Medical Device Regulation

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Abstract: **This abstract provides a brief overview of medical device regulations in India, including, advantage of disposable medical device regulations and disadvantage of disposable medical device regulations. this abstract also provides security challenges of medical devices and also include History of medical devices regulations and its overview. Patient care for the practicing physician increasingly relies on medical devices. The U.S. Food and Drug Administration is responsible for the safety and effectiveness of medical devices in the United States. In addition to playing a role in the clinical use of devices, physicians may also participate in their design, production, use, and safety by expressing their need for certain products, by providing practical input and feedback into product design, by participating in device-related research, and by reporting device-related adverse events.**

INTRODUCTION

Medical device means any instrument, apparatus, implement, machine, appliance implant, in vitro reagent or calibrators, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination.

The regulation of medical devices is a vast and rapidly evolving field that is often complicated by legal technicalities. In an attempt to make this complex subject easier to grasp, this guide Present a common framework that integrate, the regulatory system of the five countries or regions with the most advanced medical device regulations. Non-technical language, graphics, tables and memory anchors are used to present an overview of Medical Device safety issues and regulatory philosophy. The guide begins by explaining how safety is risk management issues, and how to optimum safety and performance required co-operation. The term “medical devices” includes everything from highly sophisticated computerized medical equipment down to simple wooden tongue depressors. The intended primary mode of action of a medical device on the human body, in contrast with that of medical products, is not metabolic, immunological, or pharmacological.

Medical device includes everything from simple wooden tongue depressor and stethoscope to highly sophisticated computerized medical equipment according to the world health organization (WHO), A intended for use in diagnosis, prevention, monitoring, and treatment of diseases or other condition. The FDA uses a similar definition, classes of medical devices have been defined differently in for example the U.S., Canada, Europe, or Australia. example for the FDA specialty panels include cardiovascular device, dental, orthopedics device as well as ear, nose and throat devices.

For human being for one or more of the specific purpose of medical device are: -

• Diagnosis, prevention, monitoring, treatment or alleviation of disease

• Diagnosis monitoring, treatment, alleviation of or compensation for an injury

• Investigation, replacement modification, or support of the anatomy or of a physiological processes

• Supporting or sustaining life

• Control of conception

• Disinfection of medical devices

• Providing information for medical purposes by means of in vitro examination of specimens from the human body and which does not achieve its primary intended action in or on the human body pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

The optimum assurance of medical device safety has several essential elements:

• Absolute safety cannot be guaranteed• It is a risk management issue

• It is closely aligned with device effectiveness/performance

• It must be considered throughout the life span of the device

• It requires shared responsibility among the stakeholders

HISTORY OF MEDICAL DEVICE REGULATIONS AND ITS OVERVIEW

The Food and Drug Administration (FDA) is the oldest comprehensive consumer protection agency in the United States. The FDA’s oversight of food and drugs began in 1906 when President Theodore

Roosevelt signed the Pure Food and Drugs Act. Since then, Congress has expanded the FDA's role in protecting and promoting the development of human and veterinary drugs, biological products, medical devices and radiation-emitting products, human and animal food, and cosmetics. In the 1960s and 1970s, Congress responded to the public's desire for more oversight over medical devices by passing the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. In 1982, the organizational units at the FDA that regulated medical devices and radiation-emitting products merged to form the Center for Devices and Radiological Health (CDRH). The chronology below highlights milestones in the history of medical device legislation in the United States. For additional details, please see the text of the individual Acts.

- 1906: Pure Food and Drugs Act (sometimes also called the Federal Food and Drugs Act)
  • Established the precursor to today's FDA
  • Prohibited interstate commerce of misbranded and adulterated food, and drugs
- 1938: Federal Food, Drug, and Cosmetic Act (FD&C Act)
  • Primary statute that authorizes the FDA's regulation and oversight of medical products
  • Extended prohibition of interstate commerce to misbranded and adulterated cosmetics and therapeutic medical devices
  • Authority for factory inspections
- 1944: public health services act
  - Established certification of laboratories
  - Expanded oversight of biologics
- 1968: Radiation Control for Health and Safety Act
  • Intended to minimize exposure to electronic product radiation and intense magnetic fields
  • Created performance standards for radiation-emitting products, such as diagnostic x-ray machines, MRIs, microwave, ultrasound or diathermy devices, UV devices and laser devices

1970: President Nixon established the Cooper Committee

• Chaired by Theodore Cooper, M.D. (then director of the National Heart and Lung Institute) to study the need for medical device legislation

