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Review Article

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A Review on Approval Process and Regulation of Medical Devices as per US FDA and CDSCO

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Abstract

Regulatory affairs play a significant role in the pharmaceutical industry, it is "the process of gathering, reviewing, and monitoring the existing regulatory environment and creating regulatory plans and gaining a competitive edge for securing regulatory approvals required more than just acquiring facts". A medical device is a treatment instrument that "does not work on or in the human body in a way that is primarily intended by pharmacological, immunological, or metabolic mechanisms". In other words, a medical device is essentially any medical product, not a medicine or biological product. By the Drugs and Cosmetics Act, Central Drugs Standard Control Organization (CDSCO) oversees approving drugs, conducting clinical trials, setting standards for drugs, monitoring the quality of drugs imported into the nation, and coordinating the efforts of state drug control organizations by offering professional advice to ensure uniformity in the application of the Drugs and Cosmetics Act. The US Food and Drug Administration (FDA), a single agency, oversees the regulation of a trillion dollars' worth of goods, or about 25 cents of every dollar spent, including 80 percent of the food supply in the US, all medical devices, and prescription drugs, animal products, cosmetics, and even the production of tobacco products. The FDA's Center for Devices and Radiological Health regulates companies that produce, repackage, re-label, and/or import medical devices sold in the United States (CDRH). Also, CDRH is in charge of overseeing the regulation of lasers, x-ray machines, ultrasound equipment, microwave ovens, and color televisions, among other electronic gadgets that generate radiation for both medical and non-medical purposes. The IMDR, which was published in January 2017 and became effective in January 2018, was produced by the Medical Devices and Diagnostics Division of CDSCO and is a set of structured regulations for medical devices. In February 2020, the "Medical Devices (Amendment) Regulations, 2020" were established, and they became effective in April 2020. The 2020 amendment now includes a new clause called "registration of specific medical equipment."

Keywords: Regulatory affairs, Central drug standard control organization (CDSCO), Food and drug administration (FDA), Medical devices, Medical devices Regulation, CDRH, EMEA, Sugam online portal

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1. Introduction

The pharmaceutical industries are expanding rapidly, and as regulatory affairs play a significant role in the pharmaceutical industry, the need for regulatory affairs specialists to meet the current needs of businesses for the global competition is also increasing. A regulatory affairs professional serves as the source of link between the pharmaceutical industry and international governing bodies like the Central Drug Standard Control Organization (CDSCO), the U.S. Food and Drug Administration (US FDA), Health Canada, Therapeutic Goods Administration (TGA), etc. The protection of human health, assurance of the efficacy, safety, and quality of medications, and assurance of the appropriateness and authenticity of product information are the objectives of the regulatory affairs professional. (1) As there is no uniform definition for regulatory affairs, It can be said that Regulatory affairs is "the process of gathering, reviewing, and monitoring the existing regulatory environment and creating regulatory plans and gaining a competitive edge for securing regulatory approvals required more than just acquiring facts". (2)

The organizational structure of pharmaceutical companies includes the department of regulatory affairs, which plays a key role. They communicate internally at the intersection of pharmaceutical development, production, marketing, and clinical research. Every stage of the creation of novel medicines as well as the post-marketing surveillance for approved medicinal goods is actively monitored by regulatory affairs. (1)

The protection of human health is the primary goal of regulatory affairs in the pharmaceutical sector. Many

actions are encouraged by current legislation to guarantee the quality, safety, and efficacy of pharmaceutical products. All pharmaceutical products are invented, designed, and tested by medical researchers and other specialists and, they make sure it receives country-specific health authorities' approval. (2) A regulatory affair is a special collaboration between internal industry departments and regulatory organizations that begins with the ideation of the product that will be created by that industry and ends with its marketing. It is a crucial and noticeable aspect of the development of pharmaceutical products. The development of generic medications is also an integral part of the regulatory affairs department. (3)

Many catastrophes occurred in the 1950s because of staff members' errors in judgment during production and some deliberate additions of adulterants into pharmaceutical products, which resulted in patient deaths. Following numerous events, the regulatory organization implemented new laws and regulations that enhance the item's quality, safety, and effectiveness. Additionally, this has led to tougher guidelines for Good Manufacturing Practices (GMP) and Marketing Authorization (MA) (GMPs). (1)

Responsibilities of the RA Department

Regulatory affairs professionals offer strategic and technical direction to the R&D department, Production, QC departments, etc. from the very beginning of a product's development, greatly enhancing the commercial and scientific success of a development program and the business as a whole. (1) The process of creating a novel medicine can take years and includes the identification of compounds, nonclinical toxicological research, early clinical trials, and thorough pivotal studies. Once an applicant has presented this substantial body of data, the Health Authority's review of the marketing authorization application is the penultimate step before the regulatory clearance. Because of this, each stage of the approval process for drugs is overseen by a particular regulatory body in that area. (4)

