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QUALITY CONTROL OF MEDICAL AND PHARMACEUTICAL GOODS AND STANDARDIZATION

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КОНТРОЛЬ КАЧЕСТВА МЕДИЦИНСКИХ И ФАРМАЦЕВТИЧЕСКИХ ТОВАРОВ И СТАНДАРТИЗАЦИЯ

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ABSTRACT

One common source of misunderstanding in the medical device industry is the method the various national regulatory systems use to identify standards. This article explains the method, starting with standards from the International Organization for Standardization (ISO) adopted and recognized in various regulatory systems. The article uses ISO 13485:2016 and ISO 9001:2015 as illustrations.

АННОТАЦИЯ

Одним из распространенных источников недоразумений в индустрии медицинского оборудования является метод, используемый различными национальными регулирующими системами для определения стандартов. В этой статье объясняется метод, начиная со стандартов Международной организации по стандартизации (ISO), принятых и признанных в различных регулирующих системах. В статье в качестве иллюстраций используются стандарты ISO 13485: 2016 и ISO 9001: 2015.

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Ключевые слова: область медицины, медицинское оборудование, стандарт, соответствие, сертификат, менеджмент качества, ISO 13485: 2016, GMP.

Healthcare in Uzbekistan is one of the foreground directions of the inclusive social policy implementation which experienced major reform over the past two decades. Uzbekistan has a single statutory health care system, which includes public, private and other forms of non-public actors. Today over 1,000 inpatient health institutions, 4,000 polyclinics and outpatient institutions, 501 rural outpatient posts, 2,606 RHCs and other health institutions are providing qualified public health services. Improving the supply of medicines and providing medical care has become a key principle in the concept of development of health and medical science. One of the main tasks of the state is to ensure the high quality of medicines and medical devices only through the implementation of an effective quality control system. The Law of the Republic of Uzbekistan "On Medicines and Pharmaceutical Activities" adopted in 1997 established the priority of state control over the production, manufacture, quality, efficiency and safety of medicines and medical devices. Expertise, standardization and improvement of the existing control system of state control became the first practical application of this concept. This means the creation of structures within the Ministry of Health of the Republic of Uzbekistan capable of uniting all departments of the control system, as well as in accordance with modern requirements for medicines and medical equipment quality control. In order to ensure a unified state policy in the field of regulation of medicines and medical equipment, the General Directorate for Quality Control of Medicines and Medical Equipment was established by the Resolution of the Cabinet of Ministers of the Republic of Uzbekistan No. 181 of May 25, 1995. Quality control of medicines and medical equipment The General Directorate is responsible for the organization and implementation of state control over the quality of medicines and diagnostic tools and medical equipment, medical devices, medicines and medical devices, treatment, nutrition and medical equipment coordination, supervision and guidance of institutions and organizations engaged in the examination, standardization and registration and certification.

Picture 1. ISO 13485:2016 – Standard for Medical Devices

One of the criteria for quality assurance is the establishment of independent pharmaceutical control. In the Republic of Uzbekistan, these tasks are assigned to the Pharmaceutical Inspectorate of the Main Directorate. This inspection monitors the activities of manufacturing enterprises, pharmacies, laboratories included in the pharmaceutical system. Advanced training courses are the State Center for Drug Expertise and Standardization of the Department (SCDESD). The main task of SCDESD is to exercise state control over the quality of medicines, diagnostic tools, medical equipment and medical devices, as well as medical food products. SCDESD has 4 laboratories, which are engaged in quality control and testing of medicines, local and foreign medical equipment, medical devices.

Medical equipment, equipment designed to obtain accurate and objective information during the tests of conformity to medical products (including certification) in accordance with the requirements of regulatory documents on safety and quality indicators for the life and health of patients in the system of general management and a laboratory for quality control of medical devices. With laboratory test equipment and measuring instruments has a set of documents, such as norms and other standards (GOST, OST, ISO) for measurements and tests.

The laboratory is part of the State Center for Drug Expertise and Standardization (SCDESD) and interacts with other agencies, organizations and enterprises on a contractual basis.