• Recommended that any new legislation be specifically targeted to the devices because devices present different issues than drugs

• Introduced concept of risk-based classifications for medical devices

1976: Medical Device Amendments to the FD&C Act

• Intended to provide reasonable assurance of the safety and effectiveness of medical devices

• Created a three-class, risk-based classification system for all medical devices

• Established the regulatory pathways for new medical devices (devices that were not on the market prior to May 28, 1976, or had been significantly modified) to get to market: Premarket Approval (PMA) and premarket notification (510(k))

• Created the regulatory pathway for new investigational medical devices to be studied in patients (Investigational Device Exemption (IDE))

• Established several key Post market requirements: registration of establishments and listing of devices with the FDA, Good Manufacturing Practices (GMPs), and reporting of adverse events involving medical devices

• Authorized the FDA to ban devices

1977: The Bureau of Medical Devices and Diagnostic Products was renamed the Bureau of Medical Devices

1990: Safe Medical Devices Act (SMDA)

• Improved postmarked surveillance of devices by:

1. Requiring user facilities such as hospitals and nursing homes to report adverse events involving medical devices

2. Authorizing the FDA to require manufacturers to perform postmarked surveillance on permanently implanted devices if permanent harm or death could result from device failure

• Authorized the FDA to order device recalls and to impose civil penalties for violations of the FD&C Act

• Defined substantial equivalence (the standard for marketing a device through the 510(k) program)

• Modified procedures for the establishment, amendment, or revocation of performance standards

• Created the Humanitarian Use Device (HUD)/Humanitarian Device Exemption (HDE) programs to encourage development of devices targeting rare diseases

1992: Mammography Quality Standards Act (MQSA)

• Required mammography facilities to be accredited and federally certified as meeting quality standards

• After initial certification, facilities must pass annual inspections by federal or state inspectors

1997: Food and Drug Administration Modernization Act (FDAMA)

• Created the "least burdensome" provisions for premarket review
• Created the option of accredited third parties to conduct initial premarket reviews for certain devices
• Permitted the use of data from studies of earlier versions of a device in premarket submissions for new versions of the device
• Provided for expanded access to investigational devices
• Established the De Novo program through which novel low-to-moderate risk devices could be classified into Class I or II instead of automatically classifying them into Class III

2002: Medical Device User Fee and Modernization Act (MDUFMA)

• Granted the FDA the authority to collect user fees for select medical device premarket submissions to help the FDA improve efficiency, quality, and predictability of medical device submission reviews
• Enacted the Small Business Determination (SBD) program to permit reduced premarket approval fees for qualifying small businesses
• Created FDA performance goals for decisions on certain premarket submissions
• Established new regulatory requirements for 'reprocessed' devices
• Authorized electronic registration of medical device firms
• Established the Office of Combination Products

2007: Food and Drug Administration Amendments Act (FDAAA)

• Reauthorized the medical device user fee (MDUFA II), including improvements to premarket review times
• Required that all registration and listing be performed electronically
• Required the FDA to establish a unique device identification (UDI) system for medical devices to require device labels to bear a unique identifier

2012: Food and Drug Administration Safety and Innovation Act (FDASIA)

• Reauthorized the medical device user fee program (MDUFA III), including improvements to premarket review times and added shared outcome goals with industry
• Created direct De Novo pathway, permitting the classification of novel, low-to-moderate risk devices into Class I or II (rather than Class III) without first having to submit a 510(k)
• Changed the standards associated with disapproval of an IDE
• Permitted the FDA to work with foreign governments to harmonize regulatory requirements
• Required FDA to provide a Substantive Summary when requested by the holder of the submission for significant decisions
• Expanded the application of the "least burdensome" principles in premarket reviews

2016: 21st Century Cures Act

• Mandated the creation or revision of policies and processes intended to speed patient access to new medical devices, including:

1) Codifying into law the FDA's expedited review program for breakthrough devices
2) Expanding the application of the "least burdensome" principles in premarket reviews
3) Streamlining processes for exempting devices from the premarket notification (510(k)) requirement
4) Increasing the population estimate required to qualify for Humanitarian Use Device (HUD) designation from "fewer than 4,000" to "not more than 8,000" patients in the U.S. per year
5) Permitting the use of central Institutional Review Board (IRB) oversight rather than requiring only local IRBs for IDE and HDE activities
6) Requiring the FDA to revise the regulation of combination products
7) Codifying into law a process for submitting requests for recognition/non-recognition of a standard

