

# Significance of Pharmaceutical Regularly Bodies

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**Abstract:** The regulatory bodies are being established in various pharmaceutical industries across the globe which plays a vital role to meet the requirements of legal procedures related to drug development process in a country. The Pharmaceutical industry is considered as the most highly regulated industries worldwide. The regulatory body ensures compliances in various legal and regulatory aspects of a drug. Countries possess their own regulatory Authority, which is responsible for enforcing the rules and regulations and issue the guidelines to regulate drug Development process, licensing, registration, manufacturing, marketing, labeling and the product life cycle of Pharmaceutical products. In an ever-changing regulatory environment, the role of regulatory affairs personnel is Essential to ensure compliance with legislation in all regions in which a company wishes to distribute its drug. This article describes the development of the drugs as it is a cumbersome process which includes several months Of time, volunteers, and a huge finical investment majorly through the funding process, so it is strictly regulated As per the norms and regulations as given by those individual countries to carry out the drug development which Was generally governed by the Drug Regulatory Affairs Personals.

**Keywords:** - Regulatory bodies, Product life cycle, Regulated industries, Regulatory environment.

## I. INTRODUCTION

A regulatory agency (regulatory body, regulator) or independent agency (independent regulatory agency) is a government authority that is responsible for exercising autonomous dominion over some area of human activity in a licensing and regulating capacity. These are independent governmental bodies established by the government in order to set standards in a specific field of activity, or operations and then to enforce those standards. Regulatory agencies may or may not function outside direct executive supervision. [1]

A regulatory affair (RA) is a profession which acts as the interface between the pharmaceutical industry and drug regulatory authorities across the world. It is mainly involved in the registration of drug products in the respective countries prior to their marketing. The current Pharmaceutical Industry is well organized, systematic and compliant to international regulatory standards for the manufacturing of chemical and Biological drugs for human and veterinary consumption as well as medical devices, traditional herbal products and cosmetics. The Regulatory Affairs department is an important part of the organizational structure of pharmaceutical companies. Internally it liaises at the interface of drug development, manufacturing, marketing and clinical research. Regulatory Affairs is actively involved in every stage of development of new medicine and the post-marketing activities with authorized medicinal products.

## II. HISTORICAL OVERVIEW OF PHARMACEUTICAL INDUSTRIES AND REGULATORY BODIES:

During 1950s, multiple tragedies i.e., sulfanilamide elixir, vaccine tragedy and thalidomide tragedy have resulted in substantial increase of legislations for drug products quality, safety and efficacy. This has also resulted into stricter norms for Marketing Authorization (MA) and Good Manufacturing Practices (GMPs). To understand the chronological development of the modern era of pharmaceutical industry and regulatory framework, we will glance through the historical evolution of regulations in USA, Europe and India. Let us see what happened in USA, Europe and India. [2]

## III. FUNCTIONS OF REGULATORY BODIES : [5]

The main functions of the regulatory body are typically identified as follows:

- Regulations and guides.
- Review and assessment.
- Licensing.
- Inspection.
- Corrective actions.
- Enforcement.

## IV. THE MAIN OBJECTIVES OF THE REGULATORY AFFAIRS ARE AS GIVEN BELOW:-

- Regulatory Affairs specialists coordinate and Document internal regulatory processes, Such as internal audits, inspections, license Renewals or registrations. They may also Compile and prepare materials for Submission to regulatory agencies.
- The regulatory bodies play a vital role in the companies and the government Agencies.
- Regulatory affairs department plays a vital role to ensure the safety and efficacy of uavailable to the public in the market.
- Regulatory bodies set guidelines for the main importation, distribution of drugs and also monitors adverse drug reactions (ADR's).
- Regulatory affairs help in the legalization covering all products with a medicinal claim and all relevant pharmaceutical activities, whether carried out by the public or the private sector.

## V. DUTIES OF REGULATORY BODIES

The role of regulatory bodies under the Professional Governance Act (PGA) is set out in Section 22 [General duty and responsibilities of regulatory bodies] as follows: [3]

- It is the general duty of a regulatory body at all times to serve and protect the public interest with respect to the exercise of a profession, professional governance and the conduct of registrants.
- A regulatory body has the following responsibilities:
  - To superintend the regulated practice.
  - To preserve and protect reserved titles or reserved practices, as applicable, in the public interest.
  - To govern the registrants of the regulatory body according to the PGA, the regulations and the bylaws.
  - To establish the conditions or requirements for registration with the regulatory body.
  - To establish, monitor and enforce standards of practice to enhance the quality of practice.
  - Regulatory Strategy.
  - Planning of regulatory affairs.
  - Planning of addressing critical development issues, which is dynamic and changes during the process
  - Plan of how to register a product in the global market (to be in line with corporate, business and strategy of RA.
  - unit and projects.
  - Plan how to balance time & cost & human resources Strategy is only as good as the analysis behind it.
  - To ensure that a dossier results in a SmPC (Summary for the prescribers Package leaflet.
  - Information for the patient) that results in sales.
  - To ensure that the regulators are the first supportive customers for the product.
  - Networking, regulatory intelligence.
  - The integration of regulatory into the discovery and development process.

