



QUALITY MANAGEMENT SYSTEM OF A PHARMACEUTICAL ORGANIZATION: CRITERIA AND IMPLEMENTATION

Alexandra A. Klimenkova¹, Lev N. Geller¹, Anna A. Skripko¹, Liliana A. Gravchenko¹, Natalia V. Fedorenko²

¹ Irkutsk State Medical University

1, Krasnoye Vosstaniye St., Irkutsk, Russian Federation 664003

² LLC "Pharmacy-Alex"

7a, Microrayon 29, Angarsk, Russian Federation, 665808

E-mail: anna_kulakova@mail.ru

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The aim of the study is a theoretical justification and development of a mechanism for the implementation of quality management systems (QMS) in the activities of retail trade in pharmaceutical products.

Materials and methods. The study is based on the analysis of scientific literature data and Analytical Normative Documents regulating various aspects of QMS functioning in pharmaceutical organizations. Methods of documentary content analysis of international and national ISO standards, Series 9000, were used as the basis for the development and implementation of QMS organizations despite the type of their activities.

Results. In the course of the study, the organization of the production process has been studied and the main production (business-) operations of seven structural subdivisions of "Apteka-Alex" LLC in Angarsk have been analyzed. The basic principles of QMS functioning are set forth and the author's methodology for its development for retail trade in pharmaceutical products has been presented, taking into account the specifics of the organizational structure and production activities of pharmacy organizations. The mechanisms and successive stages of the QMS implementation have been specified and given grounds for. In accordance with the requirements of GOST R ISO 9000:2015, the definitions and classification of the main production operations (business processes) of the studied pharmacies have been made up. In addition, the list of mandatory (core) and basic standard operating procedures (SOPs), detailing the main production (business-) processes, has been made up, and an algorithm for developing and testing SOPs has been outlined.

Conclusion. The results of the study allowed us to justify and propose a step-by-step methods of QMS implementation into the work of pharmaceutical organizations in the retail sector. The first results of the approbation and use of the developed methodology show that it contributes to the rational construction and functioning of the QMS, in accordance with the requirements of the existing standards, as well as the optimization of administrative management of all production (business-) processes.

Keywords: quality management system, standard operating procedure, pharmaceutical services, pharmacy organization, the subject of retail trade in pharmaceutical products

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СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА ФАРМАЦЕВТИЧЕСКОЙ ОРГАНИЗАЦИИ: КРИТЕРИИ И РЕАЛИЗАЦИЯ

А.А. Клименкова¹, Л.Н. Геллер¹, А.А. Скрипко¹, Л.А. Гравченко¹, Н.В. Федоренко²

¹ Федеральное государственное бюджетное образовательное учреждение высшего образования Иркутский государственный медицинский университет Министерства здравоохранения Российской Федерации

664003, Российская Федерация, г. Иркутск, ул. Красного Восстания, 1

² ООО «Аптека-Алекс»

665808, Российская Федерация, г. Ангарск, 29 микрорайон, д. 7а

E-mail: anna_kulakova@mail.ru

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Цель. Целью исследования послужило теоретическое обоснование и разработка механизма внедрения систем менеджмента качества (СМК) в деятельности субъектов розничной торговли фармацевтическими товарами.

Материалы и методы. Исследование проведено на основе данных анализа научной литературы и нормативных документов, регламентирующих различные аспекты функционирования СМК в фармацевтических организациях. При проведении исследования применялись методы документального контент-анализа международных и национальных стандартов ISO серии 9000, положенных в основу разработки и внедрения СМК организаций независимо от вида осуществляемой деятельности.

Результаты. В ходе исследования изучена организация производственного процесса и проанализированы основные производственные (бизнес-) операции семи структурных подразделений ООО «Аптека-Алекс» г. Ангарска. Изложены основные принципы функционирования СМК и представлена авторская методика ее разработки для субъектов розничной торговли фармацевтическими товарами с учетом специфики организационной структуры и производственной деятельности аптечных организаций. Обоснованы и конкретизированы механизмы и последовательные этапы внедрения СМК. В соответствии с требованиями ГОСТ Р ИСО 9000:2015, дано определение и осуществлена классификация основных производственных операций (бизнес-процессов) исследуемых аптек. Кроме того, сформулирован перечень обязательных (основных) и базовых стандартных операционных процедур (СОП), детализирующих основные производственные (бизнес) процессы, изложен алгоритм разработки и апробации СОП.

