amounted to UAH 41.8 billion. and 861.8 million packs.

Medicines consumption remains at a high level due to the traditional priority of self-medication and distrust of medical institutions.

Top-3 distributors of medicines provide 78.9 % of product shipments in the pharmacy network.

Reducing the population, occupation of some regions of Ukraine and reducing the population solvency has led to increased competition in the pharmaceutical market.

For a successful distribution business of medicines and medical products, it is necessary in all ways to increase the efficiency of the company to improve the quality of customer service and reduce non-target costs. As output: implementation and ongoing development of the Quality Management System (QMS) in accordance with modern principles and requirements of international standards ISO 9000 series.

Aim: development of a set of proposals for the design and implementation of a Quality Management Systems based on a typical distribution pharmaceutical company.

Materials and methods. To carry out our research, we carried out studies on the provisions of ISO 9001:2015 and Good Distribution Practice (GDP) as part of an overall management system based on the business risk analysis approach needed to create, implement, operate, monitor, review, maintain and improve of QMS. Investigated the state regulatory framework in the field of quality management and its relationship with the pharmaceutical quality system.

Results and discussion. We have developed a detailed plan for the design of the QMS to the certification phase (project duration is about 9 months). The QMS formation is proposed to be carried out in stages, with a clear regulation of all project stages and with involvement of independent auditors and experts.

We offer the following processes of quality management system:

- Manage the organization
  - Manage finances

- Manage the quality management system
- Plan the activities of the organization
- Carry out self-inspection (internal audits)
- Conduct an analysis of the quality management system
- Develop preventive and corrective actions

- Provide resources
  - Provide staff
  - Provide infrastructure
  - Provide premises
  - Provide equipment
  - Provide communications
  - Provide a production environment
  - Manage documents and records
- Purchase and sell of products
  - Interact with consumers
  - To procure products
  - Transport, control and store products
  - Supply the products to the customer
  - Make returns and reviews

Each group of QMS processes can be "decomposed" to the desired scale. Decomposition is a more detailed representation of the process for increasing detail.

The process model is needed to describe the Quality management system and develop a rational documentation system.

The QMS process model developed allowed:

- Clearly define the hierarchy, types and number of regulatory documents.
- Establish clear limits of responsibility and authority of the personnel.
- Exhaustively define the requirements for the results of each process.

Based on the process model we have proposed a list of basic documentation. Also was developed a draft regulation on process managers, documented methodology "Documentation Management", Standard Operation Procedure "Acceptance and Inbound Control of Purchased Products" etc.

Conclusions. The implementation of the QMS will provide a number of benefits:

- improve company management;
- Increase competitiveness;
- improve the quality of services;
- reduce costs etc.

Our proposals will allow pharmaceutical companies to implement and certify Quality Management Systems in the most efficient way, minimizing project execution time and eliminating the risk of common mistakes.

MAIN STANDARDS FOR COMMUNICATION WITH CONSUMERS TO IMPROVE THE QUALITY OF PROVIDING PHARMACEUTICAL SERVICES

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Introduction. Communication is a process through which the relationship between people is realized, and an important component that is almost the entire human life. But communication is not just a conversation of people, but an entire communication system, a component of communicative sides, their

interactions, ethics, communication techniques, and other components. In everyday life with loved ones, a person does not think so much about what kind of intonation he has, the tone of the voice, and how high-quality information he reports. But when the process of communication is closely related to work and depends directly on him then a person must have certain techniques for communicating with clients, methods for communicating information and guided by certain rules and ethics.

A person who deals with drug users should communicate according to the procedures regulated in accordance with the principles of Good Pharmaceutical Practice. Professional communication skills always have a final positive result for the pharmaceutical worker and the consumer, who met his needs and purchased a medicinal product and received a pharmaceutical service. Achievement of mutual understanding, exception of differences, attraction of the person as a constant consumer – these are the main purposes of communication.

Aim. Therefore, the purpose of our research is to study the methods of communication between the participants in the process of providing pharmaceutical services, which are carried out in pharmacy establishments.

Materials and methods. In the process of research, we used the analysis of scientific publications and the methodology of consumer surveys regarding their satisfaction with pharmacy visits.

Results and discussion. Each organization must develop internal rules and standards for communicating with the clients of the company. They should be aimed at the correct establishment of dialogue with the buyer and the formation of a competent sequence of communication stages with him.

On the basis of our survey, we have found that the main thing for consumers is politeness, friendly attitude, high level of service, ability to hear and listen.

We will describe some basic standards on which pharmacies should develop their own regulations.

When communicating with buyers, follow the following recommendations:

Required:

– Meet the buyer with the greetings of "Good afternoon!"
– To contact the buyer only on "You".

If the buyer turns to the pharmacy employee with any questions, it should: interrupt any work, listen carefully to the buyer's questions, give a full answer.

If the buyer applies to an employee engaged in servicing another buyer, the employee must:

– apologize before the buyer whom he serves
– return to the buyer who has just come and listen to him
– give a response to the buyer (no more than 1 minute), if it takes more time to answer the buyer's questions, you need to invite a freelance specialist to answer.

Unacceptable:

– sit in the presence of buyers,
– turn away from the buyer or return his back to him,
– cross arms behind his back or chest;
– keep your hands in the pocketbook on the belt;
– rely on shelves, furniture and walls,
– to conduct conversations among customers in the eyes of the buyers,
– discuss working problems in the presence of buyers,
– use a mobile phone,
– chew (including a chewing gum).

It is also a very important standard of appearance of employees:

– every employee of a pharmacy institution is obliged to wear a personalized badge of the established sample, which is fixed on the clothes at the level of the breast, strictly horizontal,
– every employee of a pharmacy should wear branded medical clothes, a neat form of clothing – clothing should be clean and smoothed,
– shoes should be comfortable, office and clean,
– not allowed during the work of a sharp smell of perfume or toilet water, tobacco smoke,
– every employee of the pharmacy network must have a neat hairstyle.

The employee of the first table should be able to use an individual approach to the client depending on his style of communication, listen carefully and hear orders and customer questions, provide complete and correct information about the medicinal product and the features of its use and interaction with other means or food.

