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Review Article

Overview: Aspects of regulatory affairs in medical devices

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Abstract

Aim: Regulatory affairs in the pharmaceutical industry act as a vital bridge between global health authorities and pharmaceutical companies, ensuring that medicines and medical devices are safe, effective, and of high quality. The field emerged from historical tragedies, such as the sulphanilamide and thalidomide crises, which prompted the establishment of strict regulatory frameworks worldwide. Regulatory professionals oversee documentation, drug approvals, clinical trials, and compliance with Good Manufacturing Practices (GMP), thereby safeguarding public health while fostering innovation. In India, the Central Drugs Standard Control Organization (CDSCO) plays a pivotal role, alongside global counterparts such as the FDA (USA), EMA (Europe), TGA (Australia), and PMDA (Japan). Medical devices, regulated under global and national frameworks, are classified by risk level, with oversight ensuring quality, safety, and efficacy. While regulations continue to evolve, challenges in harmonization and the need for stronger international collaboration remain. Looking ahead, regulatory affairs will be increasingly crucial in addressing advances in medical technology, improving oversight, and strengthening patient safety standards across pharmaceuticals and medical devices.

Keywords: Regulatory affairs, Medical devices, CDSCO, Classification

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1. Introduction

Regulatory affairs in the pharmaceutical industry serve as a crucial link between global regulatory authorities and the industry itself. This field ensures that pharmaceutical products comply with all standards and requirements established by government agencies. The Food and Drug Administration (FDA), a part of the Department of Health and Human Services (HHS), is the federal agency that oversees the regulation of medical devices. Before many medical devices can be marketed in the United States, manufacturers are required to obtain prior approval or clearance from the FDA. The Center for Devices and Radiological Health (CDRH), a branch within the FDA, is mainly in charge of reviewing medical devices before they reach the market.[1] Each nation has a designated regulatory authority to serve this purpose. These authorities have introduced guidelines to oversee the import, production, marketing, and distribution of medical devices. In the majority of Asian countries—such as South Korea, Malaysia, Thailand, Indonesia, Vietnam, the Philippines, and Singapore—medical devices are governed independently from pharmaceuticals. On the other hand, in India, they are regulated jointly with drugs under the Drugs and Cosmetics Act of 1940.[2]

They serve as a bridge between pharmaceutical companies and health authorities by:

1. Ensuring the safety of products
2. Confirming their efficacy
3. Overseeing proper regulatory compliance and registration.[3]

RA professionals make sure that drugs and medical devices meet all safety, quality, and effectiveness standards before they reach patients. Strong regulatory supervision helps protect public health by ensuring only safe products are approved.[4] The core responsibility of regulatory affairs is to ensure that companies follow all regulations related to the development, manufacturing, and distribution of medicines. Professionals in this area manage regulatory documentation, secure approvals for new drugs, and maintain compliance

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with legal standards throughout a product's lifecycle. They play a key role in both safeguarding public health and supporting innovation in drug development. Their duties include conducting risk evaluations, preparing regulatory submissions, and ensuring adherence to quality standards. Ultimately, the primary goal of regulatory affairs in pharmacy is to ensure that medications are safe, effective, and of high quality while fully complying with all relevant laws and regulatory guidelines.

Modern drug regulation began after the sulfanilamide tragedy in the U.S., where over 100 deaths due to diethylene glycol poisoning highlighted the urgent need for safety oversight in medicines. Pharmaceutical companies must submit comprehensive data on a drug's quality, safety, and efficacy to obtain regulatory approval for manufacturing and marketing.[5] The market entry of medical devices is strictly regulated to ensure compliance with established standards for safety, effectiveness, and quality. The EU, USA, and Japan not only lead economically but also shape global regulatory practices through their well-established medical device approval systems.[6] **(Figure 1)**

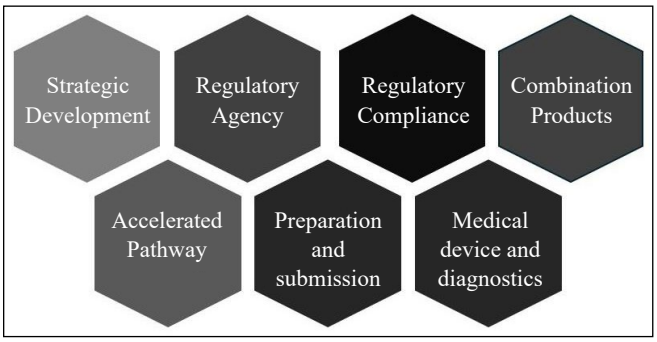

Figure 1: Regulatory phases

2. History

Past tragedies, such as the sulphanilamide incident in 1937 and the thalidomide crisis of the 1950s, prompted the introduction of stricter laws and regulations to ensure the safety, effectiveness, and quality of pharmaceutical products. To protect public health and reduce financial risks for biopharmaceutical companies, various regulatory bodies have been set up across different regions to evaluate and approve new drug products before they reach the market.

