



## Drug Regulatory Affairs

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### ABSTRACT :

The goal of governments to protect public health has led to the development of a relatively new profession known as regulatory affairs. An essential department in the pharmaceutical sector is drug regulatory affairs. Regulatory affairs in the pharmaceutical Company play an essential role because the pharmaceutical area is growing very fastly. It covers different registration parameter of pharmaceutical product and new drug application. Regulatory Affairs also has a very specific importance within the formulation and marketing of drug product in pharmaceutical industries. Regulatory Affairs is an attractive career choice for graduate students from a scientific background who enjoy communication and team work. The goal of the regulatory affairs professional is the protection of human health, ensuring safety, efficacy and quality of drugs. Regulatory Affairs professionals help the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data.

**KEY WORDS:** Regulatory affairs, Regulatory authority, New drug approval.

### I. INTRODUCTION :

Regulatory affairs play a crucial role to protect public health worldwide. Government of various countries have developed regulations for pharmaceutical product, cosmetics products, pesticides, medical product and veterinary products by controlling their efficacy and safety(1). Regulatory Affairs are also called Government Affairs. It is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries like pharmaceuticals, medical devices, Biologics and functional foods(2). Regulatory affairs are also core information about collecting, analysing and communicating the safety, efficacy, risk and benefits of health care products(3). The main strategies of regulatory

affairs depends on interpretation, application and communication within or outside the pharmaceutical industries(4). Regulatory affairs is a comparatively new profession which are developed from the desire of government to protect a public health by controlling the safety and efficacy of product in areas including pharmaceutical, medicinal, veterinary, pesticides and cosmetics also in complementary medicines(5,6). The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents(7). It is a unique mix of science and management to achieve a commercially important goal within drug development organization(8).

### Pharmaceutical drug regulatory affairs :

This department is responsible for knowing the regulatory requirements for getting the new product approved. They also submit the annual report and supplements to the agencies. Regulatory affairs typically communicate with one of the centers at the FDA headquarters, rather than the FDA local district office. (9)

The companies responsible for discovery, testing, manufacturer and marketing of these product. It also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare (10).

### Importance of Regulatory Authorities :

In currently day's competitive environment the reduction of time taken to reach the market is critical to a product. Then company get success. The proper conduct of it's regulatory affairs activities is therefore of considerable economic important for the company. A new drug may have cost prize in many millions of Europe Or dollars, pounds. To develop and even a three month delay in bringing it to market has considerable financial consideration(11,12,13).



Some other key responsibilities of regulatory affairs include:

1) Ensuring compliance with regulatory requirements: Regulatory affairs professionals are responsible for monitoring and interpreting regulations and guidelines related to drug development, manufacturing, and distribution .

2) Facilitating regulatory approvals: Regulatory affairs professionals work closely with regulatory agencies to prepare and submit applications for drug approvals. Also to provide necessary documentation and data to support these applications.

3) Managing regulatory risks: Regulatory affairs professionals help organizations to identify and mitigate regulatory risks, such as non-compliance with regulations or product safety issues, which can impact a company's reputation and bottom line.

4) Regulatory affairs professionals provide guidance and advice on regulatory issues to senior management and other stakeholders, helping to ensure that regulatory considerations are integrated into strategic decision-making(14).

A good Regulatory Affairs professional will have a 'right first time' approach and will play a very important part in coordinating scientific endeavour with regulatory demands throughout the life of the product. It also help to maximise the cost-effective use of the company's resources. The Regulatory Affairs department is very useful for contact between the government authorities and the company.

#### **Roles of regulatory affairs in pharmaceutical industry :**

Regulatory professionals are responsible for:

- Keeping track of the ever-changing legislation in all the regions in which a company wishes to distribute its products.

- Provide accurate and complete information about the quality, safety and effectiveness of product to physician.

- Advising on legal and scientific restraints and requirements.

- Collecting, collating and evaluating scientific data.

- Presenting registration documents to regulatory agencies and carrying out any subsequent negotiations necessary to obtain or maintain marketing authorisation for the products concerned.