• Clarified how certain digital health products can be regulated by defining the categories of medical software that can and cannot be regulated as devices

2017: Food and Drug Administration Reauthorization Act (FDARA)

• Reauthorized the medical device user fee program (MDUFA IV), including improvements to premarket review times and investments in strategic initiatives like the National Evaluation System for health Technology (NEST) and patient input
• Authorized risk-based inspection scheduling for device establishments and prescribed other process improvements related to device establishment inspections
• Decoupled accessory classification from classification of the parent device
• Required the FDA to conduct at least one pilot project to explore how real-world evidence can improve postmarked surveillance

2020: Corona virus Aid, Relief, and Economic Security Act (CARES Act)

• Enhanced FDA's ability to identify, prevent, and mitigate possible shortages of medical product

supply chains by requiring manufacturers of certain devices to submit notifications to FDA of an interruption or permanent discontinuance in manufacturing during or in advance of a public health emergency.

• Clarified that the FDA may issue certification for devices manufactured in a foreign device establishment and shipped to another country

2022: FDA User Fee Reauthorization Act of 2022 (FDAUFRA)

• Reauthorized the medical device user fee program (MDUFA V), including process improvement and performance goals for premarket activities such as pre-submissions and investments in strategic initiatives like patient science and engagement and international harmonization efforts

• Established new fee adjustments in later years of MDUFA V based on meeting performance goals and hiring benchmarks

• Set a 13-week cap on the MDUFA carryover balance and separately funded a new Total Product Life Cycle (TPLC) Advisory Program (TAP) pilot

2022: Food and Drug Omnibus Reform Act of 2022 (FDORA)

• Enhanced oversight of device establishments, including new authority to conduct remote regulatory audits and to inspect facilities that conduct research on devices

• Provided the FDA with express authority to approve or clear devices with a predetermined change control plan (PCCP)

• Required that information about cybersecurity be provided in premarket submissions for certain devices (referred to as cyber devices) and that sponsors of such devices must ensure their cybersecurity

• Clarified that the FDA can ban devices for one or more intended use, and that banned devices are not legally marketed devices

• Required sponsors of certain device clinical studies to submit a diversity action plan with enrollment goals and plans to meet these goals beginning 180 days after the FDA issues final guidance on the subject

• Permitted certification for devices manufactured in a foreign device establishment and shipped to another country provided the same device is also marketed in the United States and other criteria are met

• Established a new registration fee waiver for small businesses experiencing financial hardship beginning in FY 2025

SECURITY CHALLENGES FOR MEDICAL DEVICES

• Imposed steeper penalties for counterfeit devices

• Clarified that the FDA may receive voluntary device shortage notifications outside of a public health emergency and directed the Agency to create a list of device types subject to mandatory notifications

• Clarified that the FDA may rely on qualified third parties to review requests for emergency use authorizations (EUAs) for in vitro diagnostic devices Security challenges for medical devices Security challenge for medical devices

• Security risk resulting from international threats have only recently been confirmed as medical device increasingly use newer technology such as wireless communication and Internet access. International threats include unauthorized access of a medical device or unauthorized change of setting of such as device.

• A senior official in the device unit of the USFDA has often been cited with the following statements "we are aware of hundreds of medical devices that have been infected by malware."

• Medical device will increasingly become smarter and more interconnected. The risk of computer viruses in hospital and clinical is one side effects of this trend. Without suitable counter measures, more data breaches and even malicious attacks threatening the live of patients may result.

• Secure software is supposed to continue to function correctly under a malicious attack. In this sense, medical devices security is idea of engineering these devices so they continue to function correctly even if under malicious attack. These internal hardware and software aspect as well as international and un-international and external threats.

• Medical device comprise a board range of instruments and implement. for our consideration, only device with hardware, software and some of inter-operability are of interest. Artificial joints, for example, do not do any processing, that is, there is a no software involved. Thus we can ignore them from a security perspective.

• Security medical device is securing a critical infrastructure. It is about preventing malicious people from taking control of this infrastructure, about preventing a potential blackmail of devices manufacturer or health institutions, and about the senses of well bin of any person who needs to use

any such device.
• The FDA collect information regarding issues with medical device to capture and identify adverse and unexpected events for a particular device or device type each year, several hundred thousand medical device report are received about suspected device associated death serious injuries, and malfunction.

