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Quality Certification of Medical Devices in Venezuela: Process Developed by Simón Bolívar University, Caracas-Venezuela

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ABSTRACT

Background and Objective: The development of medical technology and advances in biomedical engineering are in constant growth. Every year new medical devices are found in the market that seeks to satisfy the demand and requirements of medical services in health institutions. Consequently, health systems of the countries generate methodologies to regulate and accredit medical devices that really satisfy the needs of medical services with safety, effectiveness, efficiency, and quality. A third party must guarantee the safety and effectiveness of medical technology and issue a quality certification before its available to use in medical establishments. In Venezuela, one of the institutions authorized by the regulatory entity (Ministry of Health) that grants quality certification to medical devices is the Health Technology Management Unit (UGTS in Spanish), attached to the Research and Development Foundation (FUNINDES) of the Simón Bolívar University (USB). The objective of this work is to show the protocol for UGTS certification to comply with ISO 9001 standards and guarantee the quality of the processes of the medical devices certifying unit.

Material and Methods: The process is based on the ISO 9001 standard. Five activities were determined: (i) Prepare the teaching, technical and administrative staff as ISO auditors. (ii) Carry out an external audit, to make proposals for improvement; (iii) Plan changes in our quality management system and processes and qualify as a supplier guided by the ISO 9001 philosophy by a prestigious international company; (iv) Submit our capabilities and to the Ministry of Health, and (v) Execute the protocol to certify medical devices. Medical devices certification includes the analysis not only of the devices itself but the manufacturer, distributor, and post-market services. All these stages and stakeholders are evaluated in the certification process per the guidelines established by the ISO 9001 standard.

Results: The UGTS has developed a protocol that guarantees the safety and effectiveness of new medical devices before its use in the Venezuelan health care system. The protocol is based on the national and international regulations; it has been evaluated by Johnson & Johnson Medical S.C.S. and the UGTS it has been approved as a supplier for the analysis of medical devices by the company in complying with ISO 9001 Standard. Under this new protocol, 550 medical devices have been certified.

Conclusions: Advance on technology allows the breakthrough in medical device development. It is important to acknowledge the need to incorporate less invasive, more accurate and effective devices, in which physicians often rely on to treat a patient, but also developers must be compelled to meet the bioethical principles. The UGTS protocol to certify medical devices is had been recognized and the unit is authorized by the Ministry of Health (MPPS) through the Sanitary Comptroller's Office to issue quality certificates to medical teams since 1999. Approximately 55 companies that have received service are registered in its database. In the period audited (2012 - 2014), 25 files were created. Its processes comply with ISO 9001.

Keywords – *Quality, Certification, Medical Devices, Processes, and Food and Drugs Administration.*

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INTRODUCTION

Medical devices and supplies increase productivity in health institutions, contributing to the reduction of morbidity and mortality rates; however, the use of medical devices has an associated risk. Also, with the advance of technology medical-device complexity had increased over time, representing a challenge to the health system to keep on track.¹⁻³

Currently, there is a great diversity of medical devices, due to the increasing technological and biomedical advances and developments which make it possible to improve the diagnosis and treatment of pathologies, and thus improve the quality and efficiency of medical care services.⁴ Governmental health systems seek mechanisms to regulate the acquisition of these medical devices, to ensure that their use effectively complements quality medical service.

According to the Food and Drugs Administration (FDA), equipment or medical device is Instrument, device, implement, machine, implant, or other similar or related article, including a component, part, or accessory, designed for (1) The use in the diagnosis of a disease or other conditions, or the cure, mitigation, treatment, or prevention of disease in humans or animals; (2) Affecting the structure or any function of the body of humans or animals, without this being done from chemical processes and without depending on human or animal metabolism to obtain the desired result.⁵

The definition presented shows the amplitude of the concept since it includes different teams whose functions vary. Medical equipment can range from a simple thermometer to complex angiography equipment, and both its manufacturing and the complexity of the technology are increasing. A 17.4% growth in employment related to all areas of health including prevention, diagnosis, monitoring, treatment, and care is expected.⁶ Growth will also thrive in the healthcare manufacturing industry.