Заключение. Результаты проведенного исследования позволили обосновать и предложить поэтапную методику внедрения СМК в работу фармацевтических организаций розничного звена. Первые итоги апробации и использования разработанной методики свидетельствуют о том, что она способствует рациональному построению и функционированию СМК, в соответствии с требованиями действующих стандартов, а также оптимизации административного управления всеми производственными (бизнес-) процессами.

Ключевые слова: система менеджмента качества, стандартная операционная процедура, фармацевтические услуги, аптечная организация, субъект розничной торговли фармацевтическими товарами

INTRODUCTION

Protection of the quality of pharmaceutical products in the process of circulation is aimed at ensuring pharmacological, environmental, technological kinds of safety, as well as the rational use of resources to preserve and promote public health [1]. Implementation of tasks of this level requires new conceptual approaches to quality management and it is possible only if there is a quality management system (QMS). It should be based on consistent keeping to and compliance with the requirements of good practices, which should function reliably at the level of all participants in the system of commodity circulation in the pharmaceutical market. It should be noted that the QMS serves as a basic mechanism to ensure strict compliance of the activities of medical and pharmaceutical organizations in the format

of the requirements of existing standards and regulations. In addition, the introduction of the QMS is aimed at achieving a proper level of quality of pharmaceutical services provided and serves as a guarantor of their further improvement [2–5]. In modern conditions, traditional approaches to meeting the needs of consumers are changing dramatically. Forming the loyalty of visitors and customers to the pharmacy organization occurs not only on the basis of improving the quality of products and services provided, but also due to the continuous improvement of production activities of the organization as a whole [6]. Since the QMS is a set of interaction subsystems of management of all aspects of the organization, in full compliance with the requirements of existing standards, the use of this system is aimed at continuous improvement of the quality of services provided, and

allows each organization to achieve its highest possible level [7]. Moreover, the presence of a successfully functioning QMS in an organization gives it certain marketing advantages and contributes to the formation of a positive reputation, attracting the maximum number of new customers and increasing competitiveness in a particular market segment [2, 8, 9]. Accordingly, the financial stability of the organization improves, and the loyalty of all related counterparties, including customers, employees, suppliers, etc, increases [8].

In this regard, the aim of the study was to justify and develop methods for the phased implementation of QMS in the work of pharmaceutical organizations at the retail level, taking into account the specifics of their organizational structure and production activities.

MATERIALS AND METHODS

The content analysis of the documentary contents of the international rules for ensuring quality, efficacy and safety of medicinal preparations (MP) and the concept of standardization has made it possible to establish that, at the current stage, the leading regulator of pharmaceutical care (PhC) quality is GxP standards of drug circulation [10]. In this case, the GxP standards act as a fundamental element of the quality assurance system. Globally, good practice guidelines have established requirements for ensuring the quality of drugs at all stages of the life cycle [11, 12]. This set of good practice rules is presented by good laboratory practices (GLPs), good clinical practices (GCPs), good manufacturing practices (GMPs), good distribution practices (GDPs), good pharmacy practices (GPhPs), good purchasing practices (GPPs). According to the basic concept of GxP and the concept of comprehensive study of Medicine remedies (MRs), the concept of the "quality" category which is formed at the stage of MRs development, is further confirmed during its registration and is monitored at all production stages. In the process of providing PhC, for further use of only effective and safe MRs, the achieved production level of quality must be maintained at all stages of the "life cycle" of products, including the processes of storage, distribution, transportation and use in the wholesale and retail trade entities [12, 13].

There is no doubt that the lack of adequate control can have a negative impact on the preservation and constancy of qualitative characteristics of MRs and cause poor-quality products to enter the civil turnover [14]. In this regard, the modern regulatory system of MRs quality assurance is based on strict compliance with the requirements and rules of good practices established for each stage of the product life cycle, by all participants of the scope of their circulation. Accordingly, a drug developer must comply with GLPs and GCPs rules, the

manufacturer – with GMPs rules, wholesale and retail organizations – with GDPs and GPPs standards [6].

