Journal of Biomedical Sciences | ISSN: 2960-9356
Research Article Peer-review, Open Access

Quality Management System in Pharmacy

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Abstract: A systematic system of rules, procedures, and activities known as a pharmaceutical quality management system (QMS) guarantees that pharmaceutical goods continuously satisfy quality standards and legal requirements from creation through production and distribution. It includes all actions taken to ensure the quality, safety, and effectiveness of the product, such as quality control, quality assurance, risk management, and documentation. These actions are frequently in line with current Good Manufacturing Practices (cGMP) and ICH Q1. A Quality Management System (QMS) is a structured framework of processes, roles, and resources meant to ensure customer and regulatory compliance, as well as consistent quality and services across multiple industries. A pharmaceutical quality management system (QMS) is an organized collection of recorded procedures, roles and assets that guarantee the reliable manufacturing and management of pharmaceutical goods. Requirements like ISO 9001, FDA 21 CFR Parts 210 and 211, ICH Q10, EU GMP, and PIC/S GMP govern pharmaceutical QMS. An electronic Quality Management System (eQMS) can be used by pharmaceutical companies to improve traceability, expedite QMS procedures, and guarantee compliance with relevant regulations. Simpler QMS is a cloud-based, verified eQMS for the pharmaceutical business that centralizes document control, streamlines CAPA, training, audit management, and other critical procedures, and simplifies compliance with ISO 9001, FDA 21 CFR Parts 210 and 211, ICH Q10, EU GMP, and PIC/S GMP.

Keywords: Pharmaceutical quality, management system, cGMP, ICH Q1, pharmacy, multiple industries

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Introduction. The issues of regulating the harmaceutical market through the introduction of rinciles of comliance with the requirements of relevant necessary ractices are urgent [29, 21]. The urose of harmacy ractice is to rovide the oulation with quality medicines and medical devices, and to rovide a source of

imortant information on the consumtion and use of medicines [26, 28, 38]. The Law of the Reublic of Uzbekistan “On Medicinal roducts and harmaceutical Activities” stiulates that a harmacy may be organized as a legal entity that retails medicinal roducts and medical devices [1]. Branches of harmacies, harmacies of medical and reventive institutions are also included in the category of harmacies [8]. Harmacies are required to sell sanitary and hygienic items, medicinal nutritional roducts, mineral waters, as well as medical and cosmetic roducts, biologically active additives, rovided that they have the aroriate documents for their use and sale (in articular, excet for ohthalmological roducts) [2, 3, 4, 8, 9, 144, 145]. Also, in order to rovide the oulation with more effective medical roducts and medicines, to imrove their quality, safety and effectiveness, the government has established a resonsible body at the state level, which is tasked with organizing state control over the rovision of the oulation with harmless harmaceutical roducts [5, 30, 96 ; 38, 375]. At the same time, the “Good harmacy ractice” (G) standard was introduced as art of additional measures to introduce quality management systems in harmacies that comly with international standards [11, 33, 89; 37, 99]. The requirements of the “Good harmacy ractice” G national standard are the main element of the state regulation model in the field of circulation of medicines. The process of guaranteeing that pharmaceutical items are produced to a constant standard of quality is known as pharmaceutical quality management. This procedure entails putting in place a strong QMS, which makes use of software and tools for quality management. Implementing Good Manufacturing Practices, a set of rules that guarantee pharmaceutical goods are produced to a constant standard of quality, is another aspect of pharmaceutical quality control. For good reason, the pharmaceutical sector is among the most regulated in the world. Patients' health and well-being may be significantly impacted by the goods this industry produces and sells. To guarantee the safety and effectiveness of their products, the pharmaceutical sector needs a strong Quality Management System (QMS) [34, 94 ; 35, 12 ; 42, 38 ; 59, 60, 123, 412]. International exerience has shown that G is necessary for the imlementation of harmacy ractice, and certification of comliance with the national standard “Good harmacy ractice” was introduced in 1991 [13, 14, 17, 25, 24].By the end of the 20th century, the international scientific and exert community had moved to actively romote the concet of quality management at each stage of the life cycle of harmaceuticals [12, 15, 16]. Modern pharmaceutical quality management software improves quality control for senior management, facilitates employee performance, streamlines regulatory action, and fosters a high-quality atmosphere. For the biological sciences, Agatha Quality is the best QMS. Its advancements speed up trials, enhance clinical study outcomes, and have a favorable impact on product quality. Agatha Quality is a comprehensive, ready-to-use quality management tool that can easily handle change control procedures, record corrective and preventive measures, and identify deviations. Forms, frameworks, documents, and workflows are all combined by the system to offer a comprehensive toolkit for efficient quality control [1,24,25,34,44].