Drug development optimization should be prioritized by the regulatory affairs professional (RAP) during the process' planning stages (being proactive), as opposed to the process' conclusion, when the RAP is frequently compelled to take the unfavorable positions of "making do with what you have," "putting pressure on the Food and Drug Administration," issuing ultimatums to the division or office directors, and writing letters of protest to the Food and Drug Administration (FDA). (5)

Major Regulatory bodies in the world

Table 1. Different regulatory authorities around the globe (1)

Country	Regulatory body	Year	Director
USA	Food and Drug Administration	1906	Mr. Robert M. Califf M. D
India	Central Drugs Standard Control Organization (CDSCO)	1940	Mr. Ziley Singh Vical
Australia	Therapeutic Goods Administration (TGA)	1989	Dr. Cheryl McRae
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)	2003	Dame June Raine DBE
Canada	Health Canada	1993	Theresa Tam
Europe	European Medicines Agency (EMEA)	1995	Ms. Emer Cooke

The Central Drugs Standard Control Organisation (CDSCO)

The Central Drug Control Organisation (CDSCO) carries out responsibilities delegated to the Central Government under the Drugs and Cosmetics Act. Six zonal offices, four sub-zonal offices, thirteen port offices, and seven laboratories are under the management of CDSCO. Federal and state regulators now have particular responsibilities for the regulation of pharmaceuticals and cosmetics thanks to the 1940 Drugs & Cosmetics Act and the 1945 Guidelines. By regulating the use of medications and cosmetics, it intends to consistently apply the Act's and its Rules' requirements to safeguard patients' safety, rights, and well-being. CDSCO is constantly working to improve transparency, accountability, and standardization in its services to guarantee the safety, efficacy, and quality of the medical products produced, imported, and distributed in the country. (6)

According to the Drugs and Cosmetics Act, CDSCO is responsible for approving drugs, carrying out clinical trials, establishing drug standards, checking the quality of drugs imported into the country, and coordinating the work of state drug control organizations. CDSCO also provides expert guidance to ensure that the Drugs and Cosmetics Act is applied consistently across the board. Also, the CDSCO and state regulators share responsibility for licensing some specialized categories of crucial medications, blood and blood products, intravenous fluids, vaccinations, and sera. (6)

Major functions of CDSCO

As the Central License Approving Authority, the CDSCO headquarters also serves as the site for meetings of the Drugs Consultative Committee (DCC) and Drugs Technical Advisory Board (DTAB), as well as regulatory authority over the importation of drugs, approval of new pharmaceuticals and clinical trials, and approval of some licenses.

Some of the basic functions of CDSCO:

- Clinical trials and new drug approval.
- Import licensing and registration.
- Modifications to D and C Act and rules.
- Prohibition of cosmetics and narcotics.
- Evaluation of novel medications.

- Issuing personal licenses, NOCs for export, and test licenses.
- License approval for rDNA products, LVPs, vaccines, and blood banks. (6)

U.S Food and Drugs Administration (FDA)

The US Food and Drug Administration (US FDA), a single agency, oversees the regulation of a trillion dollars' worth of goods, or about 25 cents of every dollar spent, including 80 percent of the food supply in the US, all medical devices, and prescription drugs, animal products, cosmetics, and even the production of tobacco products. (7)

The FDA's role in advancing public health includes accelerating research and development efforts that make medical products more effective, safe, and affordable as well as helping the general public get the precise, science-based information they need to use medications and foods to maintain and improve their health. The FDA is also responsible for regulating the manufacture, advertising, and distribution of tobacco products to protect the general public's health and reduce the prevalence of tobacco use. The FDA plays a critical role in the country's ability to fight terrorism. FDA performs this obligation by ensuring the security of the food supply and by promoting the creation of medical devices to address both deliberate and unintentional emerging risks to the public's health. The FDA's regulatory authority is fairly broad Some other federal agencies' responsibilities are closely tied to those of the FDA. For consumers, locating the appropriate regulatory agency can be challenging and frustrating very regularly. Here is a list of the conventionally recognized product categories that the FDA regulates. (8)

- Food
- Drugs
- Biologics
- Medical devices
- Electronic products that give off radiation
- Cosmetics
- Veterinary products
- Tabaco products
- Alcohol
- Advertising
- Pesticide
- Water (8)

The department that is always changing and expanding—as well as the one that is least affected by mergers and acquisitions, is regulatory affairs. Within companies, regulatory affairs sections are expanding. Some companies also opt to outsource or delegate regulatory matters to outside service providers due to the shifting resources required to satisfy regulatory standards. The success of a product and, by extension, the company depends on the decrease in the time needed to reach the market in today's competitive environment. The effective application of legal requirements and regulations will boost a company's economic development while also enhancing public safety. (1)

Medical devices

What are medical devices in regulatory affairs?