Thus, comprehensive compliance with the requirements of the above-mentioned standards ensures the stability of the quality characteristics of pharmaceutical products, minimizes the penetration of substandard medicinal preparations and pharmacy products assortment (PhPA) into circulation, and contributes to providing pharmaceutical services (PhS) of the adequate quality, which generally corresponds to the main postulate of pharmaceutical products – meeting the needs of the population in the preservation and maintenance of their healths [15].

It should be noted that the quality assurance system of the Organization for Standardization (ISO) in the form of ISO, Series 9000, contributes to the achievement of the same aims as the GxP system, but it is more detailed. Currently, the following 4 basic national standards have been developed, approved on the basis of international ISO standards and are in force in Russia. They should be used in the construction and improvement of the QMS model:

GOST R ISO 9000: 2015 "Quality management systems. Basic Provisions and Dictionary", which establish uniform principles of terminology and basic provisions for the QMS;

GOST R ISO 9004:2010 "Management for sustainable success of the organization. The approach based on quality management", containing methodological materials to improve the already functioning QMS and the efficiency of the enterprise. In this standard, the QMS is considered in more details, taking into account the needs and expectations of all parties concerned;

GOST R ISO 19011-2012 "Guidelines for the audit of Quality Management Systems, Inc.", which describes the basic principles of the QMS audit procedure and contains guidelines for their implementation, which makes it possible to understand the essence of the audit procedures in more details, and identify opportunities for the improvement.

The study of the Quality Management methodology based on the requirements set forth in these standards, is an integral part of the knowledge in the field of management of the organization.

RESULTS

As it has already been noted before, the documentary content analysis showed that the reviewed GOSTs are completely identical to the corresponding International Standards ISO, Series 9000. It should be noted that although these standards do not regulate the quality of specific products, they can be successfully used by different organizations regardless of the nature and type of their activities. At the discretion of the administration,

such standards, adapted for a specific organization, can be used to build and improve the QMS in the pharmaceutical sector. Due to the changes in current legislation and approval of regulatory legal acts on rules of good pharmacy practices (GPhPs) and good practice of storage and transportation of medicinal preparations by the Ministry of Health of the Russian Federation, the problem of developing and implementing the QMS is very relevant for medical and pharmaceutical organizations of our country [16,17]. In accordance with the requirements of the listed above documents, each entity in the field of circulation of drugs and pharmacy products assortment (PhPA) should justify, develop and implement their own QMS at the organization level, as well as provide the necessary standard operating procedures (SOP) for the implementation of basic production (business-) processes. Such a quality system that ensures the efficiency and safety of pharmaceutical products is mandatory administratively regulated and maintained in operational mode through continuous analysis and timely introduction of appropriate adjustments to it in order to continually improve its performance. When developing a QMS, it is necessary to take into account that the determining components of this system are:

1. organizational structure (a clear definition of the tasks and functions of each unit of a retail entity and the delineation of the rights and duties of employees in accordance with the assigned mission);
2. processes affecting the quality of products sold and services provided, including basic, managerial, auxiliary processes;
3. standard operating procedures that allow typing and standardization of production (business-) processes directly related to the activities of the retail entity;
4. resources necessary for the implementation of the relevant production (business-) processes, including labor, information, material.

The absence of any of these links breaks the organization's QMS and makes it defective.

In the format of the study, standardization is interpreted as an activity of establishing relevant rules, parameters and characteristics for the purpose of their voluntary multiple use to achieve arrangement in the areas of production and circulation of pharmaceutical products and improvement of their competitiveness.

The aim of standardization in the field of drug circulation is to protect the quality of pharmaceutical products at all stages of their life cycle, including the processes of production, promotion, storage, use, and, if necessary, destruction [18]. At the same time, standardization is primarily aimed at ensuring the pharmacological, environmental, technological safety of products and rational use of resources.

In general, the introduction of the QMS in organizations of the pharmaceutical profile is aimed at preserving the stability of the quality parameters and characteristics of goods, as well as at improving the level of quality of public services provided to the population [6]. It should be noted that in modern conditions the improvement of the quality of pharmaceutical services (PhSs) is the main purpose of any pharmaceutical organization [19, 20].