The concet of quality management was reflected in the GH rules in the 1990s and 2000s, and was further develoed by enriching the quality management system by incororating the documents of the International Conference on Harmonization of Technical Requirements for the Registration of harmaceuticals (ICH), the rules of the International Organization for Standardization (ISO) standards, the international non-governmental organization IC/S (the abbreviation of the harmaceutical Insection Convention (IC) is used for IC/S and the arallel abbreviation IC/S), which currently unites 52 countries [18, 19, 20, 21, 22, 23, 46, 48].

The general rinciles and rules of drug circulation are imlemented in accordance with the documents of the Eurasian Economic Union and the Eurasian Economic Commission (EEC). In the USA, the Federal Food, Drug, and Cosmetic Act (FD&C) includes requirements for confirming the safety of drugs before their medical use [52, 56, 70, 92, 94, 100]. Currently, the WHO document rovides guidance on the imlementation of G standards [57, 95]. Thus, G standards are mandatory in Belgium, Belarus, Kyrgyzstan, Kazakhstan, the Reublic of Moldova and the Russian Federation, and the main harmacy services include the suervised disensing of rescrition and non-rescrition drugs, rearation of drugs, quality control and storage [41, 32 ; 53, 58, 64, 75]. It sets out detailed requirements for the use of medicines, the romotion of a healthy lifestyle, disease revention and harmacological control, and counseling for

atients and healthcare rofessionals [29, 21; 131, 132].

G rules are the basis of a quality system that combines rules covering all requirements for harmacies as an indeendent document, as in Turkey, Belarus, Belgium, Kazakhstan, Serbia, Slovenia, Austria, Lithuania, and the Russian Federation. [44, 98; 97, 102, 104; 119, 55]. Ortugal and France are also among the countries where the list of services that can be rovided by a social harmacy has been udated 71, 2; 147, 48]. In order to rovide the oulation with high-quality and safe harmaceutical roducts, regulate the circulation of medicines and medical devices, and otimize the quality management system in the activities of harmacies, the Ministry of Health has develoed and aroved the national standard UzMSt 140:2024. “Necessary harmacy ractice” [10].

In accordance with the resolution of the Cabinet of Ministers of the Reublic of Uzbekistan, the state institution “Center for Essential ractices” under the Agency for the Develoment of the harmaceutical Industry is assessing and certifying comliance with the requirements of the national standard [6]. The national standard establishes the requirements for reforming the harmacy sector, imroving the safety of harmaceutical roducts, and harmaceutical services rovided by harmacists [7].

The basis of the quality management system for harmacy activities is as follows:

- main: recetion, disensing of medicines, disensing of medicines on rescrition and without a rescrition, rovision of harmacy roducts according to need, rearation of dosage forms, control of their quality and storage;
- additional: information and advisory services for the oulation, recetion of orders for harmacy roducts by telehone, home delivery of harmacy roducts, stock formation [24, 8 ; 45, 15 ; 51, 125, 62].

The foundations of the quality assurance system were first established in 1905 by Frederick Winslow Taylor [81, 13]. Also, the basis of Deming's concet of total quality management is fourteen characteristics and is aimed at achieving the overall quality of medicines [78, 795 ; 126, 5; 127, 38]. At the current level of develoment, "quality" is a general concet that includes the quality of the final roduct, the quality of management, the quality of delivery or work, and the quality of life of emloyees and society as a whole [62, 68 ; 77, 15 ; 83, 12 ; 129, 66 ; 118, 41]. Quality management system is a coordinated and interrelated management activity necessary for the management of a harmacy, ensuring reliable and uninterruted oeration [87, 53 ; 36, 79 ; 135, 111]. This, in turn, includes the following:

documents that allow ensuring comliance with the conditions for the storage and rearation of medicines and medical devices and the availability of the necessary remises and equiment corresonding to the aroriate volume of harmacy activities, accounting and distribution;

comliance with the requirements of regulatory documents in the manufacture of medicines, shelf life, storage conditions, rules for the suly and retail sale of medicines and medical devices, and accetance control;

a system of continuous training of emloyees and rovision of emloyees with the required qualifications;

comlete documentation rocesses, job descritions, standard oerating rocedures.

The quality assurance system documentation is develoed by harmaceutical emloyees, agreed with the erson resonsible for the imlementation and use of the quality assurance system, and aroved by the manager [31, 53 ; 40, 69 ; 50, 120, 2 ; 134, 256 ; 136, 59].