- Giving strategic and technical advice at the highest level in their companies, making an important contribution both commercially and scientifically to the success of a development programme and the company as a whole.

- Helping the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data(15).

- The Regulatory Affairs (RA) department of the pharmaceutical industry is in responsibility or functioning of obtaining permission for new pharmaceutical drug that ensuring the approval maintenance process for as long(16).

- Regulation is a binding instruction issued by an agency which are tells how to clarify and comply with the law, failures to follow regulation many end up into the "issued warning letter ", which is a fair for pharma industry.

- Maintain approved application and the record of registration fees paid against submission of Drug Master File and other documents.

- Regulatory affairs professional help company that avoide inappropriate scientific thinking or poor presentation of data(17).

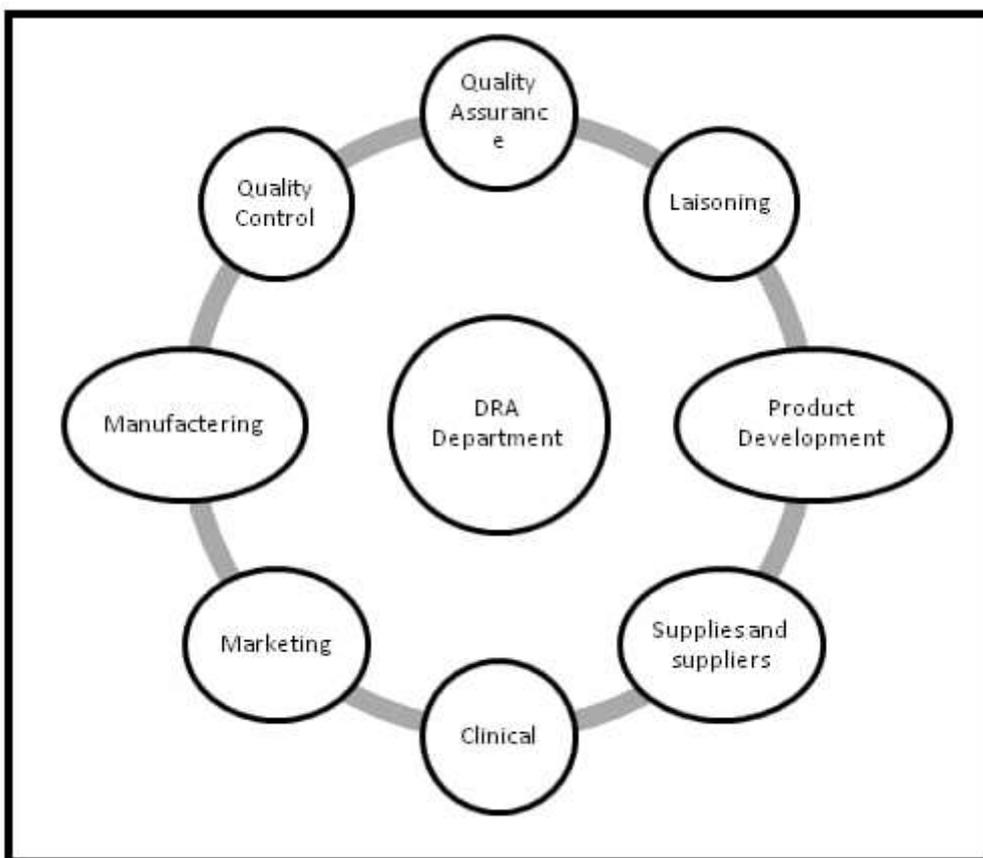


Fig. No. 2 : Roles of regulatory affairs in pharmaceutical industry (18)

**Needs of regulatory affairs in pharmaceutical industry :**

- RA professionals play a crucial role in ensuring that the company complies with regulatory requirements and avoids potential issues arising from inadequate record-keeping, flawed scientific reasoning, and subpar data presentation.
- Additionally, in product areas subject to regulatory oversight, RA professionals must adhere to restrictions on product claims in labelling and advertising.
- Inappropriate scientific thinking .
- Poor presentation of data. (19)