Internationally it is considered that all equipment or material for use in human medicine should be subject to registration and control by the health authorities of the country of origin to ensure that such equipment or material is "safe and effective."⁷

In Venezuela, the registration and control of medical materials and equipment is regulated by Resolution No.

DM-001 0-99 dated September 21, 1997. Article 1 of the resolution establishes that: "Every juridical person constituted in Venezuela interested in manufacturing, importing, marketing or providing maintenance services of materials and equipment for use at the levels of the health area, must previously register in the National Sanitary Registry that the Directorate of Regulation and Control of Materials, Equipment, Establishments and Health Professions carries out, attached to the General Directorate of Health Controllorship of the Ministry of Popular Power for Health (MPPS).⁸

Article 4 states that: "The materials and equipment used in the area of human health must be registered in the corresponding Directorate of this Ministry contemplated in Article 1 of this Resolution." Among the requirements required to obtain such registration, the interested party must present a Quality Certification issued by an accredited institution (Article 6, paragraph f).⁸

To satisfy this legality, the Venezuelan State has authorized institutions, which have the infrastructure and specialized personnel to guarantee the processes that allow issuing the appropriate certificate, based on the aforementioned principle of "safety and effectiveness." Among these institutions is the Health Technology Management Unit attached to the Research and Development Foundation of the Simón Bolívar University, which is also part of the Biophysics and Bioengineering Group and is an active part of the Biophysics Laboratory.^{8,9}

The safety of medical equipment and material is subject to the criteria of the evaluating specialist and its effectiveness will depend on fulfilling the functions for which it was designed and constructed, according to the manufacturer's technical specifications (that is, that the device does what it says it must do). These two aspects constitute the elements of judgment to issue the quality certificate.⁷

Additionally, any process developed by an organization, to be recognized must have approval of the International Organization for Standardization (ISO). ISO creates documents that provide requirements, specifications, guidelines or features that can be used consistently to ensure that the materials, products, processes, and services are suitable for their purpose.¹⁰

One of the families of the ISO standards is the one called ISO 9001. ISO 9001: 2015 establishes the criteria for a quality management system and is the only standard in the family that can be certified (although this is not a requirement). It can be used by any organization, large or small, regardless of its field of activity. There are more than one million companies and organizations in more than 170 countries certified with ISO 9001.

This standard is based on a series of quality management principles that include a strong focus on the client, the motivation and involvement of top management, the process approach and continuous improvement. The use of ISO 9001: 2015 helps ensure that customers obtain consistent, high-quality products and services, which in turn provide many business benefits.¹¹

The general objective of the work was to show how the UGTS comply with the requirements of the ISO 9001 Standard in the Quality Certification processes for medical devices in Venezuela to guarantee the highest possible quality in each evaluation process of the biomedical technologies that are intended to be commercialized in Venezuelan territory. The specific objectives were: (A) To prepare the teaching, technical and administrative personnel as internal auditors ISO 9001; (B) Request the execution of an external audit, to make proposals for improvement; (C) Plan changes in our quality management system and processes; and (D) Qualify as an ISO 9001 approved supplier by a prestigious international company.

METHODOLOGY

The research performed was a qualitative study, and was exploratory and descriptive according to its purpose.^{12,13} According to its source, the work is documentary. Information was collected from primary and secondary sources. The design of the research is not experimental and from a temporal point of view is longitudinal. Its analysis unit is the process of quality certification of medical equipment implemented by the UGTS-USB. Within the aforementioned process, a series of requirements were identified that must be met for the process to be effective.