The Committee on New Medical Technologies is one of the leaders in the formation of state policy in the field of medical devices. The Committee is a structural unit of the General Directorate and is called upon to ensure a unified state policy on quality control and standardization of medical equipment and medical devices and diagnostic tools. One of the main tasks of the Committee is to allow domestic and foreign countries to use medical equipment and medical devices for medical purposes in our country. The Committee, in accordance with the requirements of international rules and standards, including the International Council for Standardization (ISO) and the International Electro-technical Commission (IEC), organizes and coordinates the testing of medical equipment, new medical equipment and medical devices. Medicine decides on its application in practice, issues the relevant certificate and decides to include it in the State Register of Medical Equipment and Medical Devices.

The development and approval of the procedure for registration of domestic and foreign medical equipment and medical devices in the Republic of Uzbekistan has made it possible to establish a simple procedure for the import of medical equipment and medical supplies into the country. The list of drugs and medical devices approved for use in medical practice is determined by the Ministry of Health of the Republic of Uzbekistan. April.

Medicines and medical equipment, organizations included in the system of quality control of medical devices have the necessary standards and other normative documents describing the quality of medicines or medical equipment, medical devices: pharmacopoeial articles (PA), provisional pharmacopoeial articles (PPA), industry standards, specifications (TU), American Pharmacopoeia, The British Pharmacopoeia, India, The India Pharmacopoeia, Germany, Europe, Japan, International Standards (ISO), International Electro-technical Board (IEC) and others. To the exact level of quality of goods specified in the regulatory documents certification process is performed to confirm compliance.

Certification is the process of confirming in writing that a product, process, or service meets the specified requirements.

The main purpose of medical product certification is to prove that medicines and medical devices meet the mandatory requirements of regulatory documents.

Certification of medical products of the Republic of Uzbekistan. In accordance with the Law "On certification of products and services" approved by the Cabinet of Ministers of the Republic of Uzbekistan "List of products and services subject to mandatory certification." Mandatory certification of medicines was introduced in the Republic of Uzbekistan on January 1, 2003 in order to implement a unified state policy to provide the population with high-quality and safe medicines and safe medical equipment and products, and to protect the interests of consumers. The sale of drugs with a certificate of conformity is allowed in the territory of the Republic of Uzbekistan.

The main tasks of the Office of Certification of Medical Products:

• Organization of certification work in the field of accreditation make, implement (issue a certificate of conformity) and manage;

• Medical hazards to human life and the environment prevention of trade in products;

• Ensuring that products can compete in international markets to help;

• Improving the certification of medical products to go.

Quality assurance is a comprehensive concept that covers all the factors that affect the quality of a product, individually or collectively.

Second, it is a set of measures taken to ensure the quality of medicines, medical supplies and medical equipment.

Ensuring the high quality of medical products is of great importance in the standardization process. According to the definition adopted by the Council of the International Organization for Standardization, standardization is the activity in a particular field with the participation and participation of stakeholders in order to achieve common reasonable savings in compliance with the conditions of use and safety requirements the establishment and application of rules for regulatory purposes.

Standard - standardization, is the basic principles of standardization and organization of work on standardization, defines the goals and objectives, normative documents, types of standards, application of basic rules, requirements and technical conditions of standardization in international cooperation, state control over measuring instruments.

Picture 2. ISO 9001:2015- Standard for Quality Management Systems

Standards define the quality requirements of the finished product, quality indicators, methods and means of their control and testing, the required level of reliability and durability, depending on the function of the product and the conditions of use.

A standard is a set of rules, general principles, descriptions, requirements, and methods for the general and repeated use of various types of activities designed to achieve a moderate level of regulation in a particular area, developed with the consent of the vast majority of stakeholders. a norm approved by a recognized authority is a document. Normative documents - standards, other equivalent documents technical conditions, technical specifications (Law of the Republic of Uzbekistan "On Consumer Protection", Article1) Standard of the Republic of Uzbekistan (Uzbekistan) - on standardization standard approved by a government agency or other government agency of the republic (UzStandard Agency, State Construction, State Committee for Nature Protection, Ministry of Health of the Republic of Uzbekistan, etc.) in accordance with its powers.

In total, the IEC and WHO have 14 technical committees and secretariats for medical product standardization, of which 7 are chaired by Germany, 3 by the United States, 2 by the United Kingdom, and 1 by Sweden and Denmark.

The total number of international standards is 586, of which technical

The distribution by committees is shown in Table 1. Standardization is particularly active in the developing committees and commissions: TC / MEK (62), the Committee on Medical Electrical Equipment and Devices - 100 documents, TC / ISO - 106.