**Historical overview of regulatory affairs :**

The healthcare industries were the first to be significantly regulated in the modern era. Much of this regulation has stemmed from avoiding the repetition of disasters, and has tended to be led by the USA due to size of the market. (20)

During 1950s, multiple tragedies are :

- Diphtheria Epidemic led to 1902 Biologics Control Act.
- Publication of The Jungle by Upton Sinclair led to 1906 Pure Food and Drugs Act.
- Elixir of Sulfanilamide led to the 1938 Food Drug and Cosmetic Act.
- Thalidomide led to the 1962 Kefauver Harris Amendments
- Dalkon Shield led to the 1976 Medical Device Amendment.
- Bjork- Shield Heart Valves led to the 1990 Safe Medical Devices Act.
- In the US, this regulation is largely written directly into law and codified in Title 21 of the Code of Federal Regulations(21)

The drug Industry in India was at very primitive stage till 20<sup>th</sup> century. Most of the drugs were imported from foreign countries.

**Table no. 1: Historical overview of regulatory affairs in India:(22)**

Year	Act	Role
1919	Poison act	To check and hold the control on chief drugs available in market.
1930	The dangerous act	The poison act was followed by dangerous drug act which include the regulation of cultivation, manufacturing and trade of opium.
1985	Narcotic and psychotropic substance act	Rules and regulations for manufacturing narcotic and psychotropic drug. The dangerous act and opium act 1887.
1940	Drug and cosmetics act	Regulate the manufacturing distribution import and sale of Allopathic, homeopathic, unani and siddha drugs.
1945	Drug and cosmetics rules	Regulate manufacturing of Ayurvedic drug for sale only and not for consumption and use.
1948	Pharmacy act	Amended in 1986 and generally control and regulate profession at pharmacy in India.
1955	Drug and magic remedies rule	Regulate the advertisement of drug in India.
1955	Drug Prices Control Order	Amended in 1995 as per this rule government has jurisdiction to review maximum sale prices for bulk drug as well as formulation.

**2000-2010 :**

Period is considered to be the Innovation and Research era. During these years, innovative research activity , patenting of the drugs formula, process, indication as well as merger of companies was started .

Patent Amendment Act 2005:- Indian Government brought out the patents (Amendment) Ordinance, 2004 to address the issues relating to the patent in the country which was later replaced by the Indian Patent (Amendment) Act , 2005 . The new Act brought some crucial changes on the legal regime of patent protection so as to address patent issue in technology , chemical and pharmaceutical sector .

Compulsory Licenses: - Such licenses can be granted for manufacture and export of the drug products “to any country having insufficient or no

manufacturing capacity, for the said product , to address public health problems .”

Few names are given below.

- Drugs and Cosmetics (First Amendment ) Rules, 2011 :- It mandates registration of Clinical Research Organization (CRO ) for conducting Clinical Trials (CT).
- Clinical Trial Registry – India (CTRI) :- It has been set up by the ICMR’S ( Indian Council of Medical Research ) National Institute of Medical Statistics (NIMS )
- Pharmacovigilance Program of India (PvPI) :- The Central Drug Standard Control Organization (CDSCO) has launched pharmacovigilance to assure drugs safety to Indian patients (22).

**NATIONAL REGULATORY AUTHORITY:**

Sr. No.	Committees	Roles and responsibilities
1	DCC	Drug Consultative Committee, which has central and state Drug Control officials as its members, ensures drug control measures in all over India. It is an advisory body for the Central Government, the State Government and DTAB.
2	DTAB	DTAB comprises of technical experts who advises central and state governments on technical matters of Drug regulation. Amendment, if any, to Drug and Cosmetic are made after consulting this board.
3	IND	The committee will advise DCGI in matters to undertake in-depth evaluation of non-clinical data including pharmacological, toxicological data, clinical trial data (if any)furnished by the applicant for approval of IND substances of chemical and biological origin.