A medical device, as opposed to a medicine, is a treatment instrument that "does not achieve its primary intended action in or on the human body through pharmacological, immunological, or metabolic mechanisms". In other words, a medical device is essentially any medical product, not a medicine or biological product. For those who create and produce novel medical technologies, the formal definition is crucial since it establishes whether a given innovation qualifies as a medical device. (9)

Any instrument, apparatus, appliance, software, implant, reagent, material, or other items that are intended to be used by a manufacturer for a human being for one or more of the following specific medical purposes are referred to as "medical devices," by [Article 2(1) MDR] the definition of a medical device: Investigation, replacement, providing information through the in vitro analysis of human body specimens, such as donated organs, blood, and tissues, which does not achieve its primary intended action in or on the human body through pharmacological, immunological, or metabolic means; diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability; Equipment for controlling or assisting conception and items specifically designed for cleaning, disinfecting, or sterilizing the devices mentioned in Article 1(4) and those mentioned in the first sentence of this point shall also be considered medical devices. (10)

Classification of medical devices

Today, a vast range of medical equipment is in use. They range from massive imaging systems the size of rooms that weigh several tonnes to tiny, barely 2-mm-long ophthalmic implants that only weigh a few grams. Most in vitro diagnostics (blood and urine tests) are governed as medical devices as well. Most devices are described in the table below using two of their properties. (7)

Table 2. Devices and their properties (7)

Functions	Form
Therapeutic	Durable
Monitoring	Implantable
Diagnostic	Disposable

Comparison of Indian and US regulations for medical devices

Compared to US standards, Indian regulations are far more recent and in their infancy. However, each of them has its own rules and regulations that must be observed.

- According to the risk they pose, the US FDA has divided medical devices into three classes, and the class they belong to determines how they should be registered. On the other hand, in India, medical devices are either recognized or not according to CDSCO rules, depending on their utility rather than their safety. Devices that

are notified must be registered, but non-notified devices may or may not need to be registered.

- If a product is registered in the US or Europe, clinical studies are not necessary for India; nevertheless, if the predicate is not available on the US or European market, clinical trials are necessary. Clinical trials are required in the US if there is no predicate listed on the US FDA list.
- Both countries permit manufacturers to choose agents as their representatives. (11)

2. US FDA Medical devices regulation

The FDA's Center for Devices and Radiological Health regulates businesses that create, repackage, relabel, and/or import medical devices sold in the United States (CDRH). Also, CDRH is in charge of overseeing the regulation of lasers, x-ray machines, ultrasound equipment, microwave ovens, and color televisions, among other electronic gadgets that generate radiation for both medical and non-medical purposes. (8)

A significant portion of healthcare and health-related products are medical devices. The Food and Drug Administration (USFDA) regulates all medical devices manufactured and distributed in the US. Certain rules are designed to guarantee the effectiveness and safety of every medical device that is produced and marketed. More than 18 000 businesses generate estimated 190 000 different medical devices that are subject to US Food and Drug Administration regulation, according to estimates from 2017 and 2018. The US spent an estimated $173 billion on medical equipment in 2019, up from an estimated $36 billion (in 2019 currency) in 1983. (9)

Medical devices are being utilized more and more in inpatient treatment. Additionally, a lot of patient consumers utilize the Internet to research new medical innovations and developing technologies, some of which may not yet have US approval for usage. Physicians need to be aware of the regulations governing the allowed and prohibited uses of medical devices, the pre-market evaluation and approval procedures, and the post-market monitoring of devices. (12) Part 21 of the Code of Federal Regulations (CFR) formalizes the initial regulatory standards for devices in the US, which were drawn from the 1976 law. A quality assurance program called Good Manufacturing Practices (GMP) was established in 1978 to regulate the production, distribution, storage, and installation of medical devices. (9)

Different branches of the US Food and Drug Administration are responsible for overseeing the regulation of pharmaceuticals and medical devices in the country (FDA). Drugs and medical devices have different modes of action, although having identical definitions. Both are goods that are advertised, utilized, or labeled for diagnosing illnesses or other ailments, or for curing, reducing, treating, or preventing diseases. However, a device does not serve its intended purpose by acting chemically on the body, within it, or because of being digested by it. Although federal standards governing labeling, promotion, production, and post-marketing surveillance must be followed by both pharmaceuticals and medical devices, The FDA's premarket review and approval procedures differ from one another. FDA clearance and prescription status of a device do not always imply that the product's efficacy and safety have been established through clinical trials have been carried out. (13)

2.1 Classification of medical devices: (according to FDA regulations)

Medical equipment can be divided into three categories.