The International Pharmacopoeia (set of rules for the preparation, testing, storage and prescribing of drugs), which sets the optimal standards for the effectiveness, purity and quality of medical products entering the international market, forms the basis of international

standards. These standards are easy to adopt by WTO members in accordance with the WHO Charter. The WHO has been publishing the International Pharmacopoeia since 1951. To date, it has published three editions (1967, 1981, 1988). Many countries have created their own national pharmacopoeias. National pharmacopoeias rely mainly on complex analytical methods that require expensive equipment and highly qualified personnel. Therefore, their requirements are not acceptable for countries with underdeveloped economies. International pharmacopoeial methods are simple and low cost. Thus, the International Pharmacopoeia is an alternative to some widely used national and regional pharmacopoeias. His its main goal is to adapt to the needs of developing countries by offering reliable quality standards based on classical methods.

Another standard is the European Pharmacopoeia, which was introduced in 1964 on behalf of the Council of Europe (EC-Russian). According to the directive of the Council of Europe (20.05.1975). Monographs of the European Pharmacopoeia are mandatory in the preparation of documents for a trade license (ie, registration of drugs). The aim of the European Pharmacopoeia is to help ensure social standards that guarantee the quality of medicines in public health.

National Pharmacopoeias were first created in European countries: Prussia (1789), Austria (1812), France (1818), Britain (1864), Germany (1872), and the United States (1820). In 2001, the Ministry of Health of Ukraine launched the 1st edition of the State Pharmacopoeia of Ukraine, harmonized with the European Pharmacopoeia.

The international system of quality control of pharmaceuticals and medical products, as recommended by the World Health Organization, includes international requirements such as "Good Manufacturing Process (GMP), "Good Laboratory Practice (GLP)", "Good Clinical Practice (GCP)".

Picture 3. GMP (Good Manufacturing Practice) Standard for Manufactruing Processes

GMP is a part of the product to ensure quality, which is constantly produced and controlled in accordance with the quality standards for which its function is relevant and requires a commercial license. GMP is primarily specific to any pharmaceutical industry, which cannot be completely eliminated by testing a controlled set of finished products aimed at reducing risk. The first GMP regulations were adopted in the United States in 1963 and are now used in more than 40 countries. In addition to the single rules, the GMPs in the countries participating in the Pharmaceutical Control Agreement (GMP PIC), GMP ASEAN (for members of the Association of Southeast Asian Nations), as well as the WHO (World Health Organization International Regulations) Has recognized and adheres to the GMR-based international trade certification system for pharmaceutical products. Quality control is the part of the selection, specialization and testing of samples, as well as the registration and licensing of products, related to the organization of sales. Quality control should be involved in all product quality decisions. Thus, quality control should focus on regulating all the processes that shape the quality of medical devices, rather than on ultimate inpatient priorities. Summing up all the above conclusions, it should be noted that quality control is not only an integral part of the quality management system, but also an integral part of the GMP rules that shape the quality assurance system. International standards belonging to the ISO 9000 family, as a quality management system, began to be developed in the 60s and 70s of the last century, following the GMP rules, based on the regulation of quality management systems and developments in other countries. The scope of ISO standards covers all sectors of the economy, manufacturing and services takes. The first version of ISO 9000 was developed by the International Organization for Standardization in 1987, the second was published in 1994, the third was released in 2000 and includes:

- Basic rules of standard ISO 9000 quality management systems defines terms;
- ISO 9000 defines the requirements for quality management systems in cases where the organization needs to reduce its capacity to meet customer requirements and mandatory requirements and to increase customer satisfaction;
- ISO 9000 - Recommendations that consider the effectiveness of quality management systems as effective The purpose of this standard is to improve the organization, meet the needs of consumers and other stakeholders;
- ISO 9000 standard - guidelines for auditing and environmental protection.

The main differences between GMP and ISO are:

- GMP rules are part of the quality management system in cooperation with GMP, GSP, GPP, ISO 9000 - an integrated universal system of quality management in all sectors of the economy (manufacturing, trade, etc.);
- GMP rules apply only to the manufacture of drugs,
- ISO 9000 is used in all industries, including medicine. ISO standards are of a recommendatory nature and their implementation in enterprises depends on the voluntary decision of the management and, above all, serves to increase the competitiveness of their products.

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