RESULTS AND DISCUSSION

Preparation of Staff

The UGTS met with all staff (teaching, technical and administrative) in January 2014 and assumed the commitment over the quality management system as its work philosophy. That same year, two courses were held on this Standard, totaling 112 hours of classes to become "ISO 9001 Auditors." Subsequently, in 2015, the same personnel carried out three courses on ISO 13485 with a duration of 60 hours.

ISO 13485 of Medical Equipment is an internationally recognized quality management system (QMS) for manufacturers of medical equipment and related services. The main objective of the standard is to establish a set of harmonized regulatory requirements for QMSs within the sector of medical devices. It is based on ISO 9001, especially on the requirements of customer satisfaction and continuous improvement, but with modifications to make them more appropriate to the regulatory objective.¹⁴

After Staff Preparation

After the preparation of the UGTS staff an external audit of the certification processes that were being used since 1999 was requested. The audit was carried out by an external university (Metropolitan University) with a School of Production Engineering. Within this university, an expert professor in processes in health institutions was contacted and the field study became degree work for two students.¹⁵

The conclusions of the audit it was found that the Ministry of Health Autonomous Health Comptroller Service does not have specific requirements established for the quality certification of medical equipment so that each accredited institution has freedom regarding the certification process to carry out the evaluation. The requirements recommended by the Food and Drug Administration (FDA)¹⁶ and the Pan American Health Organization (PAHO)¹⁷ were studied. A review of the literature was carried out at the most important universities in Venezuela using the PubMed and LILACS databases and similar works were not obtained. There was no classification of medical equipment according to the level of risk they represent. There was no post-marketing surveillance of medical

equipment. Faults were identified in the requirements related to the technical documentation, specifically related to the capacity of the applicant company to give technical support to the equipment.

Changes in the QMS

To plan the changes in the QMS and its processes several activities were carried out. Once the results of the external audit were known, the UGTS adopted the classification of the FDA's medical equipment¹⁸ and began to request that companies that require the certificate in writing describing their capacity to give technical support for the equipment. The processes were as follows:

- (i.) Company Documentation: Name of the Company; Person to contact; Address and telephone numbers of the company; Technical capacity; List of equipment to be certified with respective technical documentation (catalogs and technical sheets); Estimate of the approximate sale price; Written evidence of technical personnel that will perform after-sales service; Sanitary registry issued by the Ministry of Popular Power for Health of Venezuela. In cases where the company had never been evaluated, we visited its facilities.
- (ii.) Characteristics of the manufacturing company (of the equipment to be evaluated): Name of the Company; Address and telephone numbers of the company; Development areas; Technical capacity.
- (iii.) If the equipment or instruments have a certificate from their country of origin, the most important being those of the FDA (USA), European Conformity (CE) according to Directive 93/68 / EEC, IEC 60601, ISO 13485 and ISO 9001, ISO 62353, the application must be accompanied by the documentation referring to the international certification. Copies of the standards taken as a basis for the issuance of such certificates, as well as of the free sale certificates issued in the country of origin should be included. The required copies must be in Spanish or English and duly legalized by the Consulate or Venezuelan Embassy in the country of origin. In addition, the applicant must issue a letter committing to supply the required material and cancel the invoices for expenses generated during the certification process.
- (iv.) For the issuance of the Certificate by the USB, the equipment must be operational in Venezuela so it can be verified by the specialists in clinical engineering and medicine. If the equipment is not located in Venezuela and the documentation presented meets the requirements, a provisional certificate and a recommendation for its importation will be issued to the respective official body. Once the equipment enters the country and is operational, the technical visit will proceed, and the final certificate will be provided.
- (v.) If the requesting person or company does not have the aforementioned documentation, if the equipment is manufactured locally, or there is a standard for the certification of the equipment and its accessories, the specialists of the USB will proceed with its study to define the protocol or design the set of tests required. The USB will notify the applicant about the materials and equipment that must be supplied to carry out the tests.
- (vi.) If the documents presented are valid, or if it is feasible to initiate the procedures, after a thorough evaluation of its contents and it contains all the sufficient elements required, the certification process will begin, and all interested parties will be notified. If, on the other hand, the documentation submitted does not meet all the requirements required by the Law, or the procedures are not feasible, the pertinent recommendations will be made and all the material will be returned.
- (vii.) After carrying out these steps we will proceed to the analysis and decision-making regarding whether to guarantee or not the quality certificate to the medical team.
- (viii.) After having the new QMS, a working meeting was requested with the Venezuelan Association of Distributors of Medical, Dental, Laboratory and Allied Equipment (AVEDEM),¹⁹ with the objective convey our impressions to our main clients. After the rigorous explanations, AVEDEM remained in agreement as it follows the guidelines of the main specialized agencies in the field.