Class I: Class I devices are the simplest equipment, with the fewest dangers, and those subject to broad rules. Class, I devices make up most medical device varieties. Brushes, oxygen masks, and irrigation syringes are a few examples of class I devices.

Class II: There are a lot of intermediate-risk devices in class II. Before commercialization, the manufacturer must receive approval of a 510(k) premarket notice to market a class II device in the US. Each year, the US market is cleared for around 4,000 class II products.

Class III: The majority of class III devices need PMA certification before being marketed in the US. These are gadgets that aren't comparable to any class II gadget. They are frequently cutting-edge technologically. (7)

The design, development, and marketing of novel medical technology are significantly influenced by medical device regulation. Successful medical device innovation thus requires a thorough understanding of the numerous regulatory requirements and their practical application. Many regulations are to be considered while the development of different types of medical devices is regulated by particular regulatory authorities. (9)

2.2 History of FDA medical devices

This historical background served as the impetus for the 1976 Medical Device Amendments to the 1938 Food, Drug, and Cosmetic Act in the United States. By 1978, when the rules mandated by this new law went into full effect, the Food and Drug Administration (FDA) was reviewing the development and clinical testing of medical devices. The FDA had to assess a lot of new devices before they could be sold in the US, either through the 510(k) premarket notification procedure or the premarket approval (PMA) process. The 1976 Amendments have undergone numerous revisions over the years and now also encompass the creation of devices. The classification of medical devices, the creation of premarket submissions, clinical research on medical devices, and manufacturing rules are all introduced in this chapter. (14)

Before 1902, the American government was not involved in the regulation of drug use. As a result of each drug having a descriptive or patent name, many of the readily available drugs were referred to as "patent medicines." No laws, rules, or requirements existed to any appreciable level, notwithstanding The United States Pharmacopoeia (USP), the country's first official compendium, which was created in 1820. The USP

established strength and purity criteria that could be used by doctors and pharmacists who need centralized testing of existing procedures for extracting, preparing, and otherwise utilizing medicinal components. (15)

The Drug Importation Act was the first American medicine law, though, and it was passed in 1848 after the discovery of contaminated quinine, an antimalarial drug, had a major negative impact on American troops stationed in Mexico. This rule mandated laboratory examination, the holding of unsatisfactory medications, and even their destruction. Later, in 1902, the Virus, Serum, and Toxins Act (Biologics Control Act) was passed as a reaction to diphtheria antitoxin produced by a little laboratory in St. Louis, Missouri, which was tetanus infected. The contaminated serum caused the deaths of ten schoolchildren. For purity or potency, there were no national standards in effect yet. The act gave the Public Health Service the power to license and oversee the interstate distribution of biological items intended to cure or prevent disease, such as serum, vaccinations, and related biologic products. (15)