Examples of these authorities include the US Food and Drug Administration (FDA) in USA, European Medicines Agency (EMA) in Europe, Pharmaceutical and Medical Device Agency (PDMA) in Japan and National Medical Products Administration (NMPA) in China.

The term "quack" originates from the Dutch word quacken, meaning "to boast," and has been widely used in the U.S. to refer to fraudulent medical practitioners. For many years, these individuals sold adulterated and misbranded medications across the country without facing legal consequences. This changed in 1906 when Congress enacted the Food and Drugs Act, which included provisions to curb such practices. Over the next 50 years, Congress introduced two significant laws that expanded the FDA's authority. The first was the Federal Food, Drug, and Cosmetic Act (FFDCA) in 1938, which mandated that drugs must be proven safe before being sold across state lines. Then, in 1962—following severe consequences from the use of thalidomide in Europe, including birth defects and deaths, Congress passed the Kefauver-Harris Drug Amendments. These amendments strengthened safety requirements and added the need to demonstrate drug efficacy. Since then, the FFDCA has been amended multiple times, shaping the FDA's current role in ensuring that drugs are both safe and effective for public use.[7]

3. Objective

Regulatory Affairs (RA) ensures that pharmaceutical products meet all legal and safety requirements before and after reaching the market. Its main goals are to protect public health, support regulatory compliance, and facilitate drug approvals.

1. **Purpose of drug regulations:** Drug regulations were developed to ensure the safety, efficacy, and quality of medicines. In the U.S., these rules were established in response to serious health incidents and the growing need for standardization in the pharmaceutical industry.
2. **Major U.S. regulations:** Key laws include the Food, Drug, and Cosmetic Act and later amendments that shaped the role of the FDA in drug approval and monitoring.
3. **Indian regulatory framework:** India's pharmaceutical laws are primarily based on the Drugs and Cosmetics Act and Rules, regulated by bodies like CDSCO and DCGI.
4. **European Union regulations:** The EU has a harmonized system that governs drug approval and safety, with the EMA playing a central role.

4. Medical Devices

The classification of certain products—such as disinfectants, assistive technologies for disabled individuals, devices incorporating biological tissues, and equipment used in assisted reproductive techniques—varies across jurisdictions, with some countries considering them medical devices while others do not.[6] The Global Harmonization Task Force (GHTF) has suggested a set of unified definitions for medical devices worldwide. According to the World Health Organization (WHO), medical devices are intended for one or more specific purposes, such as diagnosis, prevention, monitoring, treatment, or alleviation of disease.[8]

1. Disease diagnosis, monitoring, therapy, and / or amelioration
2. Identification, mitigation, monitoring, treatment, prevention, or payment for an injury

3. Study, replacement, or encouragement of any anatomical region or physiological process
4. Life's foundation and nourishment
5. Controlling conception
6. Sanitizing medical devices.[8]

5. Importance of Medical Devices

The regulation of medical devices is still evolving. This is to be expected since the regulations and relatively new. Indeed, the major directive has only been fully operational for 2 years and the in-vitro diagnostics directive has only just recently begun its transitional period. The regulations have largely worked satisfactorily and much better than many had predicted. However, some problems have been identified leading some to call for the creation of a European Devices Agency. The UK does not currently support the call for such an institution but does believe that some re balancing and refocusing of the Device Directives is required. The UK has suggested that this is a good time to evaluate the operation of the regulations. In particular there is a need to consider increasing the risk category for many implants, subjecting them to closer scrutiny. There is perceived to be a need to increase European co-operation. The UK has also called for the creation of a European group to oversee the work of Notified Bodies. There has been considerable support for this concept of a Notified Body oversight group. Finally, the UK has called for an improvement in the production of standards and guidelines, with the provision of more detailed premarketing requirements.