The process is summarized in Figure 1.

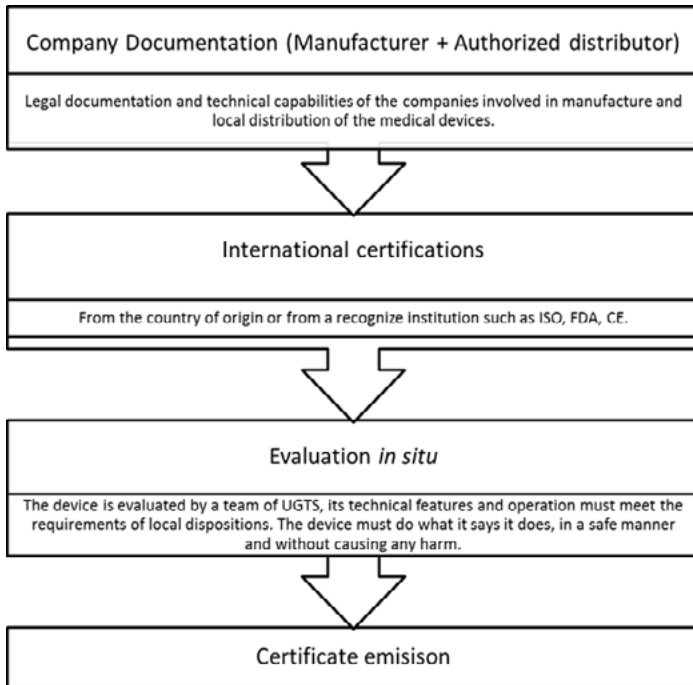


FIGURE 1. Diagram of medical device certification stages. Each stage must be accomplished in order to advance to the next.

Qualifying as a Supplier Under the Performance Standards According to ISO 9001

The prestigious transnational company Johnson & Johnson Medical S.C.S. requested that we in Bogotá (Colombia)²⁰ conduct a remote audit to qualify them as an approved supplier for the certification service of its products in Venezuela. After completion, in January 2017 they were informed that their services were based on the ISO 9001 standard.

Medical Device Certifications

Since 1999 more than 80 companies have requested medical device certifications from the UGTS, for one or more of the devices they manufacture, distribute, and sell in Venezuela. The UGTS have issued certification for over 3000 medical devices since that year. After the incorporation of the ISO 9001 normative to the certification process in 2017, 550 medical devices were certified. These, more recent, certifications correspond to 4 companies with a greater number of devices grouped in families or series. Another aspect that has influenced the certification of

medical technologies in Venezuela is the Venezuela-China cooperation agreement,²¹ signed in 2013 which allows the acquisition, selling, distribution, and commercialization of medical technologies between these countries without the quality certification. Due to this agreement, the presence of Chinese technology in Venezuela, without quality certification, has increased during the past few years.

The most recent 1200 medical devices certified by the UGTS are shown in a graphic form as classified by medical function (Figure 2). It is important to note that this classification is only for this paper as a reference of the certified technological diversity. Figure 2 and Table 1 present the certified devices according to their main function.