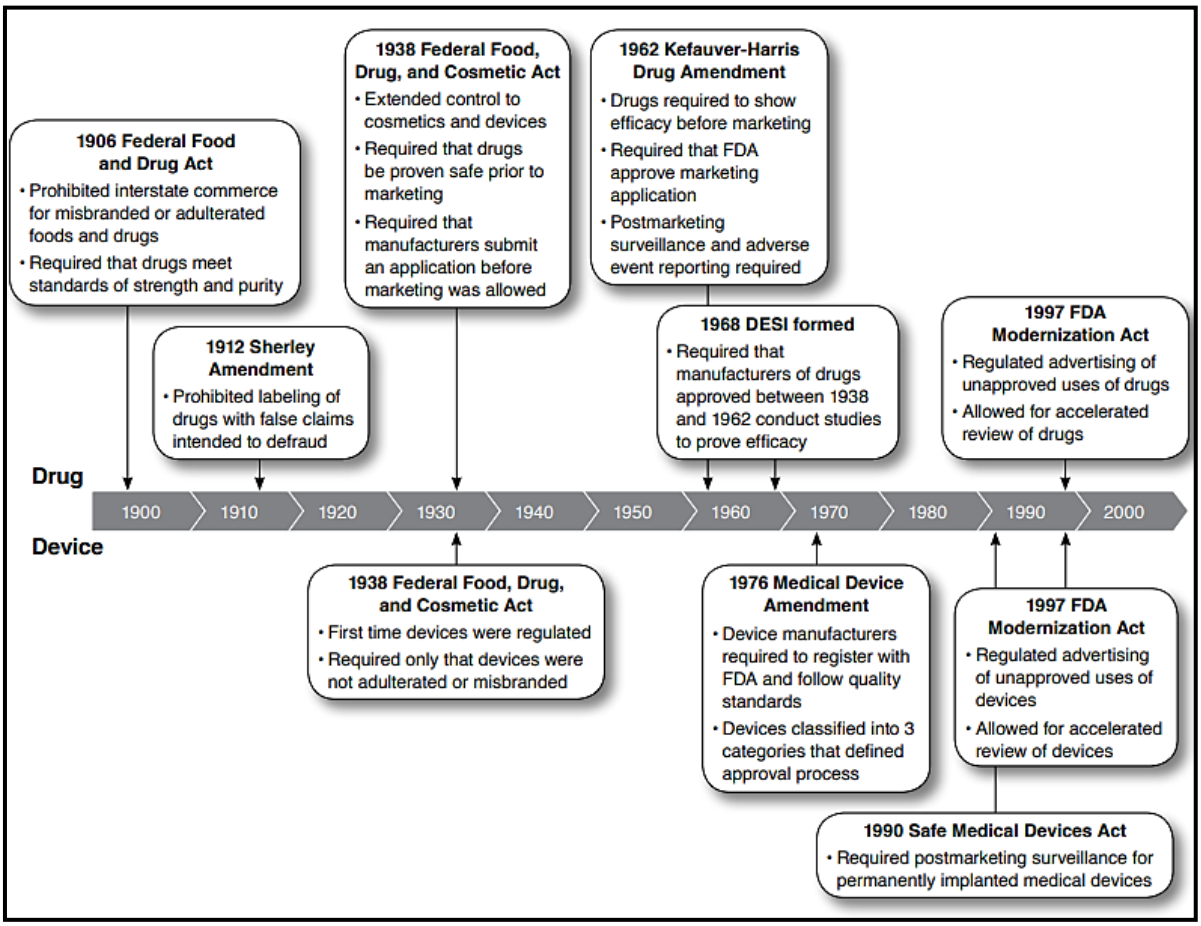

Figure 1. History of significant drug laws and medical device restrictions in the United States. (15)

2.3 Medical Devices Approval Process in the U.S

A medical device developer usually faces more than one regulatory route to the US market, unlike the pharmaceutical regulatory system. If a device, such as software that analyses magnetic resonance imaging (MRI) pictures, solely evaluates the size or volume of anatomical structures, it is classified as a class II 510(k) product. The indication for use is crucial in determining the regulatory process since the software would be classified as a class III PMA device if it detected problems or offered diagnostic data. A device developer may decide to "start small" and begin FDA interactions with a less complex 510(k) before moving on to the more difficult PMA after a revenue stream is established and accumulating expertise. In general, both the business additionally, the FDA favor 510(k) reviews for medical devices. This procedure saves the FDA's review resources while providing the sector with timely reviews. (15)

All medications and medical equipment are known to involve some level of risk. In actuality, the United States removes about 1-2 medications and 6–8 medical devices per year due to worries about safety in the market. The FDA is tasked with examining the efficacy and safety of medications and medical devices and weighing the advantages and disadvantages of each one. However, the FDA approval procedures utilized for medications and medical equipment might vary greatly. (13)

2.4 Steps for marketing approval in the USA:

a) Classification of medical devices.
b) Establish a quality assurance program (GMP Requirements).

c) Clinical Trial Data Submission, Where Applicable (Investigative Device Exemption) (IDE).
d) Submitting a 510(k) Premarket Notification Premarket Approval Application for marketing approval.
e) A PMA approval letter or FDA 510(k) clearance letter.
f) A manufacturing facility's quality system is inspected by the FDA.
g) FURLS System listing for medical devices.
h) Registration of an establishment in the FURLS system). (16)

3. CDSCO Medical devices regulation

Although India's medication regulations have been in place for many years, there hasn't been a clear set of guidelines for medical devices. Nonetheless, the Indian regulatory system for medical devices has been highly active recently. The Medical Devices and Diagnostics Division of CDSCO have created structured regulations for medical devices which is IMDR, which was published in January 2017 and took effect in January 2018. The "Medical Devices (Amendment) Regulations, 2020" were created in February 2020 and went into effect in April 2020. A new provision, "registration of certain medical equipment," was made to the 2020 amendment. The introduction of the IMDR and other accompanying recommendations has allowed India to take its first step towards improved patient safety regarding medical devices, even if many medical devices remain to be regulated as pharmaceuticals under the Drugs and Cosmetics Act of 1940. Future revisions of the IMDR can concentrate on closing the gaps that would have brought these laws into line with the MDR and IVDR of the EU, which are the most recent global regulations for medical device performance and safety. (17)