➢ Device security: -
We consider a medical device to be security critical if it does same from of processing and communication, typically by running same from of software on specialized hardware and often employing a range of sensor the difference between safety and security is not always obviously because the security can clearly have an effect on safety generally speaking, safety is about the protection of a device environment, that is mainly the patient, from the device itself.

- Pacemaker scenario: - we will illustrate security issues through an example of pacemaker that is medical device that are implanted in patients to regulate the patient heart rate. The purpose of such a device is to maintain an adequate heart would not be able to do so otherwise. Pacemaker are classified as class III, the highest safety category.

- Clinical perspective: - Implantable medical devices are prevalent in many medical devices are prevalent in medical specialties. The implementable cardiac pacemaker and defibrillator can be especially critical for the patient health and welfare. These devices are implemented in hundreds of thousands of patients every year; many of these patients would not be able to live without a fully functional device. Implantable cardiac pacemaker and defibrillator are highly reliable. Nevertheless, failure of devices components has occurred and highlighted the potential medical and legal implications. With the increase prevalent of web-based wireless remote device follow up system, concern about device security have arisen.

- Risk assessment: - In our pacemaker scenarios we distinguish different risk according to the confidentiality, integrity, and availability. First confidentiality sensitive data about the patient and her pacemaker may be disclosed. Second integrity data on a device may be altered, resulting in a range of slightly to highly severe impact on the patient. Third availability may render a device inoperable. An architectural overview of the pacemaker environment.

- Software: - Vulnerabilities in software are bugs of flows in software that in software that can directly be used by attackers to gain access to a system or network, software for pacemaker is confidential and proprietary. A system specification is available for academic purposes. Functionality including device monitoring lead support, pluses pacing, various operating modes and State as well as extensile diagnostic features. Software is not only needed on the pacemaker itself, but also on the programming device and on the home monitoring.

- Hardware: - The hardware of pacemaker is, like software, configurations and proprietary. A hardware reference platform available at the University of Minnesota. Hardware for programming device and home monitors is less constrained.

- Challenge: - The security of medical devices is different and more challenging vis- a- vis regular IT security for several reasons, not just because of the fact human life is at stake. Emergency situation provide an additional challenge that is not prevent in other domains. Medical device must prevent unauthorized access vet may need to allow for quick and simple access in emergency situations.

- Organization: - A systematic plane for the provision of software update and patches is needed. Last but not least, a security response team has to permanently, identify, monitor, resolved security incidents and security vulnerabilities.

- Regulation: - It is important to know at any time the level of danger and to take appropriate counter measures. Design and distribution of medical devices is tightly regulated. In USFDA has the authority over medical device distribution.

ADVANTAGE OF DISPOSABLE MEDICAL DEVICES

Disposable medical device regulations help ensure patient safety and infection control by:
1. Reduced risk of infections: - Disposable devices are used once and then discarded, which reduces the risk of patient-to-patient contamination. This is

especially important in procedure where sterilization may be challenging. For example; syringe, needle etc.

2. Improving patient safety: - Disposable devices are kept in sterile packaging until use, which reduces the risk of contamination. Single use device reduce the chance of human error associated with cleaning and sterilization process. This can enhance patient safety by minimizing the risk of device related complications.

- ✓ Use disposable devices in appropriate settings- disposable devices are better for invasive procedures and situations where cleaning is inconsistent or infection risk is high.
- ✓ Use disposable supplies to prevent healthcare-associated infections (HAIs)- Disposable supplies can help prevent the spread of infection, which can be a public health concern.
- ✓ Improve medical device surveillance. A medical device surveillance system can improve patient safety throughout a hospital stay.
- ✓ Create a non-punitive culture for error reporting- A culture that values resolving system-based problems over punishing practitioners for errors can encourage more error reporting.
- ✓ Provide incentives for error reporting - Incentives can include protection from legal action and fear of criticism, blame, or disapproval.

3. Ensuring consistent performance: -
Disposable devices are designed for single use, ensuring consistent performance with each use.

4. Eliminating cross-contamination: -
Surgical teams dispose of these devices after each use, which decreases the likelihood of cross-contamination between patients decrease significantly, enhancing infection control.