#### VI. IMPORTANT REGULATORY BODIES ARE AS UNDER[6]

1. Advertising Standards Council of India.
2. Competition Commission of India.
3. Biodiversity authority of India.
4. Press Council of India.
5. Directorate General of Civil Aviation.
6. Forward Markets Commission.
7. Inland Waterways Authority of India.
8. Insurance Regulatory and Development Authority.
9. Reserve Bank of India.
10. Securities and Exchange Board of India.
11. Telecom Disputes Settlement and Appellate Tribunal.
12. Telecom Regulatory Authority of India.
13. The Food Safety and Standards Authority of India (FSSAI).
14. Central pollution control board.
15. Financial Stability and Development Council.
16. Medical Council of India.
17. Pension Fund Regulatory and Development Authority.

#### VII. MISSION OF REGULATING BODIES:

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering the development of medical products to respond to deliberate and naturally emerging public health threats. [8]

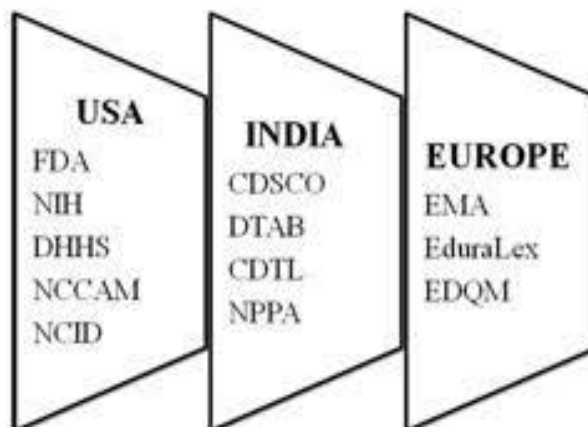
REGIONAL REGULATORY BODIES:

**Table: 1Regional Regulating Bodies[7]**

s.no	COUNTRIES'	REGULATORY BODIES
1	Australia	Therapeutic Goods Administration (TGA)
2	Brazil	Agencia Nacional de Vigilancia Sanitaria (ANVISA ), National Health Surveillance Agency
3	Canada	Health Canada
4	China	State Food and Drug Administration
5	Denmark	Danish Medicines Agency
6	Europe	European Medicines Agency (EMA)
7	India	Central Drug Standard Control Organization (CDSCO)
8	Italy	Italian Medicines Agency (AIFA)
9	Ireland	Irish Medicines Board
10	Japan	Ministry of Health, Labour and Welfare (MHLW)
11	Malaysia	National Pharmaceutical Control Bureau

12	New Zealand	Med Safe – Medicines and Medical Devices Safety Authority
13	Netherlands	Medicines Evaluation Board
14	Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)
15	Singapore	Centre for Pharmaceutical Administration Health Sciences Authority
16	South Africa	Medicines Control Council (MCC)
17	Switzerland	Swissmedic, Swiss Agency for Therapeutic Products
18	Thailand	Thailand Food and Drug Administration
19	USA	Food and Drug Administration (FDA)
20	United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)

Many countries include various sub-coordinating bodies in order to achieve the effective functioning of the Implemented guidelines.