Achieving this goal becomes possible not only with the rational construction and implementation of the QMS, but also maintaining it at the proper functional level. In turn, the list of pharmaceutical services provided by a particular pharmacy organization is formed in the context of the functions performed. In this regard, solving the issues of optimization of the quality of pharmaceutical services performance is possible through standardizing production (business-) processes directly related to the activities of a pharmaceutical retail entity, based on the development of corresponding SOPs [21, 22]. In accordance with the research plan, in 2016–2017, the labor organization was studied and the main production (business-) operations of 7 structural divisions of the pharmacy chain of LLC "Apteka Alex" in Angarsk were analyzed.

During the study, in full compliance with the requirements of GOST R ISO 9000:2015, the main production operations (business processes) of the studied pharmacies were identified and classified. In accordance with the methodology, all production operations (business processes), repeated cyclically during a shift at least 5 times, were assigned to the main ones.

While classifying and characterizing the main production business processes of pharmacies, the process was interpreted as a set of interrelated specialists' labor activities and labor operations. These activities transformed the **input** data of such processes into **output** ones [23].

At the next stage of the study using the methodology of the PDCA (Plan-Do-Check-Act: Planning – Action – Check – Adjustment) or the Deming Cycle, which is an algorithm for a sequence of administrative actions for the proper management of a specific production process to achieve this goal, we have chosen a process approach.

The application of the process approach involves determining the system of business processes performed in the organization and further work to improve them. In turn, the PDCA cycle can be reliably applied to all processes functioning in the organization and to the QMS of the organization as a whole.

The implementation of the Deming Cycle with the established periodicity allows all the processes to be

implemented to provide the necessary resources, manage them, and look for opportunities for continuous improvement [24–27]. In accordance with the PDCA

methodology, the process approach to the management of production activities of the organization includes a number of criteria and elements (Fig. 1).

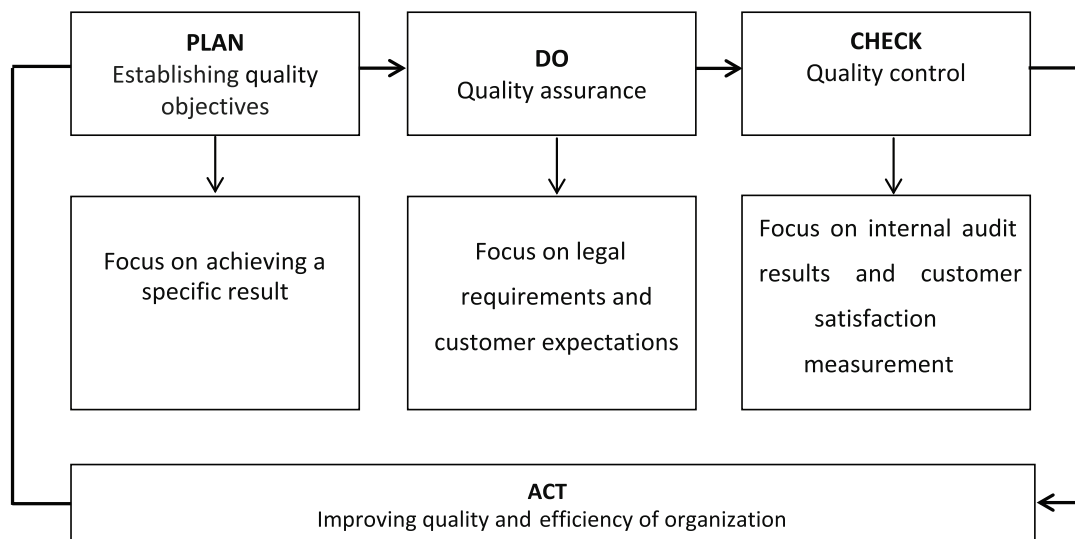


Figure 1 – Management of the pharmacy organization’s production activities from the perspective of the PDCA (process approach)

In accordance with the proposed concept for the proper management of the retail entity, first of all, it is necessary to rationally manage the relevant production (business-) processes and take into account their possible interaction and impact on the work of the entity. As a result, thanks to the process approach, it is possible not only to build an optimally functioning QMS, but also to improve the efficiency of effective management of the organization.