To prevent crass contamination: -

- ✓ Use personal protective equipment (PPE) like gloves, masks, and gowns
- ✓ Practice aseptic technique
- ✓ Use engineering controls like sharps disposal containers and biological safety cabinets
- ✓ Use work practice controls like proper handling and disposal of sharps
- ✓ Ensure that institutional policies are consistent with national guidelines
- ✓ Discard contaminated carrying

5. Testing and labeling: -
Medical device companies must test to identify the average number of uses a device or component can withstand while working effectively. They must also label the device accordingly to indicate how many times it can be used.
6. Cost- efficiency: -
The cost to purchase disposable device is lower than their reusable counter parts. When you consider overall cost, the cost of disposable medical device could be even lower when factories in the expenses associated with cleaning, sterilization, and maintenance of reusable devices. For example; coronary by-pass graft surgery, cancer surgery etc.
7. Convenience and time savings: -
Disposable device eliminates the need for extensive cleaning and sterilization processes, saving time and resources for overwhelmed health care team. This reduces in time spent disinfecting can lead to increased efficiency in medical procedures. For e.g. Hypodermic needle, face mask, drug test, bandage, etc.

DISADVANTAGES OF DISPOSABLE MEDICAL DEVICES

Some disadvantages of disposable medical device regulations include:

1. Environmental impact: -
Disposable medical devices can have a significant environmental impact. One of the significant drawback of disposable medical devices is their environmental footprint. The production, use and disposal of these devices can contribute to medical waste, which can be challenging to manage. IML (Intravascular malignant Lymphomatosis) is proud to work with partner such as quanta system who are committed to sustainability in terms of material and packaging, helping us her in a more environmentally -conscious era in health care. Impact: - 1) waste, 2) greenhouse gas emissions, 3) micro plastic, 4) Fossil fuel, 5) incineration (toxic to human),

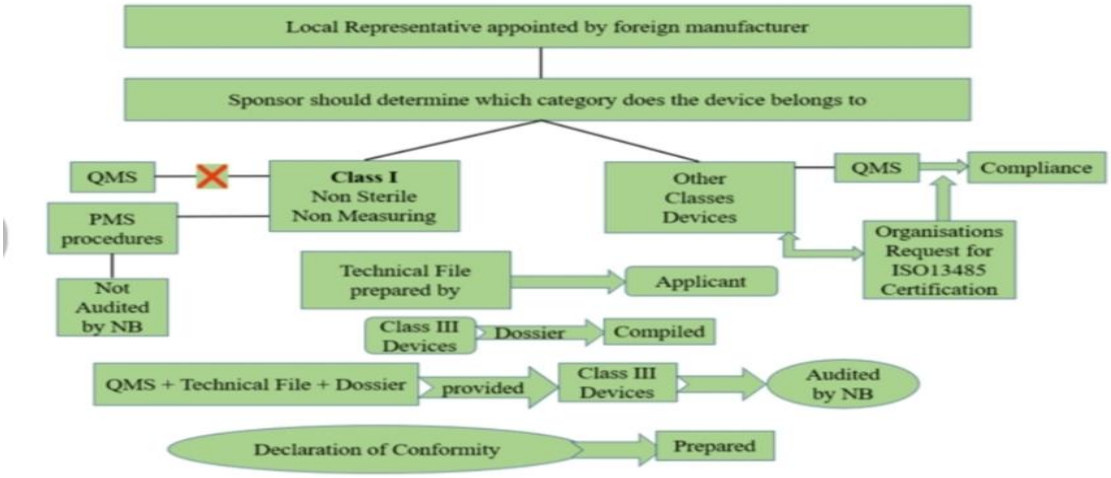
2. Risk to patients: -
Reusing single-use medical devices without proper cleaning or sterilization can increase the risk to patients.

3. Safety concerns: -
In developing countries, the reuse of single-use medical devices can lead to unsafe interventions and infections.

4. Cost over time: -
In developing countries, the reuse of single-use medical devices may be due to cost restraints. While disposable device may have lower initial costs, the total cost over time can be higher than investing in reusable device that can be sterilized and used multiple times.
5. Resources consumption: -
The manufacturing and disposable of disposable device required resources such as energy, material, and water. This contributes to the overall ecological footprint associated with these products.
6. Limited customization: -
Disposable device generally easy for broad use. They may not provide the same level of customization or adaptability as some reusable device. This can be a limitation in specific medical situation.
7. Technology limitations: -
Certain advanced medical procedure may require sophisticated, reusable devices that disposable alternatives cannot easily replace. This limitation can affect the usage of disposable devices in some medical specialties.

Limitation: -
i. supply chain issues
ii. limited customization
iii. advance medical procedure
iv. electronic components.
8. Potential supply chain issues
Replying having on disposable devices may pose challenges in the supply chain especially during time of increased demand or distribution. This is the potential to impact health care delivery in emergencies or pandemics.
For e.g. row material, limited personnel/workers.