Conclusions. All these means of influence during communication with consumers are not only necessary, but carefully designed and tested, so there is no doubt in their success. If they are used continuously, then the consumer will want to return to this pharmacy over and over again. Therefore, it is worth developing an internal standard of communication with consumers and teaching their staff to do it to improve the quality of service and the full provision of pharmaceutical assistance.

QUALITY MANAGEMENT SYSTEM FOR PHARMACEUTICAL COMPANIES

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Introduction. Any modern pharmaceutical company is inconceivable without observing certain quality assurance procedures and ensuring that the products manufactured comply with the registration dossier, i.e. is high quality and efficient.

In world practice, one of the most important documents defining the requirements for the production and quality control of medicines is the Good Manufacturing Practice of Medicinal Products (GMP).

GMP rules provide for system management and monitoring activities of the enterprise, including training and certification of personnel, workflow, production processes, audits, validation of technological processes and methods of quality control, equipment qualification, storage and handling of medicines, etc.

An analysis of the current status of quality assurance activities in domestic enterprises has shown that the greatest problems arise in several activities: validation, technical equipment, use of reference materials, documentation management, and staff competence. At the same time, in our country, great attention is paid to ensuring the quality of medicines at all stages of their life cycle – from development and production to wholesale and retail. The processes of laboratory research and clinical trials in healthcare institutions are also being improved. Nevertheless, there are still many problems with the implementation and maintenance of the effective functioning of Pharmaceutical Quality Systems (PQS).

Aim. To substantiate the optimal algorithm of PQS introducing on the basis of domestic pharmaceutical enterprises, their subsequent development and improvement.

Materials and methods. To carry out our research, we carried out studies on the provisions of ISO 9001:2015 and GMP as part of an overall management system based on the business risk analysis approach needed to create, implement, operate, monitor, review, maintain of a medicine quality. Investigated the state regulatory framework in the field of quality management and its relationship with the pharmaceutical quality.

Results and discussion. First of all, when developing a quality system in pharmaceutical production, management should ensure that authorized persons properly perform their functions of controlling all processes that affect product quality. In addition, a modern pharmaceutical quality system provides for close cooperation between the Quality Assurance Department (QA), the Quality Control Department (QC), and the purchasing and production department.

The Quality Assurance Department should ensure and monitor compliance with GMP requirements. The QA must also be the arbiter between the Quality Control Department, production units and technical services.

In the implementation of all current functions, QC makes final conclusions about the quality of products and their compliance with the specification requirements.

The QA together with the QC conducts an investigation of the identified deviations and inconsistencies (nonconformities), the consideration of complaints, and carries out change control.

The analysis of GMP standards shows that, in general, they imply the need to eliminate inconsistencies / nonconformities in the production process and quality control preventively, as a result of taking into account those factors that may adversely affect the finished product.

GMP rules are systemic and *preventive* nature. GMP rules require constant availability of:

– qualified and competent personnel;
– a sufficient number of premises suitable for production and auxiliary processes;
– appropriate qualified equipment and support systems (water treatment, air conditioning, air treatment, etc.);
– raw materials and other materials of good quality;
– approved process schedules and work instructions;
– systems for ensuring appropriate storage and transportation conditions;
– sufficient resources for proper quality control etc.

Conclusions. The reason for the ever-growing demands for quality assurance in the development, research, production and sale of medicines is that quality is inextricably linked to the safety and effectiveness of medicines.

Understanding the concept of quality assurance of medicines and the implementation of GMP and ISO 9001 standards helps eliminate or minimize the main risks to the quality of manufactured medicines.

In order to create a truly effective Pharmaceutical Quality Systems, it is necessary to focus on personnel competence, and the key stages of all production processes should be clearly defined and documented, taking into account the ongoing risk analysis.

Very important for the diagnostic of the Quality System functioning is internal audits. Only competent specialists who are well aware of the specifics of drug production and the regulatory requirements of the pharmaceutical industry should carry out such audits.

ANALYSIS OF TYPICAL DISSOCIATIONS IN THE IMPLEMENTATION OF THE RULES OF GOOD LABORATORY PRACTICE IN THE TEST AND CALIBRATION LABORATORIES TO CONTROL THE QUALITY OF MEDICINAL PRODUCT

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Introduction. The principles of good laboratory practice (GLP) were developed in 1979 and 1990 by an international team of experts. In Ukraine, the principles of GLP operate within the framework of the standard of the Ministry of Health Protection «Decree. Medicinal product. Good laboratory practice», which establishes the principles and rules (requirements) for preclinical testing of drug safety.

GLP is a quality system for organizing the process and the conditions under which planning, conducting, monitoring, recording, storing and reporting on preclinical (non-clinical) research is carried out. Certification of laboratories and obtaining relevant certificates is impossible without confirmation of the quality of the data obtained. The main task is to ensure the possibility of complete tracking and restoration of the entire course of the research. The application of these rules allows you to compare and trust the results of research obtained in different laboratories, and forms the basis for the mutual recognition of the data obtained by different countries.

The quality of research in laboratories is affected

- developed and functioning quality management system
- resources (laboratory rooms, staff, material and technical base, microclimate parameters, etc.)
- appropriate management (protocols, standard operating procedures, regulation on the study leader)
- adequate planning of research parameters (composition stability, need for consumables)
- adequate documentation system (work logs with primary data, final report, archives, etc.).

Aim. The purpose of this work was to analyze typical inconsistencies in the implementation of the principles of good laboratory practice in testing and calibration laboratories for Medicinal product quality control.

Material and methods. Typical discrepancies were identified by questioning employees working in the organization. For processing the questionnaires used the methods of mathematical statistics. Results are presented as a percentage.

Results and discussion. Thus, in the course of the study, we found the following typical non-compliance with the rules of GLP.