Substances used for in vitro diagnosis- Surgical dressings, bandages, staples, sutures, ligatures, blood, and blood component collection bags with or without anticoagulant are all included under this sub-clause. (ii) chemicals such as pesticides, disinfectants, and mechanical contraceptives (condoms, intrauterine devices, and tubal rings) are notified under subclause devices that receive periodic notifications under subclause (ii). Section 3 of the 1940 Drugs and Cosmetics Act, subsection (iv). Under the 1940 Drugs and Cosmetics Act and the 1945 Rules promulgated thereunder, only notified medical devices are now controlled in India as drugs. (6)

3.1 Functions of CDSCO medical devices regulation

a) Grant of Certificate of Registration for a Notified Body for audit of Class A and Class B Medical Devices: For the issuance of a registration certificate in MD 2, a notified entity recognized by a National Accreditation Body (established by the Central Government) may apply to CLA in MD 1.

b) Grant of Import Licence: The applicant must submit an MD-14 application through the Sugam online portal to be granted an MD-15 import license for medical device imports.

c) Grant of license or loan license to manufacture for sale or distribution: To get a manufacturing license, a loan license to manufacture goods for sale, or a distribution license for class C or class D in MD-9 and MD-10, the applicant must apply in MD-7 and MD-8 on the Sugam online portal.

d) Grant of test license to manufacture for test, evaluation, and clinical investigations: To get a license in MD-13 to produce medical devices for clinical studies, tests, evaluations, examinations, demonstrations, or training, the applicant must apply in MD-12 using the Sugam online portal.

e) Grant of test license to import for test, evaluation, and clinical investigations: To get a license to import medical devices for use in clinical research, tests, evaluations, examinations, demonstrations, or training, the applicant must submit an MD-16 application through the Sugam online portal.

f) Grant of license to Import investigational medical device by Government hospital or statutory medical institution for treatment of patient: The Central Licensing Authority may approve the import of a small quantity of an investigational medical device if it is approved in the country of origin and the application is made by a medical officer through the medical superintendent of a government hospital or a statutorily recognized institution for the treatment of a patient with a life-threatening illness, a condition that results in serious permanent disability, or a condition that requires therapy for an unmet medical need.

g) Permission to conduct a clinical investigation of an Investigational Medical Device: The applicant must submit an MD-22 application using the Sugam web portal to be approved for the MD-23 clinical trial of the investigational medical device.

h) Permission to conduct a clinical performance evaluation for a new in vitro diagnostic medical device: To request approval to undertake a clinical performance evaluation of a new in vitro diagnostic medical device in MD-25, the applicant must apply MD-24 through the Sugam online portal.

i) Permission to import or manufacture a medical device that does not have its predicate device: After completing its clinical investigation, the applicant must apply Form MD-26 via the Sugam online portal to the CLA for authorization to import or manufacture medical devices without a predicate medical device.

j) Permission to import or manufacture new in vitro diagnostic medical device: The applicant

must apply in MD-28 on the Sugam online portal for approval to import or manufacture a new in vitro diagnostic medical device in MD-29 for sale or distribution.

k) Registration of Medical Device Testing Laboratory: To award registration in MD-40 to a medical device (MD) testing laboratory for a test or evaluation on behalf of the manufacturer, the applicant must submit an MD-39 application through the Sugam online portal.

l) Creation of FAQs and guidelines for important tasks.

m) Handling of requests for domestic medical device producers to receive free sale certificates.

n) Processing of the Market Standing Certificate and Non-Conviction for Medical Devices applications.

o) Not of Standard Quality (NSQ) Verification Complaint.

p) Periodically updating the list in accordance with the Classification of Medical Devices.

q) Modifications made to medical devices after approval.

r) The committee of MD experts' composition.

s) CLA/SLA inspect the manufacturing site for QMS compliance.

t) Activities aimed towards enhancing technical management capacity.

u) Writing and submitting responses to RTIs, clarification requests, NOCs, and port office inquiries.

v) Supplying an applicant with clarity regarding the product's regulatory standing. (6)

