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A Comparative Study of Medical Device Regulation in US and India

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Abstract

Articles, instruments, apparatuses, or machines used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose, make up the medical technology industry (commonly referred to as medical devices).

Medical supplies India's medical market is one of the top twenty in the world. By 2025, it is estimated to be valued $5.2 billion. India produces very little medical equipment and currently imports more than 70% of its medical supplies. In India, medical devices were governed by The D&C Act is a federal law that regulates the sale of drugs and cosmetic of 1940, which included specific medical device laws. India Medical Device Rules 2017, which are new medical regulations in India, were issued to fill this hole by the CDSCO. There are many doctors and pioneers in the field.

On the other hand, the United States continues to be the world's largest medical device market, with $156 billion in sales. It is estimated to reach $208 billion by 2023. In 2018, the United States exported $43 billion worth of medical equipment in key product categories specified by the Department of Commerce.

Keywords: Medical device, FDA, CDSCO, Regulatory requirement, D&C Act, USFDA

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1. Introduction

The center for Devices and Radiological health protects Americans with protects to make sure that medical devices are safe and radiation – pouring out by-products are reasonably safe to use and that they work as expected. Medical gadgets are used for a variety of purposes. The FDA was granted the authority to regulate devices in 1976 Medical Devices changes of the food drug and cosmetic (FD&C) Act passed by congress before now the medical device adulteration , The FDA had the authority to file accusations of adulteration or disbandment, but not to request premarket testing or review or approval. (1) Subsequent lows most recently, the United States Food and Drug Administration medical devices' authority. The United States FDA is the U.S. Food and Drug Administration. Salutatory mission the FDA regulates all medical devices market in the United States. In November 2018, news broke of hundreds of patients harmed due to a number of medical device and implants. A recent global investigation into business of medical devices spans 36 countries and includes thousands of reports of problems relating to devices approved for use in patients. (2) In India, the "Central Drug Standard Control Organization" (CDSCO) under "Directorate General of Health Services" in "the Ministry of family and health Welfare, "Government of India is the main "National Regulatory Authority" (NRA) which is liable for the enforcement and implementation of the MDR-2017, which With immediate effect, it came into force. Through the Gazette of Indian notification "G.S.R. 78(E)", dated 1st January 2018 by the ministry of family and health welfare, government of India. (3) Medical devices play a high-priority part in the lives and health of multiplicity of persons worldwide. From day by day folk's Patients and the general public rely on regulators to ensure that lawfully sold medical devices are safe and effective, from simple oral thermometers to complicated implantable devices like deep-brain stimulators secure and efficient. (4)

2. Objective

Our objective is to evaluate the authentication and the regulatory approval of medical devices in countries such as US & India and to understand the outcomes of current

trends on the approval process. To conducting the comparative study it is clearly represented that to validate a license for sale and distribution purpose, ministry of health and family welfare , India has generated online portal for each individual application process registration. According to the device classification from Class A (LOW Risk) to Class D (High Risk), license compliance takes place.

Acquiescence of license from US is comparatively time consuming process; Class I Device has to comply with the QSR, While Class II & III COMPLY with QSR & QMS. Pre Submission and 510(k) application are also required to receive the approval of medical device from USFDA

3. India CDSCO Medical Device Regulation

As medical devices deal with the health and safety of the patients, their manufacturing is done in a strictly regulated nature, and they fulfill stringent regulatory requirements and guidelines. While the drug regulations in India are well institute for declare, a well-defined regulation for medical devices was missing for long. Even so, the Indian regulatory regime for medical devices has not long ago been very active. Medical Devices and Diagnostics part of Central Drug Standard Control Organization (CDSCO) has event structured medical device regulations. (5)

Documents Required for Clinical Trial Application of Notified Medical Device

Covering Letter

Dully filled application in form 44, appeal for allotment of consent to shipped or manufactures a new drug or undertake clinical trial.

i. Particular of subject Device

- Generic Name
- Brand Name
- Composition of device
- Specification /standard of device
- Observational and measurable specific of constituents.
- Information on sterility , style or size of the device ,if applicable.
- Physician laboring and promotional literature in English.
- Risk classification.
- Roll of attachment or device to be well used in association· with idea medical device.
- Indication which clinical study is to be carried out.
- Name and address of the person you're writing to the contract manufacturer.
- Regulatory position of the gadget in question specific 5 GHTF Countries that E.U,USA , Japan ,Canada, Australia

ii. Technical data to be given in beyond the application in addition to the application for the subject medical device.