Quality assurance system:

- 91% of managers do not hold conversations with staff about the practical application of the developed and approved assurance system
- 80% of staff cannot answer the question «What is the meaning of the quality assurance program developed in the organization?»
- 78% of staff perceives the developed quality system as a «formal document»
- 63% of staff does not inform the manager about non-compliance of any approved documents with practical use
- 49% of staff do not discuss problematic issues directly with the manager
- 32% of staff does not seek to improve their own skills, the acquisition of new knowledge and skills, self-improvement.
- Resources:
- 63% of organizations have formalism in training and conducting various types of briefings
- 48% of organizations do not conduct regular and timely employee training
- in 35% of organizations there is an overload of employees with job responsibilities
- in 31% of organizations there is an insufficient number of fully staffed jobs
- 28% of organizations have air preparation systems installed that do not provide enough oxygen in laboratory rooms throughout the working day
- 19% of organizations use equipment that is used to obtain physical and / or chemical data that does not have the necessary productivity
- in 17% of organizations there is insufficient laboratory space
- in 8% of organizations, staff untimely register the received primary data
- Relevant documentation management:
- in 62% of organizations there is information overload of standard operating procedures, fuzzy and / or incorrect description of the performance of a particular operation
- in 48% of organizations use a complicated form of documentation for registration of primary data
- in 18% of organizations there is a remote storage of standard operating procedures from the workplace.

Conclusion. Thus, during the identification of typical inconsistencies in the implementation of GLP rules in testing and calibration laboratories for quality control of medicinal product, it was found that typical inconsistencies belong to the quality and resource management system. Further work is aimed at developing a warning set of measures.

THE MAIN ASPECTS OF THE FORMATION STAFFING POLICY OF PHARMACY ORGANIZATION

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Introduction: The personnel policy of the organization is the general direction of personnel work, a set of principles, methods, forms, organizational mechanism for the development of goals and

objectives aimed at preserving, strengthening and developing human potential, creating a cohesive, qualified and highly productive team capable of responding to ever-changing requirements market taking into account the development strategy of the organization and its personnel management strategy. In a narrower sense, personnel policy is a set of rules and norms, goals and ideas that determine the direction and content of work with personnel.

Purpose: The study of the main aspects of the formation personnel policy of the pharmacy organization.

Materials and methods: The main goal of the personnel policy is to increase the efficiency of personnel management by creating a human resources management system for a pharmacy organization aimed at maximizing profits and providing leadership in a competitive environment based on economic incentives and social guarantees, and promoting a harmonious combination of interests of both the employer and the employee. developing their relationship for the benefit of the organization.

The object of the personnel policy of the pharmacy organization is its personnel, which is considered as a set of individuals with general and professional knowledge and consisting with the organization in relations regulated by the employment contract.

The structure of the staff of the pharmacy organization includes: managers, pharmaceutical staff, junior pharmaceutical staff, employees, support staff.

The subject of the personnel policy of a pharmacy organization is the organization's personnel management system, consisting of personnel management services, independent organizational divisions of the organization, united according to the principle of functional and methodical subordination, and line managers at all hierarchical levels of management. Such a system is typical for large pharmacy organizations operating in the form of a network association.

For individual pharmacies, the subject of personnel policy is the system personnel management, which focuses on the activities of the leader as a team leader, who performs the professional functions of a pharmaceutical worker and the functions of team management. The content of the document is the declaration of basic principles of personnel policy, which should be shared by all subjects of the organization as an integrated system.

Results: In the course of the study, we identified the main principles for the formation of personnel policy, which require mandatory consideration of:

- personnel in a pharmacy organization should be considered as a human resource capable of providing it with competitive advantages, provided that it is planned and ensure its optimal use, development and quality;
- organization personnel management should be based first turn on the predominance of economic and socio-psychological methods and constitute one of the most important functions of the organization’s management at all hierarchical levels of management.
- the staff of the pharmacy should be considered as capital acquired in the course of competition, and personnel costs – as a long-term investment in the development of the organization;
- the organization's personnel is the carrier of its corporate culture and values, and in many respects contributes to the creation of its positive image in the eyes of visitors.
- the manager and staff should act as social partners, sharing the goals of the organization and the ways to achieve them, determined by its strategy and policy. The manager must ensure that his employees meet the social, spiritual and material needs in accordance with the contribution of each of the employees to the achievement of the goals and objectives of the organization;
- the work of the manager with each employee should be oriented towards the establishment of long-term labor relations based on compliance with the requirements of labor legislation and allowing the employee to fully realize his level of professional competence, as well as improve it.

Conclusions: Solving the problems of personnel policy in the practice of a pharmaceutical organization is the essence of personnel work. This includes its activities in the planning, selection, training, placement, retraining, evaluation, education and rational use of personnel. Personnel work, therefore, is a means of implementing personnel policy.

The implementation of the tasks will ensure the optimal balance of the processes of updating and bringing the quantitative and qualitative composition in line with the needs of the pharmacy organization, the requirements of current legislation and the state of the labor market.

Thus, having a clear understanding and understanding of the main directions and provisions of the personnel policy will improve the organization of work and increase the competitiveness of the pharmacy organization.

PROVIDING THE INFORMATION SECURITY OF THE ORGANIZATION OF THE PHARMACEUTICAL PROFILE

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Introduction. Currently, information systems are one of the main business management tools. Information is stored and processed in IS of various degrees of secrecy and ensuring their security is extremely important. The international security standard ISO 27001:2017 defines information security (IS) as: «preservation of confidentiality, integrity and availability of information; in addition, other properties may be included, such as veracity, authenticity, reliability».

Information security of an enterprise is the security of information that an organization has (produces, transmits, or receives) from unauthorized access, destruction, modification, disclosure and delays upon receipt. Information security of an enterprise includes measures to protect data creation processes, their input, processing and output. The purpose of information security is to preserve the information system of the enterprise in its integrity and safety, to protect and guarantee the completeness and accuracy of the information it provides, to minimize damage and to modify information, if any. Nowadays there is an issue related to the protection of information systems of enterprises of pharmaceutical profile.

Aim. The aim of our research was the development of an enterprise information system program of a pharmaceutical company for the further process of implementing the requirements of ISO 27001:2017.

Materials and methods. To carry out our research, we carried out studies on the provisions of ISO 27001:2017 as part of an overall management system based on the business risk analysis approach needed to create, implement, operate, monitor, review, maintain and improve information security. Investigated the state regulatory framework in the field of information security and its relationship with the pharmaceutical quality system.

Results and discussion. The line of standards in the field of information security management was originally developed by BSI (British Standards Institute, British Institute of Standards), after which these standards were adopted in ISO, receiving international status.

The ISO 27001:2017 standard is a list of IS management system requirements and acts as an implementation guide that can be used in designing control mechanisms chosen by an organization to reduce IS risks.

