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METHODOLOGY FOR THE DESIGN AND MANUFACTURE OF DEVICES MEDICAL, RELATED TO THE SANITARY EMERGENCY CAUSED BY COVID-19

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ABSTRACT

The development of medical equipment is related to compliance with regulations, with the intention of safeguarding the physical integrity of patients, being able to ensure that a medical equipment complies with the regulations and can be registered with its respective authorization for use, it is a job long-term with the use of multiple resources. It is due to this characteristic that it is difficult for them to be able to register developments of medical equipment in most countries, either due to lack of infrastructure to carry out patient safety tests or due to the lack of regulations for the registration of medical equipment manufactured in their facilities of respective countries. In this research, a methodology is presented to be able to design medical equipment, considering the regulations and considerations regarding patient safety, as a result, a procedure based on the study of the market of similar equipment is presented in order to guarantee its possible registration and a matrix of technical information, to ensure compliance with regulations and patient safety.

KEYWORDS: FDA, Medical Equipment, Development, Regulations, Patient Safety

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Original Article

INTRODUCTION

In times of crisis, many opportunities arise, where the intention is to take advantage of the deficiencies that arise and turn them into new products or services, in times of pandemic by COVID-19, certain countries that have limited production systems and services related to the health sector and are technologically dependent on other countries, many public and private initiatives arise for the design and manufacture of medical devices, motivated by helping to mitigate the effects of the pandemic, among the devices to be developed range from masks, thermometers, oxygen saturation measuring devices to artificial respirators, which are the most requested by the pandemic. Among the works found, we find those related to testing equipment, performing functional tests, making users aware of it through the use of informed consent. [1].

We find jobs related to the optimization of resources in hospitals, where the aim is to have tools that can help improve the management of medical technology, due to the great technological advances that have been taking place in medicine. In most cases, computerized software is used, where the optimization of medical equipment in health centers is checked [2]. Biomedical engineering contributes a lot to the design of medical equipment, for this reason its specialists carry out the work from design to functional tests. Among its competences

is the development of medical instruments. The competencies necessary for the biomedical engineer to develop strong instruments to failure are listed, as biomedical engineers deploy devices and procedures that solve medical and health problems by composing their knowledge of biology and medicine with engineering principles and practices [3]. The growing development and competitiveness that exists during the clinical evaluation of devices and drugs at the international level, where the requirement to comply with the standards for their registration is of vital importance, where the development of the Procedures manuals is considered and conducting clinical trials [4]. The majority of jobs are more frequently related to the maintenance of medical equipment, rather than the development of equipment, among the maintenance jobs we can mention those that use computerized systems to help in maintenance management [5].

METHODS & MATERIALS

The methodology presented is based on good practices for the design and manufacture of medical-level equipment, taking into account the regulations that govern medical equipment, which are responsible for guaranteeing its operation and ensuring the continuity of the life of the patient, as in the case of life support equipment. Below we present the methodology to be developed in order to design the strategy for the development of medical equipment at the local level.

Blocks Diagram

The block diagram is composed of 6 stages where each one of them is characterized by defining certain special tasks, if all are fulfilled, they give rise to a design of the medical equipment with a high probability of being able to be registered in the developing country and be approved for clinical use.

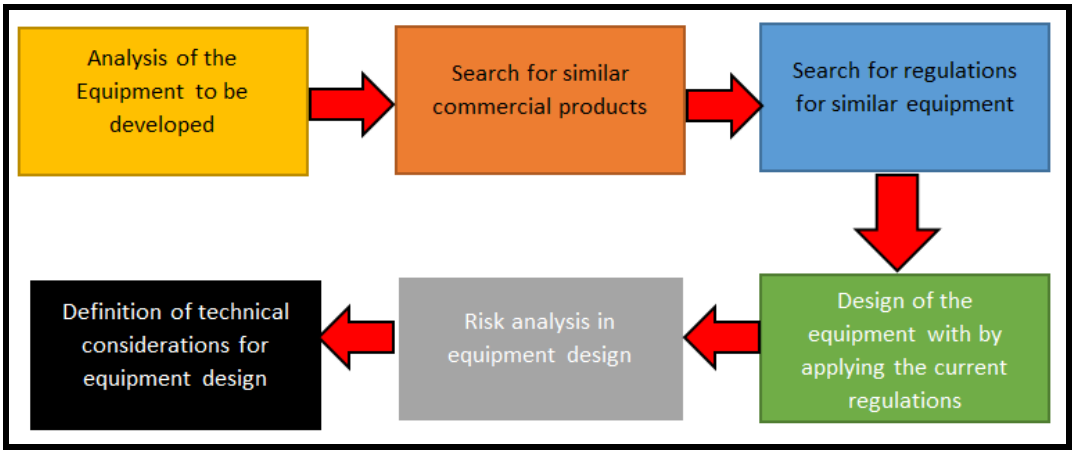

Figure 1: Block Diagram of the Proposal.