6. Regulatory Authorities in India

6.1. Role and function of regulatory authorities

Regulatory authorities, like India's CDSCO and state bodies, ensure medicines are safe, effective, and high-quality. Their key roles include:

1. Ensuring Drug Safety and Efficacy
    a. **Drug approval:** They review clinical trial data to confirm a drug's safety and effectiveness before market entry, ensuring compliance with scientific and ethical standards.
    b. **Marketing authorization:** After thorough evaluation, they grant permission for drug sales, requiring adherence to Good Manufacturing Practices (GMP).
    c. **Post-Marketing surveillance:** They monitor drugs on the market through pharmacovigilance, collecting and analyzing adverse reaction reports to address safety issues quickly.
2. Regulatory Compliance and Quality Assurance
    a. **Setting standards:** They enforce national guidelines for drug manufacturing, approval, and distribution.
    b. **Good Manufacturing Practices (GMP):** They ensure consistent, high-quality production to prevent contamination and maintain product integrity.
    c. **Inspections and audits:** Regular checks on facilities and trial sites ensure compliance, with corrective actions enforced as needed.
    d. **Overseeing distribution:** They license manufacturers, distributors, and sellers to ensure legal compliance and protect public health.[9]

7. Device Classification

Risk assessment plays a vital role in medical device development, ensuring that potential dangers are identified early so that patient safety and environmental protection are maintained.

The European MDR classifies medical devices into four categories (Class I–III), with the level of regulatory scrutiny increasing according to the potential risk to patients.[10]

The Central Licensing Authority (CLA) of India classifies Medical Devices and In-Vitro Diagnostic Medical Devices (IVDMDs) into four risk categories based on their intended use, associated risks, and parameters outlined in the Indian Medical Device Rules (IMDR):

1. **Class A:** Low risk
2. **Class B:** Low-moderate risk
3. **Class C:** Moderate-high risk
4. **Class D:** High risk

7.1. Classification principles include **(Figure 2)**

1. Classification is determined by the device's intended purpose.
2. Combination devices or accessories are classified independently.
3. Software is classified in the same category as its associated device.
4. Calibrators used with reagents share the same classification as the IVDMD reagent.
5. Devices with multiple specified uses are classified based on the most critical use.
6. When multiple rules apply, the stricter rule leading to a higher classification is followed.[11]

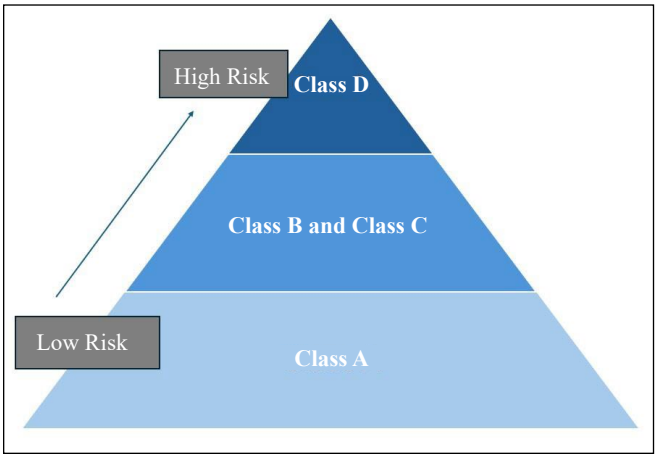

Figure 2: Classification of device

8. Comparison between different Regulations

The Drug and Cosmetic Act 1940 and Rules 1945 were passed by the India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO), and the office of its leader, the Drugs Controller General (India) [DCGI] was established.[12] **(Table 1)**

Table 1: Different regulatory bodies

Country	Regulatory body
USA	Food and drug administration (FDA)
Australia	Therapeutic goods administration (TGA)
Europe	European medicines agency (EMEA)
India	Central drug standard control organization (CDSCO)
Japan	Japanese Medicines Regulatory Agency

8.1. USA

In the United States, the Food and Drug Administration (FDA) oversees the regulation of pharmaceuticals, which includes prescription drugs, over-the-counter medications, vaccines, biologics, and generic drugs. The FDA is responsible for reviewing and approving New Drug Applications (NDAs), ensuring drug safety, and enforcing Good Manufacturing Practices (GMP) among pharmaceutical manufacturers

8.2. Australia

In Australia, the Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic products, such as medicines and medical devices. It evaluates and approves these products to ensure they meet standards for safety, effectiveness, and quality.

8.3. Europe

The European Medicines Agency (EMA) oversees the assessment and monitoring of medicines for both human and veterinary use within the European Union (EU). It evaluates the quality, safety, and effectiveness of pharmaceutical products and is responsible for granting marketing authorizations.