The ISO 27001 standard contains descriptions of the world's best practices in information security management. The standard establishes requirements for an information security management system to demonstrate the ability of an organization to protect its information resources.

The main objectives of the implementation of the international standard for pharmaceutical enterprises are:

1. Increasing the level of IS assets of the enterprise. In terms of a standard, assets are informational inputs and outputs, informational records, resources (people, infrastructure, equipment). The assets of pharmaceutical companies include patents, trademarks, licenses, permits, drug manufacturing technologies, etc.

2. Successful conduct of an information security audit in accordance with the requirements of ISO 27001.

3. Reducing the number of incidents related to the violation of information security and the severity of their consequences. Information security incidents include the theft of a company's intellectual property, breach of data confidentiality, loss of access to data, etc.

The information security management system is developed taking into account the specifics of the activities of a pharmaceutical company. The main stages of developing an information security management system at a pharmaceutical enterprise:

1) Inventory of resources (definition of valuable assets of the company in terms of information security, for example, information resources, software, tangible assets, etc.).

2) Categorization of resources (setting a gradation of the importance of protecting the (categories) of resources and assigning specific resources to the relevant categories).

3) Information risk assessment (calculation of risks, which is performed taking into account information about the criticality of assets, as well as the probabilities of the implementation of vulnerabilities).

4) Processing information risks (including the identification of specific measures to protect valuable assets).

5) Evaluation of the security of information systems.

6) Implementation of selected risk treatment measures.

The implementation of protective measures is to inform the relevant staff about the rules and deadlines for the procedure, to regularly monitor the procedure, as well as to evaluate its effectiveness, to introduce corrective and preventive actions.

7) Monitoring the implementation and effectiveness of selected measures.

8) Making corrections to the current IS program based on the data obtained as a result of an internal audit.

The program of implementing the provisions of the standard in the organization can take from 9 to 12 months, taking into account the availability of information about the resources of the enterprise and a clear hierarchy of subordination of employees of the enterprise.

Conclusions. Modern pharmaceutical enterprises are characterized by the rapid development of their information environment. Constant accumulation of information requires its proper processing and storage. As a result of working with data, an important task is the organization of information security in the enterprise.

Information security is achieved by implementing an appropriate set of information security management activities that can be represented by policies, methods, procedures, organizational structures and software functions. These activities should ensure the achievement of information security objectives of the organization.

The ISO 27001 standard establishes the requirements for an information security management system. By implementing the ISO 27001 Standard in the practice of a pharmaceutical company, a number of advantages can be achieved. Apart from the fact that certification for compliance with this standard allows you to visually show business partners, investors and clients that the company has established an effective information security management, this provides the company with an additional advantage: partners and customers see that the security requirements are met, and the company demonstrates a desire to reduce their risks; the company is able to monitor the process of executing the security policy (find and fix weaknesses in the information security system); ensures efficient system management in critical situations; achieved reduction and optimization of the cost of maintaining the security system; the integration of the security subsystem into the organization's business processes is facilitated.

For further research, it is relevant to model the organization's information security management system for the ISO 27000 family of standards.

ANALYSIS OF COMMON PROBLEMS OF QUALITY MANAGEMENT SYSTEMS IMPLEMENTING IN PHARMACIES IN UKRAINE

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Introduction. At present approaches to the formation and implementation of Quality Management System (QMS) in organizations of different industries where there is a pronounced specificity, yet finite not formed. Accordingly, there are no regulations governing in detail the project implementation QMS. Thus, for example, project formation QMS in pharmacies associated with a significant amount of work. The lack of established, well-regulated and documented approaches, methods and tools applicable in the creation and implementation of QMS causes a lot of problems in our country and abroad.

Implementation of QMS in accordance with the requirements of ISO 9001 in recent decades is becoming more common in almost all industries. This fact is due to a number of competitive advantages that can get the organization through the introduction of QMS. Such systems involve significant changes in approaches to managing the organization, directing all kinds of internal activities (business processes) to increase guarantees sustainable compliance with regulatory requirements and expectations of consumers and customers for products and services. Built-in continuous improvement processes within the QMS can not only continually reduce risks to product quality and increase the level of satisfaction of requirements, but also reduce overhead, which positively reflected on the cost of the final product.

Separate interest in implementing QMS organization with the pharmaceutical sector, which is associated with the ever-increasing demands for quality of medicines (drugs) and to work on their design, research and testing, industrial production (or manufacture in conditions of pharmacies or hospitals), wholesale and retail trade and so on. Applicable in many countries "Good Pharmaceutical Practice» (GPP), relevant standards and licensing activity at various stages of the life cycle of medicines and other legal documents requiring compliance with certain conditions of such activities. These standards include, among others, the availability of Pharmaceutical Quality System.

The competitive environment requires pharmacies to optimize the processes of purchasing goods, expanding the range, providing the necessary inventory, the competent regulation of the document circulation, the application of sound financial policies, as well as the introduction of modern standards of customer service.

It must be emphasized that there are specific problems of implementation models developed QMS in the actual practice of pharmacies. Example,

- adaptation of personnel to work under the new conditions of management;
- formulation of performance criteria QMS processes and their systematic monitoring;
- use application means initiating and implementing corrective and preventive actions (CAPA);
- Quality Risk Management (QRM) fo medicines quality and others.

In this connection it is necessary to formulate recommendations for the optimal solution described and other problems that arise during QMS project implementation in pharmacies.

The aim of the study. Identification and study of problems of implementation of quality management systems in pharmaceutical institutions of Ukraine.

Materials and methods. General requirements and recommendations for the formation of QMS, listed in the international standard ISO 9000 and GPP/GDP.

The obtained results. It was determined that the main problems that hinder the implementation of QMS in pharmacies are:

– insufficient interconnection of production processes at the pharmacy and documented requirements;

– clearly defined areas of responsibility, authority and staff interaction pharmacies;

– improper preparation of documented procedures (standard operating procedures (SOP), guidelines, etc.);

– no documented mission, policy and strategy of the organization determined by senior management;

– insufficient staff motivation pharmacies to involve activities to ensure the quality of customer service and more.

The QMS implementation should be initiated by senior management. This project in general has to constantly underpin management, because leadership and staff motivation are the necessary conditions for ensuring the quality of products of any company.