At the final stage, using the results of the study and the data of comparative and critical analysis of ISO, Series 9000, from the standpoint of the process approach, an algorithm has been scientifically justified and proposed for the implementation of the QMS in the work of pharmaceutical organizations at the retail level. The algorithm of this technique, which includes purposeful, systematic and continuous sequential interaction of labor cyclically repeated operations of six levels, is presented in Fig. 2.

DISCUSSION

In accordance with the presented algorithm, the construction and functioning of the QMS in pharmaceutical organizations at the retail level can be considered in the form of repetitive labor (production) operations of the following 6 levels:

Labor Operations of Level I comprise awareness and establishing objectives of QMS. by the administration. As a rule, the objectives of the QMS are consistent with the objectives of the organization and are aimed at maximum satisfaction of the requirements and expectations of consumers. In this case, the objectives of the QMS are reflected in the document “Quality Policy of the Organization”. The administration should foresee and plan the processes required to deliver the desired results. It is necessary to carry out continuous work to optimize functioning of the QMS to achieve the planned results.

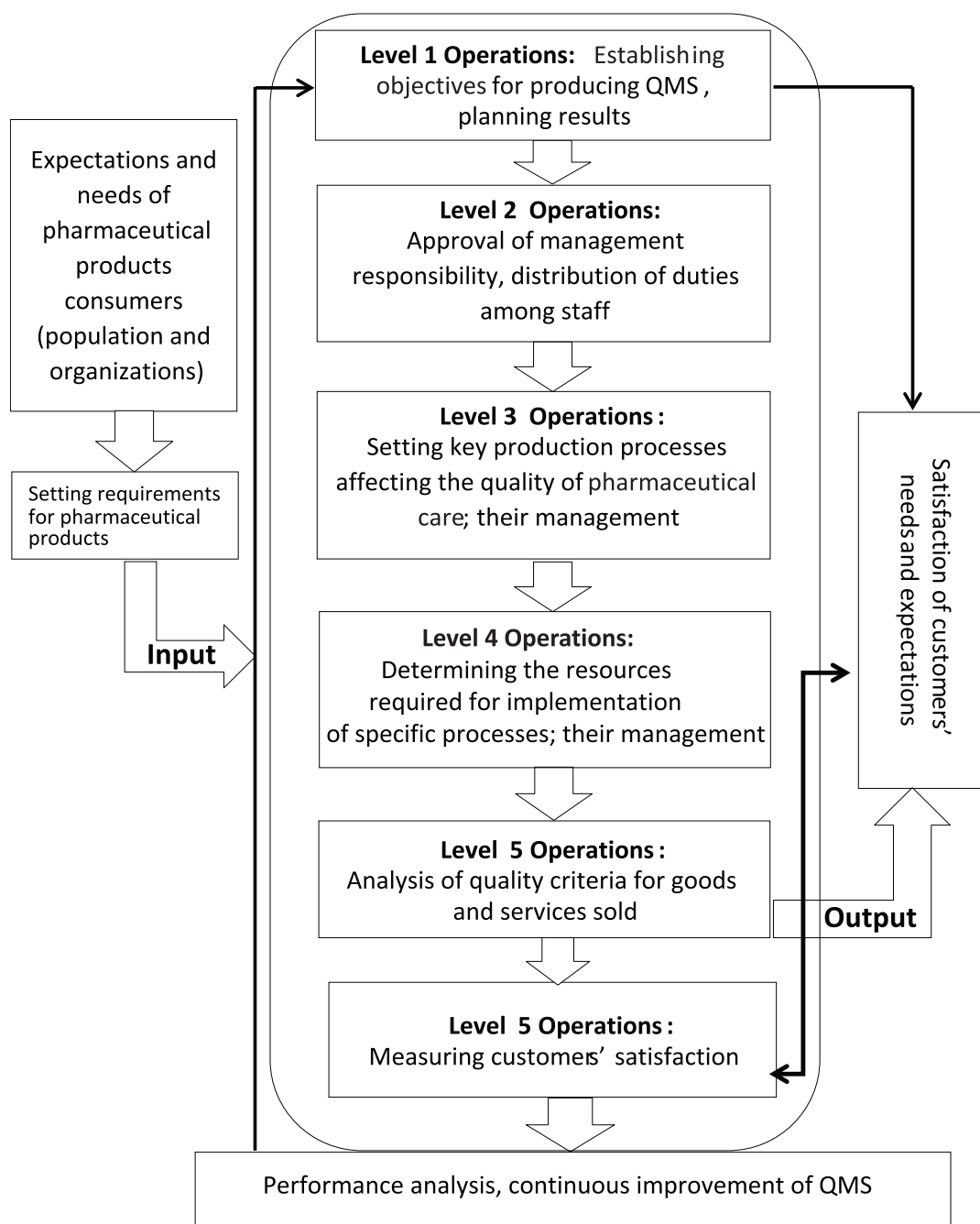


Figure 2 – Algorithm of QMS implementation methods in pharmaceutical organizations at retail level

Labor Operations of Level 2 comprise justification and establishing of management responsibility, distribution of duties. The administration should distribute all kinds of responsibility among the staff, determine the complex of their obligations, take an active part in developing and maintaining the QMS, demonstrate their leadership and commitment to the QMS, take responsibility for the effectiveness, ensure the availability of the necessary resources and promote understanding of the importance of working in the QMS among the staff.

Labor Operations of Level 3 comprise justification and setting key production processes that have a significant impact on the quality of the pharmaceutical care

provided, and their management (including the step-by-step sequence of these processes, their interrelation, setting objectives of the processes, their sources and performers, the distribution of responsibility among the staff, description and documentation of the processes, the establishment of checkpoints and criteria, assessment of the possibility of the QMS implementation in real conditions). Basing on the production specifics, any pharmaceutical retail entity has the right to determine the number and contents of such processes. First, these include the processes focusing on the purchase, acceptance, storage of products and bringing them to the consumer.