4	SEC and MDAC	Each of the panels set up to advise in matters related to review and regulatory approval of clinical trials and new drugs, except for Investigational New Drugs (INDs), relating to different (12)therapeutic areas for Subject Expert Committee (SEC) formerly called as NDAC and 07MDAC. “The committee will advise DCGI in matters to undertake in-depth evaluation of non-clinical data including Pharmacological, toxicological data, clinical trial data (phase I, II,III, and IV) furnished by the applicant for approval of new drug substances of chemical and biological origin to be introduced first time in the country including vaccines and rDNA derived products. MDAC for Medical Devices.
	TRC	Technical Review committee (TRC) shall review the recommendations provided by SEC on applications of clinical trials and new drugs after thorough evaluation. DCGI will grant approval of clinical trial and new drugs based on recommendations of TRC.
5	Technical committee	Clinical trial protocol will be referred for review by technical after the same has been approved by NDAC. Technical committee and Apex Committee meet once every month.
6	Apex committee	Apex committee will send their recommendations/ opinions after review of proposal sent by Technical committee for clinical trial application which have been approved by TRC.
7	Expert committee	The prof. Ranjit Roy Chaudhary expert committee to Formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs The Prof .C.K. Kokate expert committee to formulate policy and guidelines for approval of new drugs, clinical trials and banning of FDCs.

Table no. 2: Different committees set up by ministry of health and welfare: (23)

### New drug approval process in India:

The India's parliament enacted the Drug and Cosmetic Act 1940 and Rules 1945 to oversee the import, production, distribution, and sale of drugs and cosmetics. This legislation led to the establishment of the Central Drugs Standard Control Organization (CDSCO) and the appointment of the Drugs Controller General (DCGI) as its leader. In 1988, the Indian government introduced Schedule Y to the Drug and Cosmetics Rules 1945. Schedule Y outlines the protocols and prerequisites for conducting clinical trials, which were subsequently revised in 2005 to

align with internationally recognized procedures. To manufacture or import a new drug in India, a company must seek permission from the licensing authority (DCGI) by completing Form 44 and providing the necessary data as specified in Schedule Y of the Drugs and Cosmetics Act 1940 and Rules 1945 (24). Furthermore, to demonstrate the drug's effectiveness and safety in the Indian population, the company must conduct clinical trials in accordance with the guidelines outlined in Schedule Y and submit the corresponding report in the prescribed format (25).