**Fig: 1**Coordinating Bodies in Various Countries

#### VIII. INTERNATIONAL REGULATING BODIES:

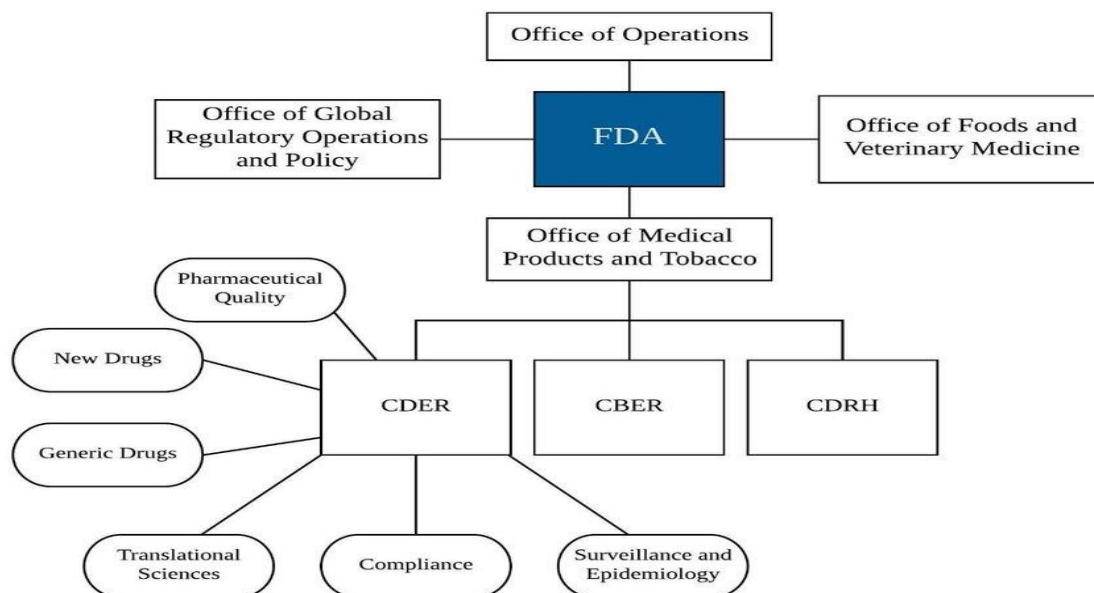
Many of the countries don't have their own regulating bodies or the improperly regulated agencies so they follow the global guidelines. The majority of the Gulf countries don't have their own regulatory bodies, some of the countries such as Iran, Israel, Iraq, Jordan, Kuwait, Oman, Palestine, Qatar, Saudi Arabia, Syria etc., so they adopt the most suitable guidelines according to their region.<sup>(9)</sup>

**Table: 2**International Regulating Bodies[7]

Regulating body	Headquarters
World Health Organization (WHO)	Geneva, Switzerland
World Trade Organization (WTO)	Geneva, Switzerland
International Conference on Harmonization (ICH)	Belgium, Europe
Pan American health organization (PAHO)	Washington D.C. USA
World Intellectual Property Organization (WIPO)	Geneva, Switzerland

#### IX. ROLE OF REGULATORY BODIES IN DRUG DEVELOPMENT PROCESS:

This department is responsible for knowing the regulatory requirements for getting new products approved. They know what commitments the company has made to the regulatory agencies where the product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs is a comparatively new profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines.<sup>[4]</sup> The companies responsible for the discovery, testing, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. Regulatory Affairs Professionals, with their detailed knowledge of the regulations and guidelines, are frequently called into advice on such matters. The drug approval process is not same for every country as it changes from country to country. In some countries, only a single body regulates the drugs and responsible for all regulatory tasks such as approval of new drugs, providing a license for manufacturing and inspection of manufacturing plants e.g. in the USA, FDA performs all the functions. However in some countries all tasks are not performed by a single Regulatory authority, such as in India, this responsibility is divided between Centralized and State.<sup>[3]</sup>



**Fig no: 2 Organisation structure of FDA.**

#### **X. SCOPE OF REGULATORY AFFAIRS PROFESSIONAL IN INDUSTRIES[5]**

Regulatory affairs professionals are employed in industry, government regulatory authorities and academics. The wide range of regulatory professionals includes in these areas:

- Pharmaceuticals
- Medical devices
- In-vitro diagnostics
- Biologics and biotechnology
- Nutritional Products
- Cosmetics
- Veterinary Products.

#### **XI. ROLE OF REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSTRIES:**

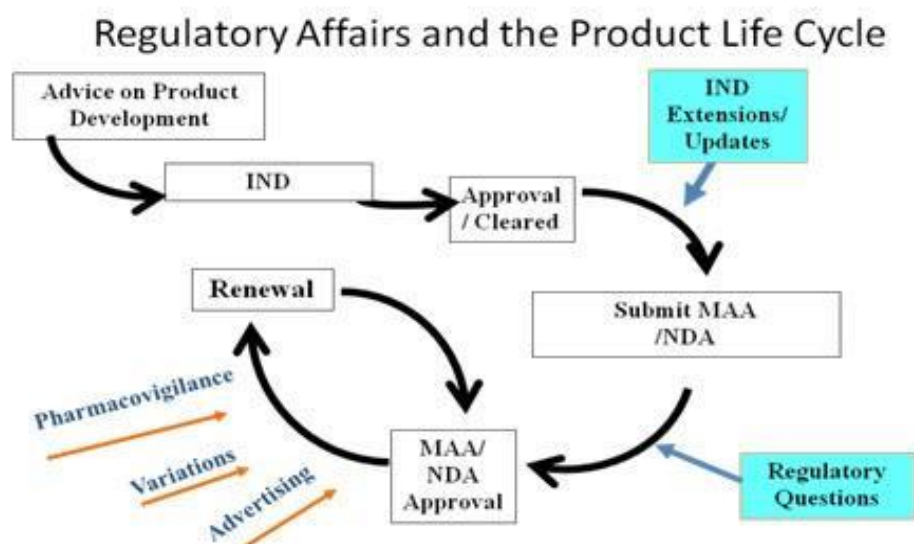
Regulatory affairs professionals provides tactical and practical guidance to R&D, Production, QC department etc. Just aid the drawn of the progress of a product, making main benefaction both together economically and scientifically to the triumph of a evolution scheme and company as a entirely. It takes time of about up to 15 years to evaluate and to put a new pharmaceutical product and many issues may stand up in the process of scientific progress and because of an altering regulatory habitat. Regulatory professionals help out the company to keep out of issues originated by immaterial documentation, unsuitable scientific reasoning or impoverished presentation of records.<sup>[9]</sup>The roles of regulatory affairs Professional is to act as cooperation with Regulatory Agencies:

1. To audit on constantly changing constitution.
2. Adapted documents to regulatory agencies.
3. To give tactical and practical advice to R&D, Production, QC Department.
4. Preparation of well ordered and Ensure fidelity and complaisance with all the applicable CGMP, ICH, GCP, GLP guidelines regulations and laws.

This department is responsible for knowing the regulatory requirements for getting new products approved. They know what commitments the company has made to the regulatory agencies where the product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be notified. Regulatory Affairs is a comparatively new profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicine. The companies responsible for the discovery, testing, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. Regulatory Affairs professionals, with their detailed knowledge of the regulations and guidelines, are frequently called in to advice on such matters.

#### **XII. REGULATORY AFFAIRS IN PRODUCT MANAGEMENT:**

The key role of RA professional is broader than registration of products, they advise companies both



**Fig : 3 Regulatory affairs and the product lifecycle**

strategically and technically at the highest level. Their role begins right from development of a product to making, marketing and post marketing strategies. Their advice at all stages both in terms of legal and technical requirements help companies save a lot of time and money in developing the product and marketing the same. For countries that do not have their own regulations the World Health Organization guidelines on health matters and World Trade Organization on trade regulations between nations is followed.[8]

### **XIII. REGULATORY AFFAIRS IN CLINICAL TRIALS:**

The RA professional is the primary link between the company and worldwide regulatory agencies such as US Food and Drug Administration (USFDA & Center for Devices and Radiological Health) Medicines and Healthcare Products Regulatory Agency, United Kingdom (UKMCA), Therapeutic Goods Administration, Australia European Medicines Agency, Organization of Economic Collaboration and Development (OECD) and Health Canada. He also communicates and interprets the seemingly endless maze of laws, regulations and guidelines to the other departments of the company. The RA personnel develops strategies to overcome delays and presents findings of clinical trials to the regulatory bodies so as to get quick clearance thus reducing the time for approval of new molecules. At its core, the RA professional facilitates the collection, analysis and communication about the risks and benefits of health products to the regulatory agencies, medical and health systems and the public. Operationally RA is responsible for assuring that government obligation, market driven demands and evolving scientific conventions are understood and addressed by various stakeholders.

### **XIV. REGULATORY AFFAIRS IN RESEARCH & DEVELOPMENT:**

The regulatory affairs personnel work hand in hand with marketing and R&D to develop, innovative products that take advantage of new technological and regulatory developments to accelerate time to market. With new products expected to add significant revenues to the company's bottom lines, small decreases in time to market equate to large material gains in revenue and profit. Employing adaptive clinical trial strategies, obtaining quick approval from regulatory authorities and avoiding pitfalls in processes can accelerate development of new products and help to reduce costly errors and time lags.

### **XV. REGULATORY EDUCATION**

The personnel in the regulatory affairs should have a good knowledge of all documents related to the respective country guidelines. Regulatory affairs personnel should be well known about the WHO, ICH, GMP, and other regulatory documents which have to be revised and submitted.

These people are the primary communication barrier between the pharmaceutical companies and worldwide regulatory bodies such as USFDA and the European Union, etc.(9)

### **XVI. CONCLUSION**

The regulatory affairs profession believes the new approach to regulation will eventually be adopted for all healthcare products as it represents the best model for delivering new healthcare advances to market in a reasonable time with acceptable safety. The regulatory bodies will deal with the growing and is the one which is least impacted during the acquisition and merger, and also during the recession. Regulatory Affairs departments are growing within companies. Due to the changing resources which are necessary to fulfill the regulatory requirements, some companies also choose to outsource or task regulatory affairs to external service providers. In today's competitive environment the reduction of the time taken to reach the market is critical to product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is considerable for the economic growth of the company.

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