Analysis of the Equipment to be Developed

In the development of medical equipment, it begins with the choice of the equipment to be developed. The choice is related to the need or urgency of the devices that are required, it is at this time that a detailed analysis of the equipment is required, considering the level of complexity, the materials necessary for implementation and, most importantly, the national regulations. to be fulfilled, this requirement is the most important because the detailed analysis of the regulations will allow the choice of the equipment to be developed and to be able to conclude with the decision of compliance with the standard and start with the design, it is important to indicate at this stage the main tasks, first consider in the design compliance with the standard and second the availability of resources and materials necessary for the implementation of the equipment such as medical grade sensors and actuators.

Search for Similar Commercial Products

One of the good practices in the design of medical equipment is to be able to choose for development a medical team that is registered and authorized, to take as a reference. So be able to develop a similar one.

In the design of medical equipment there is a regulatory framework where according to the FDA these are classified as follows:

Class I Devices

They are devices that are Low Risk, are subject to general controls in the manufacturing phase, are not intended to protect life and do not represent an unreasonable potential risk of illness or injury, having the following characteristics:

General controls sufficient to ensure Efficiency and Safety and must have the following requirements: Adulteration, Erroneous identification, Premarket notification, Establishment registration, Device listing, Records and reports, Notification, repair, replacement.

Example: Gloves, Bandages, Swabs, Cotton for medical use. Electrodes, Stethoscope, Paper.

Figure 2: Class I Medical Devices, such as Medical Instruments and Electrodes.

Class II Devices

Devices with Moderate Risk are subject to general and special controls in the manufacturing phase to demonstrate their safety and effectiveness, having the following characteristics:

General controls and performance standards to ensure Efficiency and Safety and must have the following requirements: Observation: from 1981 to 1991 no standards were generated, ANSI / AAMI: EC-11 EC-38, among others.

Example: Thermometer, Needles, Syringes, Condoms, Micas.

Figure 3: Class II Medical Devices, such as Syringes and Needles.

Class III Devices

They are the devices that have High Risk and are subject to special controls in the design and manufacture to demonstrate their safety and effectiveness. They are intended to provide Life and Implantable support and have the following characteristics:

General controls sufficient to ensure Efficiency and Safety and must have the following requirements: Pre - Market Review by FDA to establish safety and effectiveness of each device, Subject to general controls and performance standards.

Example: Electrosurgical units, External defibrillators, Infusion pumps, Pulse oximeters, Ventilators, Lithotripters, Hemodialysis machines, Catheters for angiography, EEG, X-ray equipment, Ultrasound diagnostic systems, Linear accelerators, Surgical sutures.

Figure 4: Class III Medical Devices, such as External Defibrillators, and Catheters.

Class IV Devices

Are the devices that have Critical Risk are subject to special controls in the design and manufacture intended to protect or maintain life or for a use of substantial importance in preventing the deterioration of human health, or if their use presents a potential risk of illness or injury.

Example: Cardiac pacemakers, Cardioverters, Implantable defibrillators, Implantable electrical stimulators, Heart valves, Coronary stents, vascular prostheses, Catheters for angioplasty, Clips for aneurysms, among others.

Figure 5: Class IV Medical Devices, such as Implantable Defibrillators and Prosthetics.

Search for Regulations for Similar Equipment

The methodology presents as a recommendation the review of similar equipment found in the market, the search for a commercial equipment that is very similar to the one to be designed, is of vital importance, because with the analysis of the similar equipment many Doubts about the technical specifications and the regulations that it may comply with, this analysis will lead to defining the technical specifications of the equipment, thereby ensuring knowledge of the regulations that govern the operation of medical equipment.

Design of the Equipment with by Applying the Current Regulations

After having obtained the similar commercial equipment, which can serve as a reference both for the analysis of the technical specifications, as well as that related to the normative that governs the medical equipment. The next component is the analysis and design of the necessary requirements to be able to comply with current regulations that achieve its registration and authorization in clinical use. The analysis of the current regulations is of vital importance in order to be considered in the design stage, and with this, there are no problems after the safety tests. Among the regulatory requirements are those considered with electrical safety and electromagnetic compatibility, which are the essential requirements in the registration of medical equipment.

Risk Analysis in Equipment Design

The risk analysis in the design of medical equipment is very important, because depending on the level of risk caused by the use of the equipment, this can be considered in the type of medical equipment, as manifested in the classification according to the American regulatory entity FDA, who classifies medical teams according to the risk they may have in the interaction with the patient.

Carrying out a risk analysis in the design stage of the medical equipment, defines the technical characteristics of the equipment as well as its classification according to FDA, as well as allowing the design of possible solutions when there are possible failures in the equipment and how these can be solvable, with This analyzes the level of irrigation with respect to the patient. Analyzing the risks allows to improve the design and will help in the stage of medical registration before the national health authorities.

Definition of Technical Considerations for Equipment Design

The final design of the technical characteristics of the medical equipment to be developed is characterized by the requirements of the nature of the equipment, added to the requirements of the innovation to be developed and added to the technical requirements of the commercial equipment taken as reference.. All these technical characteristics must be aligned with the regulations on the classification of medical equipment, evaluated by risk analysis and classification by the FDA.