- For all medical device
  a) Biocompatibility
  b) Design analysis data
- For moderate /high risk medical device
  a) For phase I study
  b) For phase II/III

Requisite fee

Delegation of responsibility

Protocol should include following points

a) Title page

b) Contents of the book

- Background and introduction
- Study rationale
- Study objective
- The design of the study
  - The population of the study
  - Subject eligibility

Indian regulatory system

Medical gadgets are classified as pharmaceuticals under India's regulatory system by the Ministry of Health and Family Welfare. In October 2005, the manufacturing of devices came under the control of the Central Licensing Approving Authority. The eleven items included cardiac stents, drug-eluting stents, catheters, intraocular lenses, bone cements, heart valves, scalp vein sets, and other medical devices. To be study drugs and involve other side on March 20, 2009; there were 19 sterile medical devices. This category includes extension tubes, arterial venous fistulas, and spinal needles, as well as volume measuring sets, heart lung packs, and other equipment provisions in this regard. (6)

Future of Medical Device Industry in India

When the particular measurable hardly achievement novel of medical device industry unable build India *self*-sufficient in medical devices, the medical device production is swap because of the new tax organization corroborate by the government. The worldwide medical device industry has cut across 350 billion USD in yearly pay as of 2011.(7) Even the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) and the European Union (EU) standards governing medical device manufacturers are being assessed and amended on a regular basis. (7)

4. USFDA

Regulatory Structure

In the United States, The FDA regulates medical equipment by the core for radiological health and medical devices health in the FDA. The FDA oversees

all aspects of devices regulation, as well as consent and post market surveillance. The FDA is a large governmental office, and the device regulating aspects of the agency was making for the motive of protecting the public's health. (8) The medical device categories that were commercialized in the United States as of The date is May 28, 1976 of passage of medical device legislation .FDA categorized the amendments and allowed them to stay on the market. Medical gadgets that are introduced after May 28, 1976, are categorized. In terms of intended use and technological attributes, the legal market medical devices are compared to lawfully sell medical equipment. (9) The FDA categories devices. If The gadget has been installed one of three regulatory classes depending on its intended use, if the device is intrusive or implanted, as well as the risk the gadget poses to the user.. Although their producers are susceptible to a broad definition regulations, such as registering their name and products with the FDA, Class I devices are those that normally exempt from premarket notice (510[k]) and FDA clearance before being marketed. (10) History in the United States, there is a lot of talk about medical device regulation. The first piece of legislation governing the safety of the public was enacted in the year .The United States Congress passed the Medical Products Act in 1938, primarily as a result of the Great Depression series of dangerous pharmaceutical manufacturing procedures. (9)

History of medical device regulation in the United States

Early ordinance, regulating the guard of medical products was passed by the United States Congress in 1938, primarily as a reaction to a series of unsafe practices in pharmaceutical Consumers were directly harmed as a result of the compounding. The Federal Food, Drug, and Cosmetic Act empowered the US Food and Drug Administration (FDA) to regulate the marketing and sale of pharmaceuticals and medical devices.

1) The official National Formulary, The United States Pharmacopoeia must be acknowledged, as well as any supplements to it.

2) Intended for use in the diagnosis of illness or other issues, as well as the cure, mitigation, treatment, or prevention of disease in humans or animals affecting the structure or function of man's body, or

3) Designed to alter the structure or function of man's body hurting other animals, and which fails to accomplish its basic objectives chemical action within or on the human or animal body. (10)

Guidance Documents Available to the device Industry

The FDA publishes guidance documents that include important information for device manufacturers and often provide extremely specific advice on how to comply with rules. A list of the currently available guidance documents from FDA's ODE can be found on the FDA's website. (11)

Exporting to the United States

The US FDA regulates the sale In the United States; there are a lot of medical gadgets. In the United States, all gadgets are promoted. Have approval by the FDA prior to sale in the United States. A brief history of the US FDA Prior to 1976, medical devices were regulated under the Food, Drug and Cosmetics Act of 1938. (12)