Conclusions. Thus, it can be argued that the introduction of QMS in any organization, including at the pharmacy, is a rational step towards strengthening the market position and further expansion of the organization.

A properly implemented QMS is able to provide more accurate execution of all activities and minimize risks of any inconsistencies, so you can expect an increase in the quality of service, growing image in the market and increasing economic performance.

RISKS OF PHARMACEUTICAL ACTIVITY AND PROFESSIONAL RESPONSIBILITY OF PHARMACEUTICAL PERSON

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Introduction. The activity of any pharmacy organization is associated with production risks. The economic dictionary considers risk as a «combination of probability and consequences of adverse events». Under adverse events means economic losses and damage to the business reputation of the organization.

The risks of the pharmacy organization consist of the risks inherent in any commercial organization, as well as the specific risks associated with the implementation of pharmaceutical activities. In pharmaceutical activity, distinguish the main processes: the order, acceptance, storage and sale of pharmacy products. Emerging at these stages risks present both to the pharmacy and to the consumer of pharmaceutical services, as the consequence of the risk in most cases is low-quality goods. The leading place in the ranking of reasons for the quality of pharmaceutical activities has related to staffing, namely, «insufficient qualifications of staff» and «unfair attitude of staff to work». It has noted that these risks lead to a decrease in turnover up to 50%. Low liability – a risk that leads to violations in the process of performing individual operations with associated economic losses.

The low level of competence and unfair attitude of the staff towards the work is also a consequence of the lack of responsibility of the pharmaceutical staff. The risks arising from these factors in the implementation of the basic processes of pharmaceutical activity have a significant negative impact, which determines the relevance of their study.

Aim. Study of the risks arising in the implementation of the basic processes of pharmaceutical activity of the pharmacy organization, connected with the lack of responsibility of the pharmaceutical staff.

Materials and methods. In the process of research, the following methods were use: analysis of scientific publications, logical, grouping, comparison, questionnaires, and expert evaluations. The empirical basis for the study was 256 questionnaires of pharmaceutical specialists working in a pharmacy organization; 68 questionnaires of heads of human resources departments, heads of training departments and their managers; expert interview materials of 15 specialists responsible for the pharmaceutical procedure.

Results and discussion. Because of the analysis of current normative documents, the main threats identified for each of the four pharmaceutical processes associated with insufficient employee liability were identify. This became the basis for the development of questionnaires. 20 risks were assigned to the order process, up to the acceptance process – 25; to the processes of storage and implementation – 30 risks. Thus, only 105 risks were assess.

To assess each risk, based on the results of the questionnaire of pharmaceutical specialists, its value was calculate according to the formula:

$$R = v * Q$$

where: R – is the risk value, points, v – the probability of occurrence of risk points, Q – the magnitude of the expected consequences of risk points.

Because of the research, the risks were categorize.

The first category includes the most significant risks (26.7% of all risks), their probability and magnitude of the consequences are maximized. Examples: the inability to order goods due to debts to the supplier, resulting from late payment; wrong order of goods; order of goods is not in accordance with the need, lack of inventory; untimely order of goods; wrong order item; Ordering goods not according to need – creating a poor assortment; lack of information about the structure of the range and running goods; inability to order goods due to the overstocking of the pharmacy; inability to order goods, lack of skills to eliminate errors of work with the program and computer; wrong choice of supplier, high prices; lack of freedom to choose size and delivery interval; inflexible response to changes in demand; order of goods is not in accordance with the need, glut; non-compliance with the procurement interval; no delivery contract; ordering goods from a supplier with a disadvantageous minimum order size; ordering goods from a supplier with a bad reputation; ordering goods from a supplier with unfavorable payment terms; the choice of time-consuming method of ordering goods (by phone) due to incompetence in working with a computer.

The second category (44.7%) includes high-impact risks, but their probability is low. Examples: late acceptance of goods in quality and quantity; acceptance of goods that do not correspond to the invoice by quantity; lack of responsibility for the acceptance of goods; acceptance of goods that do not correspond to the invoice on the shelf life; acceptance of non-order goods; acceptance of goods that do not correspond to the consignment note for the series; acceptance of goods in a damaged shipping container; no selected area of acceptance of goods; theft of goods by staff at the time of acceptance; the absence of the log of receipt of goods; lack of acceptance for quality and quantity; violation of storage of goods during acceptance; acceptance of goods in damaged packaging; Acceptance of goods without information about the documents confirming the quality; late placement of goods in the quarantine zone; acceptance of goods with errors in the accompanying documents; lack of acceptance for quality and quantity; lack of documentation of acceptance; acceptance of the goods by an intangible person in charge.

Third – the least dangerous risks (18,1%), their probability and the consequences are minimal. Examples: Untimely control of expiration dates, expiration; storage of goods on the floor without pallets; lack of quarantine zone; choose the wrong light mode; choose the wrong temperature mode; joint storage of goods subject to separate storage; the lack of the ability to find goods promptly, the inconvenient systematization of places of storage; violation of the order of storage of medical products.

The fourth category (10.5%) was risky with a high probability of occurrence, but a low magnitude of the consequences. Examples: sales of pharmaceutical products by a staff member who does not have a pharmaceutical education; rudeness with buyers; improper appearance of the employee; improper registration of showcases and trading room; incomplete counseling; lack of log of incorrectly written recipes; excess of leave rules; ignoring buyers; conflicts between employees in the presence of buyers; realization of a product that meets the needs of the buyer; The grading of all risks is based on the probability of occurrence and the magnitude of expected losses. Linguistic risk assessment was conducted according to the table.

The magnitude of the risk in points	**Linguistic evaluation**
from 101 to 121	critical risk
from 76 to 100	significant risk
from 51 to 75	high risk
from 26 to 50	average risk
from 1 to 25	low risk

The analysis of critical and maximal risks shows that most of these risks arise in the process of storing and ordering the product. The risks associated with the acceptance and sale of goods are present among the critical and significant risks, but in a smaller number. This result is explain by the inevitable occurrence of material liability because of the appearance of inappropriate goods.

Controlling organizations pay close attention to the storage of pharmacy goods, and its violation leads to the imposition of a significant fine. The quality of information and consulting support and the product acceptance process are not evaluate by regulatory organizations, but they are important for the reputation of the pharmacy among pharmaceutical service consumers and suppliers.