RESULTS

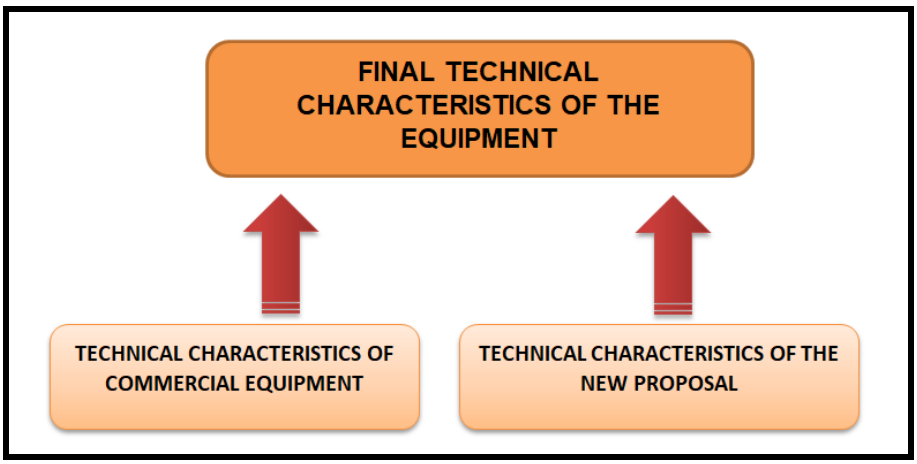

Figure 6: Design of the Technical Characteristics of the Medical Equipment.

Among the results obtained in this research, the recommendations on the study of technical definitions are considered, considered as the starting point in the design of medical equipment. The definition of medical equipment that is recommended as good medical equipment design practices are the characteristics determined by the commercial equipment that has obtained authorization for sale and clinical use, as well as the new requirements according to the nature of use, taking into consideration the level of risk and current regulations on the equipment to be developed. Below is a picture representing the choice of technical requirements.

Another important characteristic in the design of medical equipment is the risk analysis that is linked to the type of medical equipment according to the FDA classification and its corresponding level of risk that is natural due to the way the medical equipment works.. Figure 7 shows the graph where it is indicated by the risk, the classification according to FDA and its corresponding level of risk that may be generated.

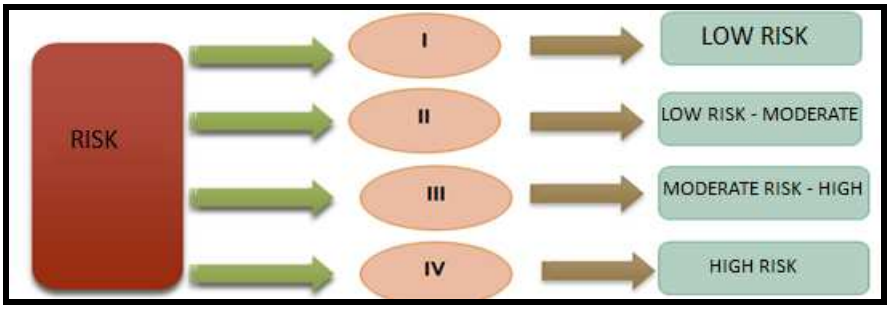

Figure 7: Analysis of the Level of Risk According to the Classification of the Medical Team.

In compliance with the regulations that regulate the registration, operation and proper use of medical equipment, they must be considered, if it is desired that a design of medical equipment can be marketed and can be used in the clinical field, as established the regulations to be met and how in the design stage must be considered. In compliance with the regulations, the possible tests to be carried out must be considered, in addition to the level of the test, the level of compliance and some guidance to be able to comply with the development of the test, as well as the respective compliance, as stated presented in the following figure.

Table 1: Analysis of the Tests to be Considered in the Design Stage

Immunity Test	Test Level	Level of Compliance	Advice and Guidance
Test description	Test level description	Description of the level of compliance	Orientation description

CONCLUSIONS

Once the design of the temperature control system for the adiabatic chamber of the energy laboratory has been completed and after having performed the necessary tests, the following conclusions have been reached:

The conclusions that are reached at the end of the investigation, after presenting how medical equipment is classified according to the FDA and what levels of risks are presented in each of them, added to the requirements that must be met, is very important because it will help to researchers from many countries who are with the intention of being able to design and build medical equipment according to the needs of each country.

In each country the pandemic is causing evidence of many weaknesses in the health system and with emphasis on the medical equipment parquet, added to it the technological dependence that we have with the countries that manufacture medical equipment, limit the action of the strategies For this reason, many initiatives arise in order to build equipment that they consider necessary to be able to mitigate the effects that the COVID-19 pandemic is causing. Therefore, the regulations in force must be considered at the time that it is decided to build medical equipment, so that it can have the possibility of obtaining authorizations for manufacture, marketing and use in the clinical field.

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