Labor Operations of Level 4 comprise identification of resources required for the implementation of specific processes and functioning of the QMS as a whole, the establishment of requirements for them and maintenance in working (good) condition. Among the resources necessary to perform such procedures, the following resources should be highlighted:

labor resources – a set of employees of a retail entity. The level of staff training is determined by a set of specific requirements for them, for example, the availability of the necessary qualifications, work experience, timeliness of instruction pass, etc.;

material resources and infrastructure – the criteria necessary for a proper organization and equipping workplaces (zones) where the labor process is directly implemented (for example, equipment, technical and auxiliary aids, documentation);

information resources – a set of data on electronic and paper media necessary for the execution of the relevant processes (information systems, software, tools, allowing to obtain reference information).

Labor Operations of Level 5 comprise the analysis of product quality criteria by the administration in order to provide the parties concerned with pharmaceutical services of the adequate quality and meeting their expectations and needs. Since monitoring is one of the most important management functions and an integral part of the QMS, the analysis of the quality of pharmaceutical products and the assessment of the correct functioning of the production (business-) processes of an organization are achieved by conducting an internal audit aimed at identifying discrepancies between the current work of the organization and current regulatory requirements [28].

Labor Operations of Level 6 are measurements of customers' satisfaction. Organizations monitor and analyze the data on the requirements of the parties concerned and the extent to which their needs and expectations are satisfied (for example, consumer surveys, consumer reviews, meetings with consumers, segmentation and analysis of the pharmaceutical market share, availability of acknowledgments, analysis of claims, etc.).

Analyzing and evaluating the information obtained in the course of continuous monitoring and guided by the degree of customers' satisfaction, the administration of the organization is able to objectively and timely assess the effectiveness of the QMS of the organization, to identify existing shortcomings and weak points in the work, continuously working on further optimization of the QMS and its improvement.

Thus, a properly formed QMS allows to quickly and efficiently manage all production (business-) processes of the organization administratively at the institutional level, making decisions aimed at improving the quality of the provided pharmaceutical services.