Conclusions. Risks in the processes of acceptance and storage of goods are most significant. Reducing the risks of the basic processes of pharmaceutical activity will avoid economic losses and losses for the reputation of the pharmacy organization. Increasing the responsibility and competence of pharmaceutical staff, standardizing and controlling the processes of pharmaceutical activity is a priority task in terms of reducing risks.

QUALIFICATION OF ANALYTICAL EQUIPMENT IN THE SYSTEM OF QUALITY MANAGEMENT OF THE ENTERPRISE

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Introduction. Qualification of equipment is a necessary prior step for validating analytical methods. Even if all servicing of equipment is carried out under a contract, it is the responsibility of the laboratory to monitor the condition of the equipment (especially during routine analysis).

Qualification of laboratory equipment is a necessary procedure for any research center. GMP (Good Manufacturing Practice or Good Manufacturing Practice) and GLP (Good Laboratory Practice or Good Laboratory Practice) rules determine the quality control of testing for pharmaceutical companies. During the qualification procedure, the greatest attention is paid to the equipment configuration, since standard equipment is often supplemented with separate test and standardized samples. The quality and effectiveness of subsequent research depends on their compliance with the required indicator. In order to ensure a pharmaceutical quality system, it is important that not only equipment with calibration, but also the method of analysis must pass the qualification.

The process of qualification of analytical equipment in the laboratory is documented in accordance with the requirements of modern WHO documents (World Health Organization), PIC / S (the Pharmaceutical Inspection Co-operation Scheme, convention on cooperation of pharmaceutical inspections), FDA (Food and Drug Administration, Sanitary Inspectorate quality of food and medicine), ISO 17025 (General requirements for the competence of testing and calibration laboratories, General requirements for the competence of testing and calibration laboratories) of leading pharmacopoeias and regulatory documents Tami for specific pieces of equipment available in the laboratory of the enterprise.

Aim. The goal of our work is to develop a standard working methodology for the qualification process of analytical equipment "The order of work on qualification (DQ, Design Qualification, Project Qualification; IQ, Installation Qualification, Installation Qualification; OQ, Operational Qualification, Functional Qualification; PQ, Performance Qualification, Performance Qualification or Performance Qualification)."

Materials and methods. As materials of research and development used the regulatory documentation mentioned above.

As above, the regulatory documentation mentioned above.

The main requirement for all equipment used in specific laboratories is compliance with its intended use. Therefore, the internal qualification process of the equipment must establish that the working specification (what the manufacturer claims) is suitable for the intended application and that the equipment operates in accordance with this specification. The ISO 17025 standard describes in detail the requirements that a laboratory must meet to guarantee its competence from a technical point of view and the ability to produce reliable results.

Results and discussion. In the process of creating a standard working methodology, we considered and identified those responsible for carrying out and the scope of work on qualification, eligibility criteria, thought out experimental studies and tests, determined the type and method of

recording the assessment of the results obtained as a set of documentation on the qualification of analytical laboratory equipment (file for each unit equipment).

We established a step-by-step procedure for qualification work, to confirm that the equipment or system is working properly and gives the expected results, in accordance with the requirements of the current GMP rules.

Have described each stage of qualification, which is carried out in four successive stages:

Project Qualification (DQ, Design Qualification)

Installation Qualification (IQ)

Functional Qualification (OQ, Operational Qualification)

Performance or Performance Qualification (PQ, Performance Qualification).

The set of tests for qualification varies depending on the task in each particular case when choosing the object of qualification.

Conclusion. The development of a standard working procedure for qualifying analytical equipment used for analyzing drugs, and applying it to the overall pharmaceutical quality system allowed us to conduct qualification of all performance characteristics (PQ) and some procedures for qualifying functioning (OQ) throughout the life cycle.

Allowed us to confirm the fact that the equipment works correctly when performing routine analyzes.

Thus, we confirm that our equipment is and is constantly maintained in a state of maintenance and calibration that is appropriate for its intended use.

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

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Introduction. The role of the analytical laboratories at the state medicines quality assurance system is extremely important in view of the importance of the test results to make a decision about the possibility of medicines use.

This predetermines the considerable responsibility of the laboratories and assumes the existence of an effective quality system focused on the accuracy and reliability of the test results.

For the harmonization and standardization of requirements for laboratories at the international level, WHO has developed a «Good Practices for Pharmaceutical Quality Control Laboratories» (WHO Technical Report Series, No. 957, 2010, GPCL). These recommendations are used as the basis of their national rules by many countries of the world to confirm the reliability and accuracy of test results.

These guidelines provide advice on the quality management system within which the analysis of active pharmaceutical ingredients (APIs), excipients and pharmaceutical products should be performed to demonstrate that reliable results are obtained.

These guidelines are applicable to any pharmaceutical quality control laboratory, be it national, commercial or nongovernmental. However, they do not include guidance for those laboratories involved in the testing of biological products, e.g. vaccines and blood products. Separate guidance for such laboratories is available.

These guidelines are consistent with the requirements of the WHO guidelines for good manufacturing practices and with the requirements of the International Standard ISO/IEC 17025.

Compliance with the recommendations provided in these guidelines will help promote international harmonization of laboratory practices and will facilitate cooperation among laboratories and mutual recognition of results. Special attention should be given to ensure the correct and efficient functioning of the laboratory. Planning and future budgets should ensure that the necessary resources are available inter alia for the maintenance of the laboratory, as well as for an appropriate infrastructure and

energy supply. Means and procedures should be in place (in case of possible supply problems) to ensure that the laboratory can continue its activities.

The GPCL Guide contains requirements for all critical aspects of laboratory activities, for example:

- qualification of equipment and validation of analytical procedures,
- risk analysis for measurement quality,
- quality management system (QMS),
- staff competency etc.

The main risk factors for the quality of laboratory measurement results are: personnel, premises, equipment, instruments and other devices, materials, reagents, reference substances and reference materials, calibration, verification of performance and qualification of equipment, instruments and other devices, working procedures, incoming samples, analytical worksheet, validation of analytical procedures, testing, evaluation of test results, certificate of analysis, retained samples and some other.

All these risks need to be systematically identified, assessed and eliminated or minimized with the help of an effective quality system.