8.4. India

The Central Drugs Standard Control Organization (CDSCO) serves as India's regulatory body for pharmaceuticals and medical devices. It is responsible for approving new drug applications, overseeing clinical trials, and ensuring compliance with drug safety regulations.[13]

8.5. Japan

The Pharmaceuticals and Medical Devices Agency (PMDA) is Japan's regulatory authority that operates in collaboration with the Ministry of Health, Labour and Welfare. Its primary role is to safeguard public health by ensuring the safety, efficacy, and quality of pharmaceuticals and medical devices. The PMDA conducts scientific evaluations of marketing authorization applications, oversees post-marketing safety, and provides compensation to individuals affected by adverse drug reactions or infections caused by pharmaceuticals or biologics.[14] **(Figure 3)**

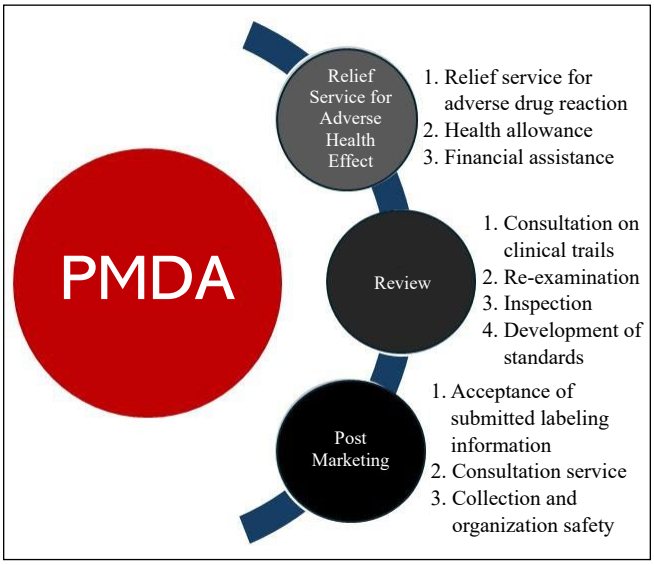

Figure 3: Regulatory authority of Japan

9. Future Aspects of Medical Device Regulation

About a century ago, the field of medical devices was still in its infancy, and medical electronics had not yet emerged. However, three devices were already in use that significantly influenced medical practice at the time and continue to form the foundation of important technologies in healthcare today. One of these was the stethoscope, first developed in 1816 by French physician René-Théophile-Hyacinthe Laennec. The original model was a hollow wooden tube with a funnel-shaped end that was placed on the patient's chest, while the opposite end was held to the physician's ear. This innovation replaced the earlier practice of doctors—almost all of whom were men then—pressing their ear directly to the patient's chest, a method that was both inconvenient and uncomfortable, especially for women. Over time, the stethoscope has become not only a vital diagnostic tool but also a universal symbol of the medical profession. Despite its modern appearance, its core design, function, and purpose remain remarkably similar to Laennec's invention nearly two centuries ago.[15] The successful adoption of AI in radiology depends on an institution's IT setup and policies, with deployment options including both on-premise systems and cloud-based SaaS platforms. Sophisticated imaging AI solutions assist with data handling by detecting elements like anatomical regions and contrast use, enhancing study- and series-level organization.[16] Advancements in healthcare, medicine, and the pharmaceutical and medical device sectors are reshaping the role of regulatory affairs teams. What was once a predominantly task-driven workload is increasingly being transformed by digital tools and automation, creating a need for stronger strategic and leadership capabilities. To thrive in this changing environment, regulatory professionals must continuously build their skills, knowledge, and mindset to

progress in their careers. Today's workplace is often described as volatile, uncertain, complex, and ambiguous (VUCA), and the global pandemic has further intensified these challenges, creating a "new normal" in the world of work.[17]

10. Conclusion

Regulatory Affairs in medical devices plays a pivotal role in ensuring patient safety, product quality, and global compliance. It is not just a legal obligation but also a strategic function that guides the entire lifecycle of a medical device—from design and development to post-market monitoring. Through classification systems, technical documentation, clinical evaluations, and risk management, RA ensures that only safe and effective devices reach patients.

The integration of quality management systems (ISO 13485), risk management (ISO 14971), and international regulations (FDA, EU MDR, CDSCO, etc.) provides a harmonized framework that manufacturers must follow to maintain trust and transparency in healthcare. Additionally, the emphasis on post-market surveillance, vigilance reporting, and corrective actions reflects the continuous responsibility of regulatory professionals to safeguard public health even after a product is launched.

In a rapidly evolving healthcare landscape, regulatory affairs professionals must stay updated with global regulatory intelligence, technological advancements, and ethical standards to support innovation while maintaining compliance. Ultimately, regulatory affairs serves as a bridge between innovation and patient safety, balancing scientific progress with strict legal frameworks.

Thus, the aspects of regulatory affairs in medical devices are not only about obtaining approvals, but also about ensuring a culture of quality, accountability, and patient-centric responsibility throughout the device's life cycle.

11. Source of Funding

None.

12. Conflict of Interest

None.

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