A mandatory condition for successful implementation of the quality management system is the formation

of a block of documents ensuring and accompanying functioning of the entire QMS of the organization [28]. The basis for the creation of the necessary document flow of the QMS can serve the previous documents of this retail entity, modified in accordance with the requirements of the existing standards and supplemented in the process of development and implementation of the QMS. Therefore, the organization's QMS documentation is constantly updated, improved and supplemented. The level of elaboration and quality of the documentary block largely determine the effectiveness of the QMS of the organization as a whole [29].

One of the fundamental principles of the formation of the QMS documentary block, is the development of standard operating procedures (SOPs), which are a formal algorithm of labor step by step actions of employees (a set of written instructions), the subject of retail trade to perform the relevant production (business-) process.

According to QMS requirements, all production (business-) processes of a pharmaceutical organization that affect the quality, efficiency and safety of medicinal preparations and other pharmacy products assortment must be carried out in strict accordance with the SOPs. It should be noted that the SOPs contain a strictly regulated and documented set of labor operations for the implementation of the relevant production (business-) process, which allows to establish what and in what sequence is implemented, where, when, how and by whom specific labor operations or functions are performed.

Since SOPs are a description of specific actions for the implementation of existing legal and regulatory settings in a particular pharmacy organization, their use allows to unify the entire production (business-) process, clearly define the duties and responsibilities of employees, ensure the sequence of their step-by-step actions, successfully train and evaluate employees' knowledge, reduce the number of their mistakes, eliminate duplicate and unnecessary operations and functions [26].

Development and compilation of SOPs are implemented through preliminary study, timing, documentation and description of the necessary production (business-) process. As a rule, the development of SOPs is carried out by key production (business-) processes, necessarily included in the QMS of the retail entity and subject to control. Basing on production specifics, each retail entity independently determines the number and composition of such production (business-) processes. All concretely established and fixed production (business-) processes are justified and studied.

For each process of this kind, an objective and the following data are established: the availability of the required resources, criteria for control check-points (taking into account the requirements of current legislation), the boundaries of personnel responsibilities and duties, and the procedure for acting in case of impossible performance of labor operations in the SOP format.

In order to assess the acceptability of the requirements developed by the SOP and the compliance of the procedure with the performed labor operations, it is advisable to conduct training of employees on the rules of working with SOPs before their approval. As a result, based on the results of the training conducted (analysis and study of staff SOPs), appropriate adjustments to the SOPs are made aimed at optimizing production (business-) processes.

SOP testing is carried out after the development of their primary version (draft documents), the study and analysis of the submitted documents by all employees involved in the production process. Work on the practi-

cal application of SOP is carried out with each employee involved in the implementation of this operation.

In the process of SOP testing, the availability analysis is carried out to understand the requirements of the SOP by all employees, the detection of unrecorded elements during the production (business-) process, the validity of the practical application of the developed document. After SOP testing, employee training and making the necessary adjustments, the head of the retail entity approves the updated SOP.

Algorithm of development and SOP implementation in the practical activity of the retail trade subject is shown in Fig. 3.