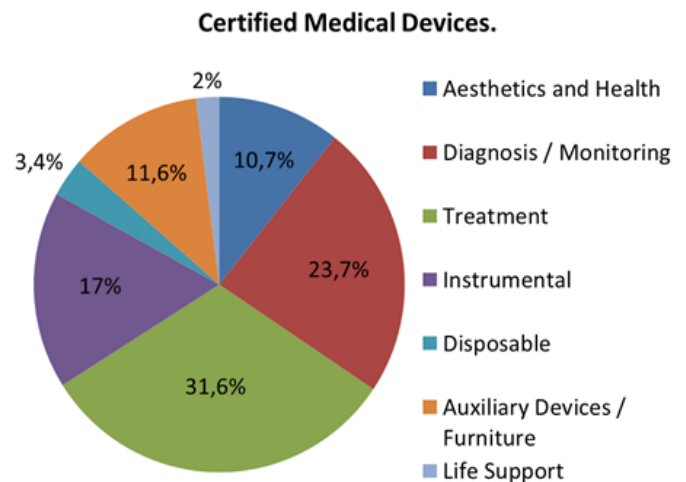


FIGURE 2. Certified medical devices classified by function.

TABLE 1. Certified Medical Devices Classified by Function

Medical Devices Function	Percent (%)	Medical Devices
Aesthetics and Health	10,7	128
Diagnosis / Monitoring	23,7	285
Treatment	31,6	379
Instrumental	17	204
Disposable	3,4	41
Auxiliary Devices / Furniture	11,6	139
Life Support	2	24
TOTAL:	100%	1200

Some aesthetic devices that use radiofrequency and radiation emission are aimed to preserve or restore the health of the skin, as a consequence, they are also

considered medical devices. Diagnosis and monitoring medical devices include those that provide information directly related to pathology and biological variable registries such as electric signals, anatomical images, or metabolites concentration. Treatment and therapy medical devices are those designed to mitigate or eliminate the pathology or condition such as implants, nebulizers, hyperbaric chambers, or infusion pumps. Instrumental medical devices are all metallic reusable tools used during surgeries. Disposable devices are those designed for single-use such as needles, injectors, and condoms. Auxiliaries and furniture are those devices that support a clinical procedure but are not directly in contact with the patient such as centrifuges, plasma extractors, operating room lamps, refrigeration and sterilization equipment, nebulization and oxygen masks, and clinical furniture (tables, clinical beds). Life support devices are those such as mechanical ventilators, anesthesia machines, neonatal cribs, defibrillators, and pacemakers.

CONCLUSIONS

The UGTS is certified by the standard ISO 9001:2015, which guarantees the quality operation of the unit that is authorized by the Ministry of Health through the Sanitary Comptroller's Office to issue quality certificates to medical teams since 1999.

The objective of the certifying UGTS team was to develop the protocols for action and verification, based on the ISO 9001 standard, in the Quality Certification processes for medical devices in Venezuela.

To achieve this goal, the teaching, technical, and administrative staff were prepared as internal ISO 9001 auditors. An external audit was then requested to make proposals for improvement. Based on this audit, changes were made to the QMS and its processes and was immediately made known to the clients. The clients were satisfied, as it follows the guidelines of the main specialized agencies in the field.

Part of the UGTS staff was accredited as ISO 9001:2015 auditors enabling this protocol to be incorporated into the process of medical devices certification. This will guarantee the quality of the management systems of the

companies involved in the manufacture, distribution, and post-market servicing of the intended technology.

The importance of certification, as noted by Guberta and Badnjevic¹ and Vukovic et al,²² suggested to the Ministry of Health there was a need for the existence of a clinical engineering unit in every health institution to continuously monitor the performance of medical devices.

Finally, the company Johnson & Johnson Medical S.C.S. requested an audit to qualify them as an approved supplier for the certification service of its products in Venezuela.²⁰ After this was completed in January 2017 we were informed that our services are based on the ISO 9001 standard.²³

Future work is oriented to the automation of the QMS protocol to go along with public policies aimed at paperless transactions at the Ministry of Health.

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