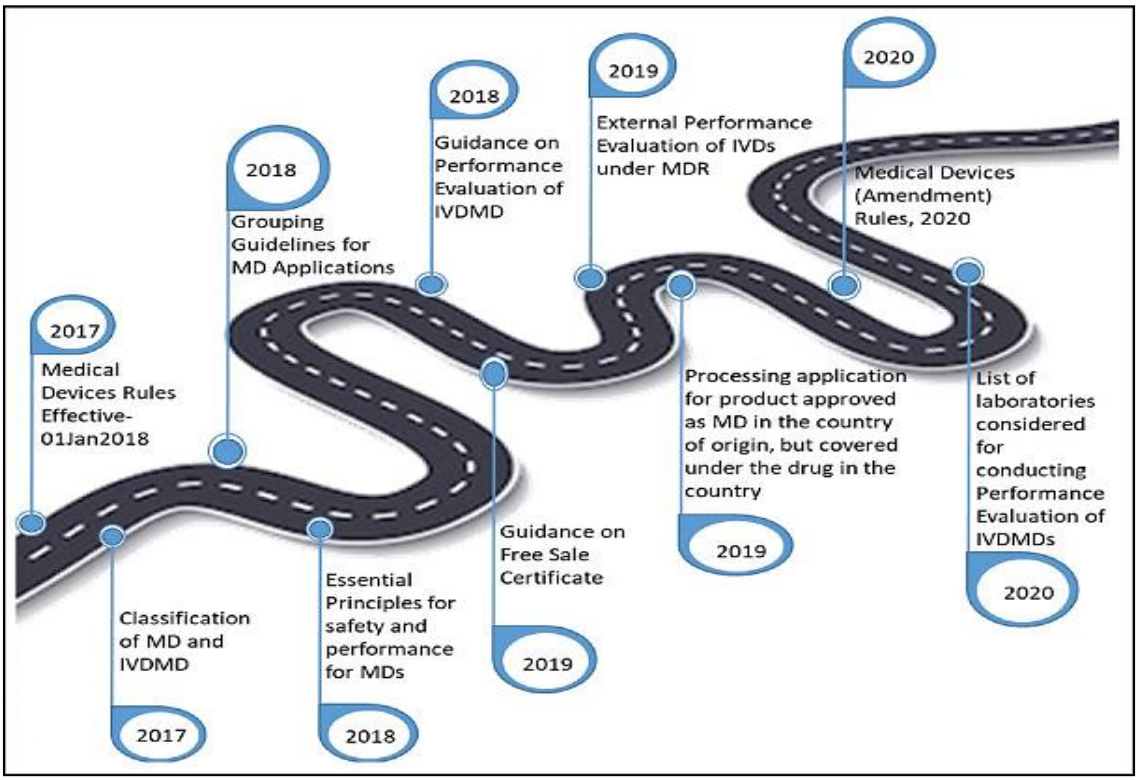

Figure 2. Indian medical device regulations road map In vitro Diagnostic Medical Device (IVDMD) (18)

3.2 History of CDSCO Medical Devices

In the past, imports dominated the Indian market for medical devices. 75-80% of India's medical device imports came from nations like the US, China, and Germany. The creation of highly advanced, technologically driven medical gadgets was pioneered by economically developed nations. Innovation in manufacturing within domestic industries would have reduced the importation of medical devices. The "Made in India" campaign was launched by the GOI in September 2014 to transform India into a global manufacturing hub and expand its market. The Indian government has approved the creation of four medical device parks in the states of Andhra Pradesh, Telangana, Tamil Nadu, and Kerala in support of the "Made in India" project. These parks would provide high-quality goods for treatment and diagnostics at competitive prices. To ensure that enterprises have the necessary infrastructure, these parks are necessary. The creation of a medical device park will reduce import expenses and make standard testing facilities easily accessible. (19)

A National Medical Equipment Promotion Council was established by the government in January 2020 to encourage the domestic production of premium medical devices and increase investment in the field. The Department of Pharmaceuticals released an updated notification under the Public Procurement Order on March 25, 2021. (PPO). The 19 medical products listed in the revised PPO rules are meant to encourage domestic medical device production and reduce import

costs by about Rs. 4,000 crores ($538.62 million). The Legal Metrology Act (Packing Regulations 2011) requirements for nebulizers, oxygen concentrators, and oxygen canisters were loosened in April 2021 by the government, making it simpler to import these products. To certify the quality, safety, and efficacy of medical devices, the Quality Council of India (QCI) and the Association of Indian Manufacturers of Medical Devices (AiMeD) developed the Indian Certification of Medical Devices (ICMED) 13485 Plus system in June 2021. (19)

The Global sales of medical devices have grown at a compound annual growth rate (CAGR) of 3.5 percent since 2015 and are expected to reach $456.8 billion in 2020. From $456.9 billion to $442.5 billion in 2020, the market decreased by 3.2 percent in 2019. Government-imposed global siege disrupted the supply chain, which led to the demise of the medical equipment business. As the market for ventilators and other medical equipment grew, the growth rate recovered to 6.1 percent CAGR from 2021 to reach $603.5 billion in 2023. (19)

3.3 List of medical devices (CDSCO):

Table 3. List of medical devices in India (6)