The quality management system is aimed not only at ensuring the stable functioning of all processes, but also at continuous improvement due to the systematic analysis and improvement of processes affecting the quality of testing. The QMS should cover planning, risk assessment, auditing, corrective and preventive actions, etc. The QMS is aimed not only at ensuring the stable functioning of all processes, but also at continuous improvement by systematic analysis and improvement of processes that affect on tests. The QMS should cover planning, risk assessment, auditing, corrective and preventive actions (CAPA), etc.

Aim: Development of a set of proposals for the formation of QMS at the domestic laboratories for medicines quality control.

Materials and methods. To carry out our research, we carried out studies on the provisions of GPCL, ISO 9001 and ISO 17025 as part of an overall management system based on the quality risk analysis approach needed to create, implement, operate, monitor, review, maintain and improve of QMS.

Results and discussion. In our work the general algorithm implementation of the system was proposed and developed some sample documents: Quality manual; some standard operating procedures; forms of required entries. We also formulated proposals for the compilation of the basic documentation of the laboratory QMS, proposed are standard job descriptions of personnel involved in the functioning of the laboratory's quality system, and corresponding documented procedures.

Conclusions. Expected changes in the implementation of QMS: operational regulation of activity (system flexibility); minimizing losses of time and resources; improving team discipline; reducing the number of errors and inconsistencies at all levels of the laboratory; improvement of the workflow system; clearer distribution of responsibility; increase employee motivation etc.

DETERMINATION OF RISKS OF PROCESSES OF THE QUALITY SYSTEM OF DISTRIBUTOR OF MEDICINAL PRODUCTS

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Introduction. A pharmaceutical distributor must have a fully developed and properly functioning pharmaceutical quality system, including good manufacturing practices and risk management for quality. This system must be fully documented, and its effectiveness is controlled.

Risk management for the quality of medicinal products is an activity that can not be just a formal fulfillment of the Licensing Terms. It is an integral and very important component of the pharmaceutical quality system. Quality risk management is a systematic process for the overall assessment, control, reporting and review of risks to the quality of the medicinal product during its life cycle.

The ICH Q9 provides guidance on a systematic approach to risk management for quality that facilitates the implementation of the principles and rules of GDP.

In this part of the article, we have focused on the practical implementation of risk management at the distributors of pharmaceutical products.

Aim. To demonstrate, by example, a disturbance of the temperature regime in the premises of the distributor of medicines, the risk analysis by bow tie methods.

Materials and methods. Was used regulatory documents, ISO specialized standards, ICH regulations and other sources of information. The comparative method of analysis the method of structural-logical modeling, the expert method was applied in the study.

Results and discussions. The method of risk assessment – "bow tie" (Bow tie) is a schematic way of describing and analyzing the development path of a dangerous event (temperature disturbance) from causes to consequences. This method combines the investigation of the causes of an event using the fault tree (before the accident) and the analysis of the consequences using the event tree (after the accident). However, the focus of the bow tie method is on the barriers between causes (control measures) and dangerous events and dangerous events and consequences (liquidation measures).

Bowtie diagrams can be constructed on the basis of identified faults and event trees, but more often they are built directly during the brainstorming process.

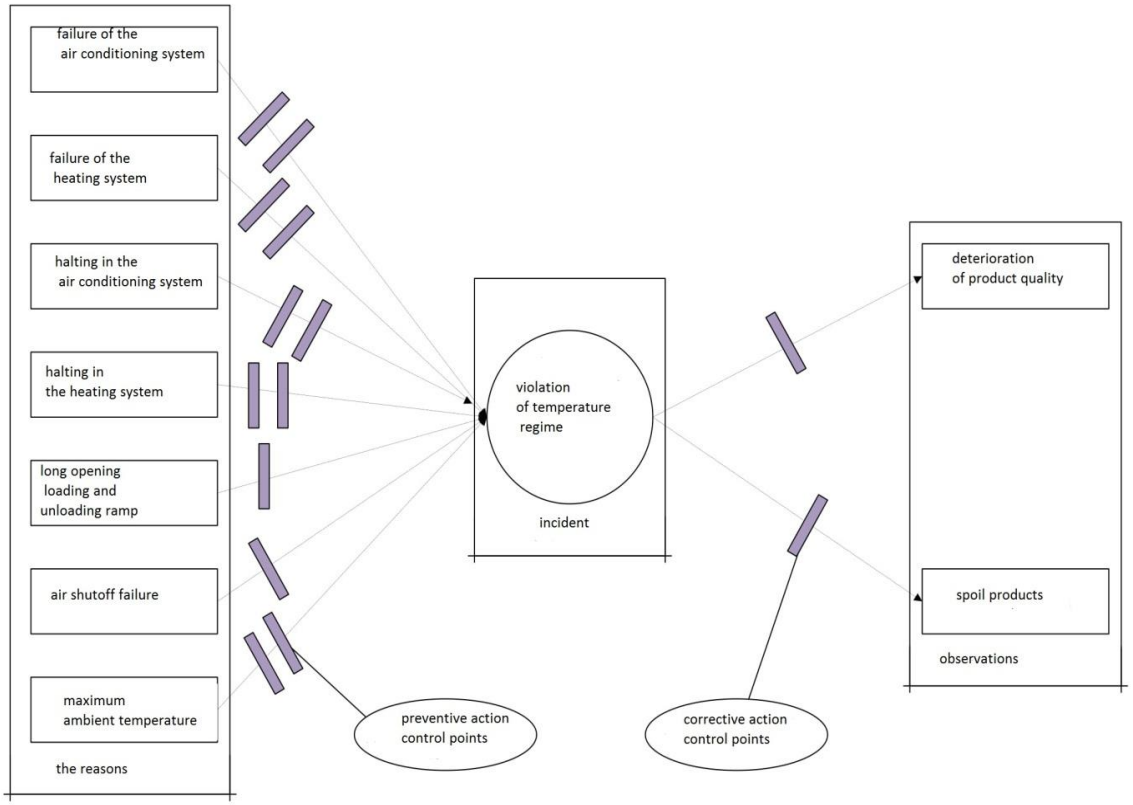

Figure 1 shows the result of the risk analysis of the Bowtie method.