Analysis of international exerience shows that the successful imlementation of quality management systems in harmacy ractice is based on the following elements:

- Develoment of oerational rocesses for all stages of harmacy activities.
- Imlementation of risk management systems and systematic monitoring of rocesses.
- Use of key erformance indicators (KIs) to assess erformance.

- Use of rocess automation and comuterization technologies to increase transarency.
- Regular training of harmaceutical workers [43, 64 ; 47, 270 ; 54, 55, 64 ; 65, 15 ; 84, 11 ; 98, 15 ; 99, 110, 133 ; 141, 384 ; 142, 207 ; 143, 197 ; 146, 1232].

To date, the entire harmacy documentation system consists of six large sections, and standard oerating rocedures should be established for all tyes of work that affect the quality of activity [63, 66 ; 103, 485 ; 149].

The requirements of the standard emhasize that all rocesses of the retail entity's activities that affect the quality, effectiveness and safety of harmacy roducts are carried out in accordance with aroved SOs [17, 48 ; 66, 210 ; 91, 72 ; 106, 48]. SOs contain ste-by-ste instructions, ste-by-ste actions that harmacy emloyees must strictly follow when erforming a certain rocedure [82, 11 ; 85, 14 ; 101, 104, 108, 29 ;]. In order to avoid misunderstandings and inconsistencies during the analysis rocess, which can lead to unsatisfactory quality of medicines, all conditions for the activities of harmacies and the ossibilities for imlementing quality control should be clearly and comrehensively defined and monitored [32, 78 ; 67, 215 ; 86, 6 ; 105, 29 ; 109, 2 ; 128, 371 ;]. According to international standards, self-control of harmacy activities is necessary [80, 278 ; 113, 44]. Self-control is carried out in order to identify, correct and take reventive measures in accordance with the requirements of the current legislation on harmaceutical activities and national standards [87, 53 ; 61, 2 ; 69, 54 ; 73, 3 ; 75, 76, 79]. Harmaceutical advice is an integral art of harmaceutical services [93, 96, 115, 22 ; 139, 56]. When roviding harmaceutical advice to the oulation, the consumer should be informed about the rocedure and methods of use of harmacy roducts, dosage regimens, theraeutic and adverse effects, storage rules, interactions with drugs and (or) food [138, 36 ; 114, 40 ; 117, 29 ; 137, 321 ; 140, 24].

The otimization rocess in a harmacy is an imortant stage, aimed at imroving the execution of rocesses, seeding u, reducing errors and deviations, increasing income, and imroving the quality of harmaceutical services. Modern pharmaceutical quality management software helps employees carry out their responsibilities, streamlines regulatory action, improves quality control for senior management, and fosters a high-quality atmosphere. The best QMS for biological sciences is Agatha Quality. Its advancements speed up trials, enhance clinical study outcomes, and have a favorable impact on product quality. Agatha Quality is a comprehensive, user-friendly quality management tool that can easily handle change control procedures, record remedial and preventive measures, and identify deviations. The system offers a comprehensive toolkit for efficient quality management by combining forms, frameworks, documents, and workflows [68, 14 ; 72, 81 ; 74, 201 ; 90, 66 ; 116, 46]. The imlementation of a quality management system creates a solid foundation for the sustainable develoment of a harmacy and research work carried out in the context of continuous imrovement of service quality, increasing consumer confidence, and achieving strategic business goals and objectives in a constantly changing external environment gives clear and high results [88, 37 ; 89, 70 ; 122, 167]. Studies have shown that the imlementation of a quality management system in a harmacy leads to comrehensive rocesses aimed at imroving the level of harmaceutical services, meeting consumer needs, minimizing risks, and enhancing cometitiveness in the market [124, 206 ; 133, 398 ; 147, 46].

Conclusions. Pharmaceutical companies can effectively manage compliance, improve product quality, and ensure patient safety by implementing comprehensive QMS software. As the pharmaceutical industry advances, adopting these technologies will be crucial for maintaining high quality standards and promoting innovation in pharmaceutical development and production. A well-executed pharmaceutical QMS is essential for meeting regulatory requirements and protecting consumer health.

Pharmaceutical eQMS software helps manage processes, ensure regulatory compliance, and ensure operational control of pharmaceutical products. It also helps ensure compliance with ISO 9001, FDA 21 CFR Parts 210/211, ICH Q10, EU GMP, or other GxP-related requirements. Its key capabilities include document control, CAPA management, audit management, change control, training management, risk management, equipment qualification, and batch traceability. Pharmaceutical eQMS can automate and

standardize quality operations, allowing for ongoing compliance with applicable requirements.

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