Sr. No	Name of the devices	Notification number	Date of notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
2	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
3	Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
4	In vitro Diagnostic Devices for HIV, HBsAg, and HCV	GSR 601(E)	27-08-2002
5	Cardiac Stents	S.O. 1468 (E)	06-10-2005
6	Drug-Eluting Stents	S.O. 1468 (E)	06-10-2005
7	Catheters	S.O. 1468 (E)	06-10-2005
8	Intra Ocular Lenses	S.O. 1468 (E)	06-10-2005
9	I.V. Cannulae	S.O. 1468 (E)	06-10-2005
10	Bone Cement	S.O. 1468 (E	06-10-2005
11	Heart Valves	S.O. 1468 (E)	06-10-2005
12	Scalp Vein Set	S.O. 1468 (E)	06-10-2005
13	Orthopedic Implants	S.O. 1468 (E)	06-10-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	06-10-2005
15	Ablation Devices	S.O. 237(E)	25-01-2016

3.4 Medical devices approval process in India

Through a specialist division known as the Medical Device and Diagnostics Division, CDSCO, of the Ministry of Health and Family Welfare, the Indian government regulates medical devices. Only a small number of Notified Devices-Medical Devices and Diagnostic Kits-are subject to regulation under the Central Licensing Approval Authority (CLAA) scheme for manufacture, import, sale, and distribution. The Central Licensing Authority is the Drug Controller General of India (DCGI). (16)

The federal and state governments jointly manage the regulation of Notified Medical Devices. The manufacturing, import, distribution, and sale of medical equipment are all activities that, depending on the legal framework in place, require licenses or approvals. Under the 1940 Drugs and Cosmetics Act and its 1945 Rules, the import, production, sale, and. In addition, the following goods are controlled as "drugs" under the Drugs and Cosmetics Act and its implementing rules, even though they are classified as "medical devices" in their country of origin. This clause is unclear and at odds with the Harmonized Standards for Medical Devices. The responsible State Drug Licensing Authority is the only entity that controls the manufacture of certain products for sale. (16)

3.5 List of requirements listed in:

CDSCO/MD/GD/CLAA/01/00 for the Issue of License in Form-28 for the Manufacturing of Medical Devices in India.

- Covering Letter
- Authorization Letter
- A duly filled Form-27
- Requisite Fee (License fee Rs. 6000/- and Inspection fee Rs. 1500/-)
- Constitution Details of form
- Approved Manufacturing Premises Plan/Layout
- Full Details of competent and regular technical staff

• Site Master File (SMF)

• Specific Environmental Requirements

• Device Master File

• Details of Standards

• Promotional literature, package insert, device label, etc.

• ISO 13485:2003 Certificate (if any), CE mark (if any), any other approval (if any). (16)

There are six key steps involved in registering medical equipment in India (Figure 1), and they are as follows:

a) Choosing whether the product needs to be registered.

b) Appointing an authorized Indian representative

c) Submitting the Form 40 regulatory dossier

d) Marketing

e) Getting an import permit on Form 10

f) Getting a Form 41 registration. (11)

3.6 Marketing of medical devices in India

The product can enter the Indian market once the registration certificate and the import license have been issued. Any changes, adverse incidents, recalls in other nations, etc., shall be immediately reported to the CDSCO by the authorized Indian agent. (11)

Challenges in India's medical devices

Medical device manufacturers are drawn to the Indian market because it relies on imports, but there are also regulatory challenges. The problem is that India's regulatory body is still in its infancy and regulations could be changed quickly, casting doubt on the licensing process. Keeping track of daily news may be a smart idea. (11)

4. Conclusion

The main goal of this review is to comprehend the Central Drug Standard Control Organization of India and the US Food and Drug Administration, the medical devices they utilise, the history of the devices, and the laws. The duties assigned to the Central Government under the Drugs and Cosmetics Act are carried out by the Central Drug Control Organization (CDSCO). Six zonal, four sub-zonal, thirteen ports, as well as seven laboratories, are all part of CDSCO. Medical device regulation in India is carried out by the Ministry of Health and Family Welfare's Medical Device and Diagnostics Division, CDSCO. Whereas the US Food and Drug Administration (US FDA), a single agency, oversees the regulation of a trillion dollars' worth of goods, or about 25 cents of every dollar spent, including 80 percent of the food supply in the US, all medical devices, and prescription drugs, animal products, cosmetics, and even the production of tobacco products. And the FDA's Centre for Devices and Radiological Health regulates businesses that create, repackage, relabel, and/or import medical devices sold in the United States (CDRH). Also, CDRH oversees regulating the use of lasers, x-ray machines, ultrasound equipment, microwave ovens, and color televisions, among other electronic items that generate radiation for both medical and non-medical purposes.

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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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