The method of risk assessment based on a bowtie analysis was used to study risk based on the demonstration of a range of possible causes (system failure) and the consequences (damage, reduced product quality). The method was applied in a situation where it is difficult to conduct a complete analysis of the fault tree or when research is more focused on creating barriers or controls for each path of failure.

The focus of the bowtie method is on the barriers between causes (control measures) and dangerous events and dangerous events and consequences (liquidation measures).

Conclusions. We applied the analysis of the "bowtie" diagram to display the risk, indicating a number of possible causes and consequences. Applying this analysis is advisable in the case when there are clear independent ways of development of events leading to failure.

An analysis of the "bow tie" diagram is simpler to understand than the "fault tree" and the "tree" of events, and therefore its use may be appropriate as a means of information interaction in cases where the analysis is carried out using more complex techniques.

PROBLEMS RELATED TO QUALITY ANALYSIS OF HONEY

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Introduction. At present, EU Directive 74/409 of 20 December 2001 has given definition of honey as a 100% bee product, from which nothing needs to be deleted and nothing has to be added. The EU legislation, like the domestic honey standard, is based on the following:

- Pollen study;
- Physical-chemical studies (moisture measurement, Hydroxymethylfurfural, diastases etc.);
- Chromatographical analysis of sugars.

Of these, the first two paragraphs are considered obsolete because of the emergence of new ways of honey falsification, which are difficult to prove. For example, pollen analysis makes it possible to determine not only the naturality of honey, but also its geographical and botanical origin.

However, large processing companies often filter honey using ultrafiltration technology to keep the product in a non-crystalline state for long periods of time. Thus, along with honey, devoid of pollen, and therefore unsuitable for pollen analysis, the market also gets cheap fake honey under the guise of natural.

Aim. Identification of problems related to the analysis of honey quality.

Materials and methods. Often falsifiers add to honey high-fructose corn syrup, close in the sugar content to natural honey. Detection of this type of falsification is based on the complex method of mass spectrometry measurement of the ratio of Carbon $^{13}C/^{12}C$ isotopes. Natural honey has a certain ratio of $^{13}C/^{12}C$, because bees chose as a source of nectar plants with C-3 type of photosynthetic fixation.

Corn, sorghum and sugar cane belong to plants with C-4 type of photosynthetic fixation and therefore have an increased content of the 13C isotope, and consequently, the negative value of the $^{13}C/^{12}C$ ratio. For natural honey it is about -25 ‰, for sugar cane about -11 ‰, for corn a little less – 20 ‰. Detecting beet sugar by this method does not seem possible, because beet belongs to plants of type C-3 and has a ratio of $^{13}C/^{12}C$ at the level -25,5 ‰.

Also, this technique is not suitable for detecting the falsification of honey by products of other plants of type C-3, such as: rice, wheat, barley, rye, potatoes, soybeans. In this case, determine the difference between the content of 13C in honey and its protein fraction. If the deviation of the value in honey to the direction of a C-3 plant is obtained, then the forging of honey can be concluded.

Results and discussion. However, the improvement of honey falsification methods inevitably leads to improved methods of counterfeit detection. For example, in 2002, AV Aganin has developed a method of honey biotesting, which allows simultaneously controlling the freshness, the presence of fermentation, heat damage to honey and falsification. The method is based on the fact that yeast, which is always contained in natural honey, is very sensitive to heating. Instantaneous heating of honey to 70° C followed by rapid cooling completely inactivates yeast, without significantly reducing diastase activity.

To study the sample, the solution of the honey is centrifuged, centrifugate is separated, micropreparation, colored with methylene blue is prepared, and examined under a microscope at 600x magnification. Living yeast cells are poorly colored or not colored at all, dead ones – colored blue.

The results are analyzed as follows: if in the preparation dominate small (0.1-0.2 microns) uncoloured or slightly coloured yeast cells with barely noticeable shell – the honey is fresh and it was not heated; a large

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

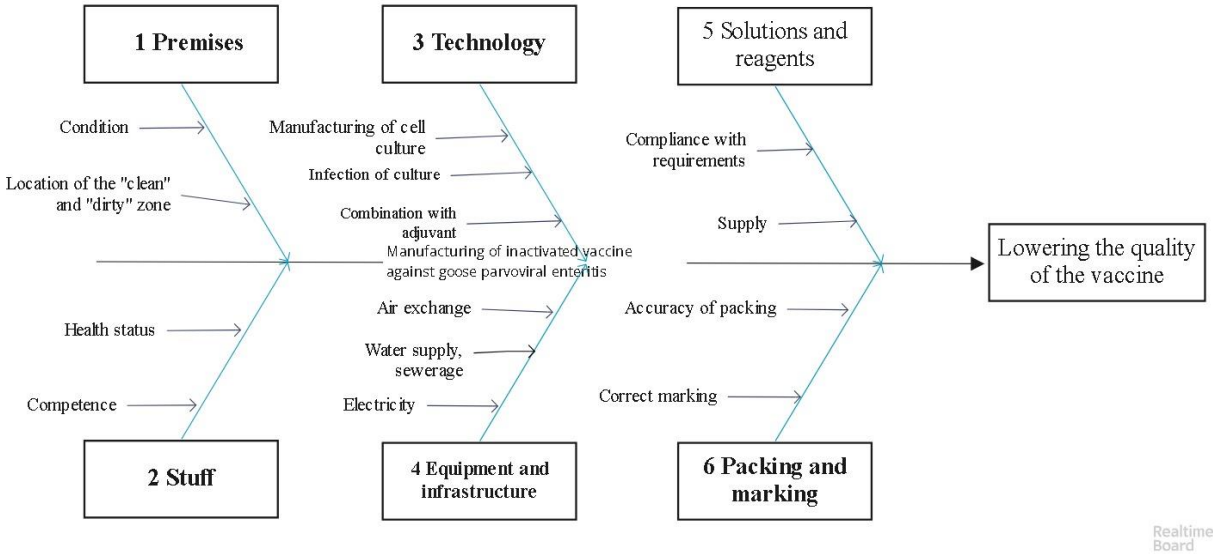

Figure 1. Ishikawa Diagram.

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

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

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

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

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

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

THE QUALIFICATION PROCESS ON THE EXAMPLE OF THE SECONDARY PACKAGING WAREHOUSE

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

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

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

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

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

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

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

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

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

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

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

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