510 (k) Pathway to marketing

A 510 (k) is a premarket notification filed with the FDA to show that the device to be marketed is at least as safe and effective as a legal market device. As previously stated, this is the premarket approval procedure that most class II and some class I drugs must go through before they may be sold device. new medical gadgets continue to a marketed A device that was legally marketed in the United States prior to May 28, 1976, for which no PMA is required, a device that has been reclassified from class III to class II, I, or a device that has been reclassified from class III to class II,The classification has been changed from class III to class II , I, or FDA previously found to be safe. Through the 510 (k) process, they are essentially equivalent. The term "legally marketed" also refers to the fact that. The predicate must not be illegal under the FD&C legislation. Before a device is marketed, it must first be tested. Each submitter must obtain an order from the submitter in the form of a letter. This determines that the gadgets are basically equivalent and declares that they can be used interchangeably be available for purchase in the United States This order "clears" the commercial distribution device Clinical trials can be used to support a significant finding, although they aren't always required. (1)

Three types of premarket notification exist

Traditional 510 (k), special 510 (k), and abbreviated 510 (k), all of which are briefly described below.

***a) Traditional 510(K)*: -** The classic 510(k) can be utilized for any new device or a modification to an already-cleared device (k). It is possible to employ the standard 510(k) technique. All circumstances FDA.

***b) Special 510 (k)* :-**relies on the quality system regulation's (QSR) design control features, which will be described in further depth later in this chapter. The design control process can serve the basis for establishing and clearing the application.

***c) Abbreviated 510 (k)*:-** Device manufactures may choose to submit an abbreviated 510(k) for their specific type of device when.

- A guidance document exists.
- A Special control has been established
- FDA has recognized a relevant consent US standard

Premarket Approval

PMA Is the FDA's scientific and regulatory assessment procedure for evaluating as previously said, as previously said, the safety and effectiveness of class III medical devices? Are those that help to maintain or sustain human life important? Importance in minimizing

human health degradation, or that have the potential to reduce human health deterioration a disproportionately high risk of disease or damage as a result of their ability to do so Use in an emergency reflects life-threatening scenarios in which the patient need rapid medical attention. The physician contacts the devices manufactures facilities providing information to the FDA. In such cases, again the physician directly contacts the manufacture who then facilities the device to the physician cases when the FDA approves a PMA. (11)

Medical Device Establishment Registration and Device Listing

Medical device manufacturers, testers, packers, labelers, sterilizers, and importers are asked to fill out a registration form their facilities, pay FDA registration fees, and list their devices with the FDA. Medical device manufacturers must also assess their medical device establishments with the FDA. Annually, they must update their registration and listing information, as well as renew their registration. FDA fundamentals offer low-cost FDA medical Registration and listing of devices services. We can provide expert advice on all regulatory requirements for medical devices based on our twenty-year experience. Our comprehensive solution will provide you with the assistance you require until you have met the FDA's entire medical device requirement. (13)

5. Development history

The federal government's first participation in food and medicine regulation was limited to imports and hence did not include interstate shipping. As an example, the 1848 Import Drug Act during the Late in the nineteenth century, it became obvious that some to prevent the interstate shipment of undesired food and medications, some type of national legislation was required. The federal government's first regulation of Food and medication shipments was being held up. The US Postal Service's authorities with the passage of the Postal Fraud Act In 1872, laws were enacted. They offered assistance. For mail fraud, there are criminal sanctions, as well as civil fines stated that mail carrying false or deceptive representations could be prosecuted. The Postmaster General will rule it unmailable. Nonetheless, these are Statutes were silent on the subject.as a result of medical gadgets Fraudulent devices grew in popularity. The enforcement of these laws has maintained to this day. In a lecture to the Medical Society of the United States in 1879, Dr. E. R. Squibb The state of New York advocated enacting a federal law to regulate food and medications. It wasn't until the following year that after 27 years, the Food and Drug Administration (FDA) President Theodore Roosevelt signed the Act of 1906 into law after it was introduced in Congress. Legislative deliberations and the Food and Drug Act itself are noticeably absent. (14)

6. Conclusion

The regulation of Medical Device in US, India is different, but in these countries pre-market process & post market process is carried out for the marketing of quality products. In US, the 510(k) process is carried out by the 90% of the manufacturer.

In India the government is expected to develop a regulatory structure leading to a quality product being developed by manufacturers.

The current regulatory structure lacks active participation from the government, Global Harmonization Task Force (GHTF) guidelines can be adopted to improve the sector and focus has to make on clinical studies.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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