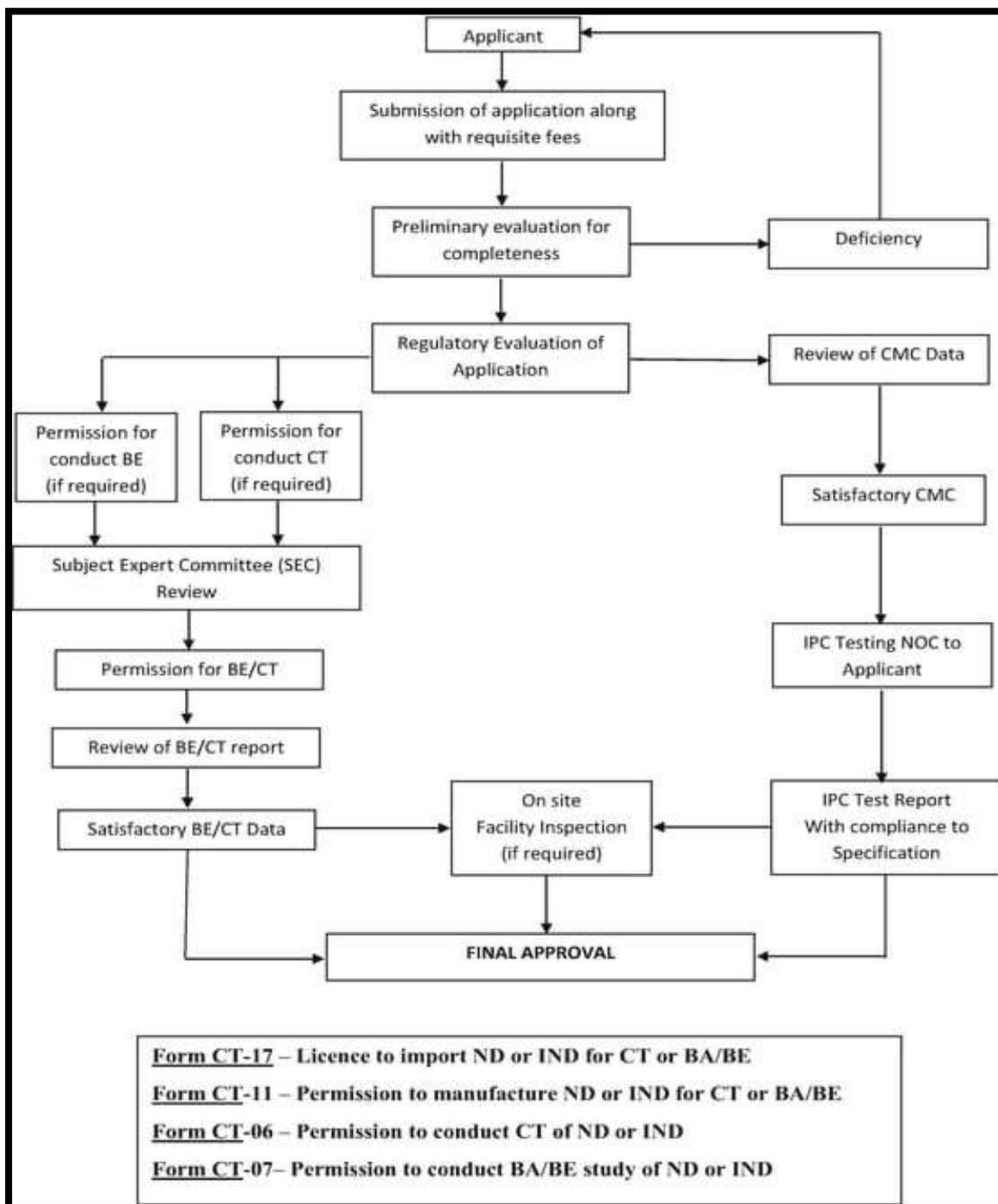


Fig. No. 2: New drug process in India

**Regulatory Affairs in R&D:**

The regulatory affairs team collaborates with marketing and R&D to create cutting-edge products that leverage recent advancements in technology and regulations to expedite the time it takes to bring them to market(26). Working closely

with marketing and R&D, the regulatory affairs personnel develop innovative products that capitalize on new technological and regulatory advancements, resulting in a faster time to market. As the introduction of new products is expected to significantly increase the company’s revenue, even

small reductions in time to market translate into substantial financial gains. By implementing adaptive clinical trial strategies, obtaining swift approval from regulatory authorities, and avoiding potential pitfalls in the processes, the development of new products can be accelerated while minimizing costly errors and delays.(27,28,29).

#### Regulatory Affairs in Clinical Trials :

The RA expert is the number one hyperlink among the employer and international regulatory businesses together with 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 financial Collaboration and development (OECD) and Health Canada. He additionally communicates the apparently countless mace of legal guidelines, guidelines and tips to the opposite departments of the employer (30).

#### Regulatory affairs in productmanagement:

The RA professional's role extends beyond product registration, encompassing strategic and technical guidance at the highest level for companies. Their involvement commences during product development and extends to the formulation of manufacturing, marketing, and post-marketing strategies. Their counsel, addressing both legal and technical prerequisites, aids companies in saving significant time and resources during product development and marketing endeavours. In the absence of domestic regulations, adherence to the guidelines set forth by the World Health Organization on health matters and the World Trade Organization on international trade regulations is observed.(3)

## II. CONCLUSION :

The Pharmaceutical Affairs Bureau puts first priority on providing a safe and secure system. Providing effective medicine to people around the world. Regulatory issues are also important for research and development, product management, and clinical research. Regulatory matters in companies, divisions grow. Respondents were academics and students areas should understand basic concepts regarding RA. RA professionals come from a variety of backgrounds specialized fields such as law, science, industrial research, and medicine. Proper implementation regulatory policies and laws will improve this . It

also improves the economic growth of companies and people's safety.

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