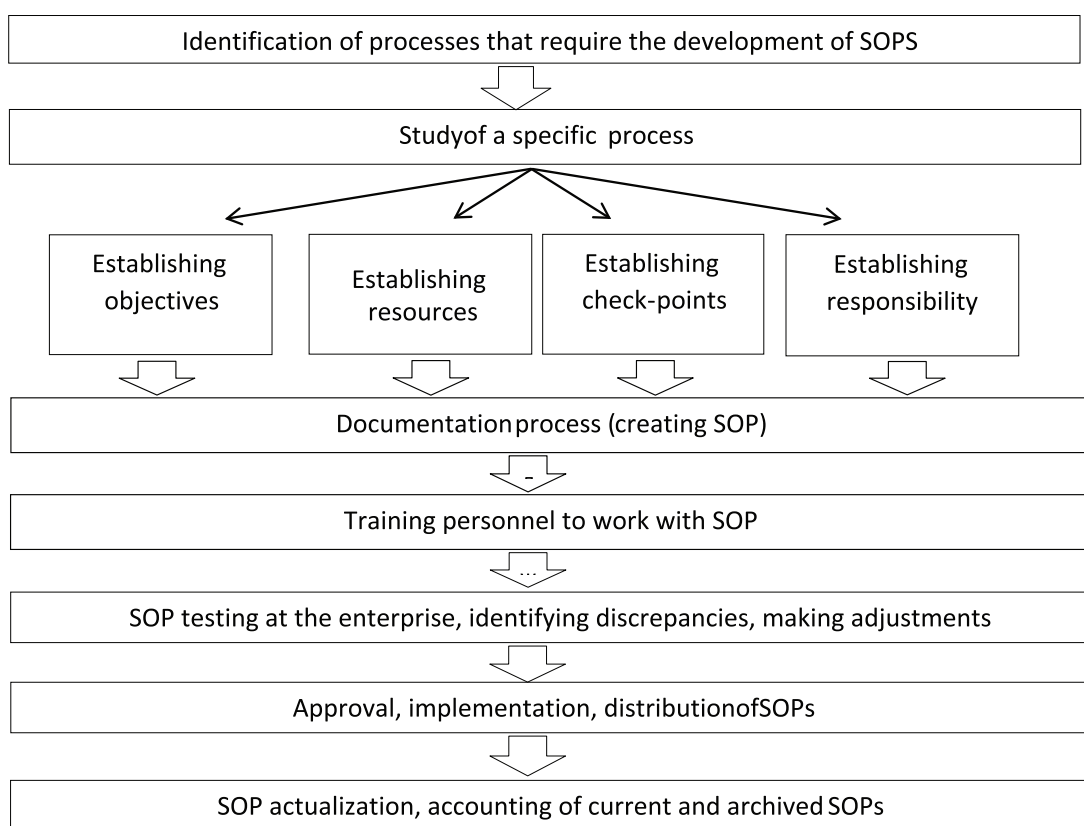


Figure 3 – Algorithm for development and implementation of a standard operating procedure in a retail entity

Since the legal acts do not regulate the requirements for a number of SOPs for each pharmacy organization, the management of the retail entity has the right to independently determine the acceptable number of production (business-) processes and describe them. However, the developed and described SOPs should cover the implementation of all necessary production (business-) processes affecting the quality of medicinal preparations and pharmacy products assortment in a particular pharmacy organization. Therefore, this block of basic production (business-) processes should be carried out in strict accordance with the approved SOPs, containing a description of specific labor actions of personnel for the implementation of existing regulatory and legal requirements in a specific pharmacy organization.

At the discretion of the management of the subject of retail trade, taking into account specifics in the specified basic production (business-) processes, additional sections of production activity which SOP and working instructions can be developed on in the same way, can be provided and allocated.

CONCLUSION

Thus, using the process approach, the results of the study made it possible to justify and propose a methodology for the justification and construction of the quality management system of the organization, as well as an algorithm for the development and implementation of SOP in the work of pharmaceutical organizations of the retail level.

The final results of approbation of the proposed methods and algorithms in the pharmacy chain of "Apteka-Alex" LLC indicate that their use is not only aimed at the rational construction and operation of the organization's QMS in accordance with the re-

quirements of the current regulatory framework, but also contributes to the optimization of administrative management of all production (business-) processes of the pharmaceutical organization of the retail level.

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AUTHORS

Alexandra A. Klimenkova – Assistant of the Department of Management and Economics of Pharmacy, Irkutsk State Medical University, Ministry of Health of Russia. E-mail: al.mas@bk.ru

Lev N. Geller – Doctor of Sciences (Pharmacy), Professor, Professor at the Department of Management and Economics of Pharmacy at Irkutsk State Medical University, Ministry of Health of Russia. E-mail: levng@mail.ru

Anna A. Skripko – Candidate of Sciences (Pharmacy), Associate Professor, Head of the Department of

Management and Economics of Pharmacy, Irkutsk State Medical University, Ministry of Health of Russia. E-mail: anna_kulakova@mail.ru

Liliana A. Gravchenko – Candidate of Sciences (Pharmacy), Associate Professor of the Department of Management and Economics of Pharmacy, Irkutsk State Medical University, Ministry of Health of Russia. E-mail: l.l.gravchenko@ismu.baikal.ru

Natalia V. Fedorenko – Director of Apteka-Alex LLC. E-mail: fedorenkoval@mail.ru