Over view of the medical device approval process



PHASE IN THE LIFE SPAN OF MEDICAL DEVICES

In figure illustration the major phase in the life span of a medical device from conception to disposable. The activity phase are simplified to make it easier to understand the regulatory system. For example, the development phase includes development planning, design verification /validation, prototype testing and clinical trials. In practice, the phases outline below may overlap and interact
Major phase in the Span of the medical device
1) Conception and development
2) Manufacturer
3) Packaging and labeling
4) Advertising
5) Sale
6) Use
7) Disposal
Above phase concept explain in following
1) Conception and development
The scientific principles upon which a device is based are fundamental to its safety and performance. For example, a cardiac size and shape that stimulates the natural functioning of the heart. Significant, deviation from this may compromise safety and performance. The more complex the device, the higher the risk of user error. Soundness of concept and adequate of design, construction, and testing (including verification, validation and

clinical trials) required the scrutiny of scientific experts to ensure that design parameters and performance characteristics don't impose unwanted risk.

2) Manufacturing

People should be identified and participate in ensuring medical devices safety, good ability, functions medical devices are produced when the manufacturing process is adequate manage. However, poor manufacturing management can proceed inconsistency in the quality of product, such that non-conforming device can filter through the production line to the market, even when the original prototype has been well designed. This consideration has led to the development of good manufacturing practices (GMP) for drug, biological products and medical devices. Now, GMP is more commonly referred to as "quality system bin manufacturing" and these are addressed later in this guide.

3) Packaging and labeling

Properly packaged medical device pose little risk to individuals handling them, even if the medical device is bio hazardous. This highlights the importance of well-designed packaging systems in delivering clean, sterile and protected medical devices to the point of use. Shipping is one of the hazard a medical device and its packaging must service. suitable damage can result during transportation and handling unless the total packaging system is designed robustly and can withstand various stressed. Well sealed packaging is essential for those medical devices that must be maintained sterile. Labelling crucial in identifying the medical device and specifying instructions for its proper use as for drugs, miss labelling medical devices can result in serious consequences for the user.

4) Advertising

advertisement has the potential to create expectations and powerfully influence the believers in medical device capabilities. It is important, therefore that medical devices and its performance. However misleading or fraudulent advertising medical devices may increase sales. However, from the buyer's perspective, the purchase of an patient of more appropriate treatment and could lead to patient or user injury

5) Sale

The sale of medical devices by the vendor is a critical stage that leads to the device b being put into actual use. If the vendor is not subject to regulations, then there is higher risk of exposing the public to low quality or in effective devices.

6) Use

User of medical device can have profound effect on their safety and effective performance. Unfamiliarity with a certain technology or operating procedure, and then use of products for clinical indication outside the scope of those specified in the labelling, can cause device failure even in the absence of any in heren't design or manufacturing defects. within the at least half of all medical devices related injuries and death. The re-use of disposable device contrary to the manufacturer instructions, and without proper control or precautions for minimizing associated rock can be dangerous, the lack of or inappropriate, calibration and maintenance of medical device can seriously jeopardize their safety and performance. These issues are often overload or underestimated.

8) Disposable

Disposable of certain types of devices should follow specific and stringent safety rules. For example, device that are contaminated after use (e.g., syringes) or device that contains toxic chemicals, can present hazard to people or the environment and must be disposed of properly.

CONCLUSIONS

Medical device contributes to the health and wellbeing of millions of patients, but they do not always function as anticipated. The safety and effectiveness of medical devices in the United States are under the purview of the FDA. The FDA task is primarily risk assessments, which is performed through the process of premarket and post market evaluation. The desire to rush a new product or technology to market must be balanced and carefully against the desired to ensure the safety of those who will benefit from the device. The FDA, congress, manufacturers, the public, and physicians each Play a vital role in the safe and effective use of medical devices.

REFERENCE

[1] Medical devices regulations introduction 9241546182-eng .pdf

[2] History of medical device regulations and its overviewhttps://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states

[3] Security challenges for medical devices 2667218.pdf.
[4] Advantages of disposable medical device regulations https://imlasers.com/articles/pros-and-cons-of-disposable-medical-devices/
[5] Disadvantages of disposable medical device regulations https://imlasers.com/articles/pros-and-cons-of-disposable-medical-devices/
[6] Approval process of medical devices regulations https://images.app.goo.gl/vnNqFH3FWS1Q9RHF7
[7] Conclusion https://pubmed.ncbi.nlm.nih.gov/14970153/