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Drug Regulatory Affairs - Role of Regulatory Affairs in the Pharmaceutical Industry

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ABSTRACT

Pharmaceutical drug regulatory affairs govern the registration parameters of pharmaceutical products. It has an extensive spectrum protecting all factors of documentation and advertising and marketing in legalized form. The pharmaceutical enterprise is a distinctly regulated industry in our country. Regulatory affairs gurus want the current market state of affairs to cater to hyperlink pharmaceutical industries and global regulatory agencies. Regulatory affairs (RA), is an occupation inside synchronized several industries, such as pharmaceuticals, clinical gadgets, and biotechnological industries. Regulatory Affairs additionally has a very precise which means inside the pharmaceutical industries. DRA is a dynamic, moneymaking subject that consists of each scientific and felony element of drug development. Regulatory affairs gurus assist the organization keeps away from issues precipitated using badly stored records, inappropriate scientific wondering, or bad presentation of data. In most product areas the place regulatory necessities are imposed, and restrictions are additionally positioned upon the claims which can be made for the product on labeling or in advertising.

INTRODUCTION

Regulatory Affairs (RA), also called Government affairs is a profession within regulated industries such as pharmaceutical, medical devices, energy, & banking. Regulatory affairs also have a very specific meaning within the healthcare industries (medical devices, pharmaceuticals, biology's functional foods). Most companies, whether or not they are the most important multinational pharmaceutical firms or small, progressive biotechnology organizations have expert departments of Regulatory Affairs professionals [1]. Nowadays the pharmaceutical industry is well organized, systemic, and compliant with international regulatory standards for the manufacturing of chemical and biological drugs for human and veterinary consumption as well as medical devices, traditional cosmetics, and herbal products. Each regulatory system had faced certain circumstances which led to the current well-defined and controlled regulatory framework this has resulted in systemic manufacturing and marketing of safe, efficacious, and qualitative drugs. With the growth of industry, the legislations from each region have become more and more complex and created a need for regulatory professionals. [2]

The regulatory professional's job is to keep track of ever-changing legislation in all the regions in which the company wishes to distribute its products they also advise on the legal and scientific control and requirements. They are responsible for the presentation of registration documents to regulatory agencies and carry out all the subsequent negotiations necessary to obtain and maintain marketing Authorization for the product they give strategic technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole. The demand for Regulatory Affairs (RA) professionals is evident across the pharmaceutical industry, consultancy companies, clinical research organizations, and regulatory agencies. [3,4]

History of Regulatory Affairs

Modern medicine regulation started in 19th-century life sciences, especially in pharmacology, chemistry, and physiology. Which laid a foundation for modern drug development and research and started to develop successfully after the Second World War. Unfortunate events have catalyzed the development of medicines regulation more than the evaluation of knowledge base. In 1937 over 100 people died of diethylene glycol poisoning following the use of a sulfonamides elixir in the United States which used the chemical as a solvent without

any safety testing this facilitated introduction of the federal food. Drug and cosmetics act with premarket notification requirement for new drugs in 1938 However, in countries with a poor regulatory environment even recently medicines contaminated with diethylene glycol have killed patients.[5]

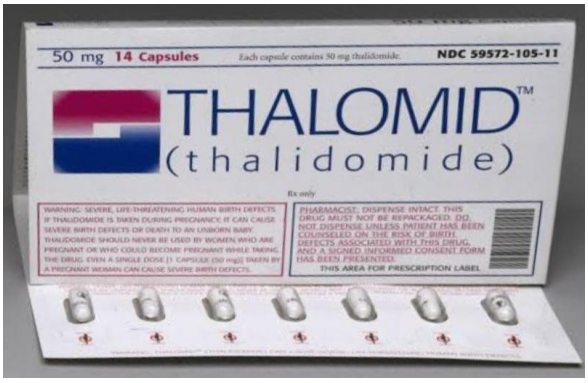


Figure No. 1: Thalidomide capsule.

The second incident that influenced the development of medicines regulation more than any event in history was the thalidomide disaster Thalidomide was a sedative and hypnotic that first went on sale in western Germany in 1956 between 1958 and 1960 it was introduced in 46 different countries. Worldwide resulting in an estimated 10,000 babies being born with phocomelia and other deformities. As result, the whole regulatory system was reshaped and substantially increased legislation for drug product quality, safety, and efficacy. This has resulted in stricter norms for Marketing Authorization (MA) and good manufacturing practices (GMPs).[6]

Role of Regulatory Affairs

Regulatory Affairs (RA), is professional within regulated industries Regulatory affairs also have a very specific meaning within the health care industries. The companies are responsible for the discovery, testing, manufacture, and marketing of these products and also want to ensure that they supply products that are safe and make Worth While contributing to public health and welfare. Regulatory Affairs is a professional developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicine, medical devices, pesticides, agrochemicals, and cosmetics by the companies. The main need of regulatory affairs is to provide the basis for the assurance of the high quality of food products which can increase Consumer's interest in ensuring efficacy, quality, and safety. [7]

Regulatory Affairs (RA) professionals are employed in industry, government regulatory authorities, and academics. They aim to protect public health in terms of the safety, quality, and efficacy of products like medical devices, pharmaceuticals, veterinary medicines, pesticides, cosmetics, complementary medicine, etc. The wide range of regulatory professionals includes this area. pharmaceuticals, cosmetics, medical devices, biologics and biotechnology, and in-vitro diagnostics. Regulatory Affairs are vital to the proper functioning of society and economies. Regulation protects the rights, safety, and health of citizens and ensures the safe and effective delivery of public goods and services.[8]

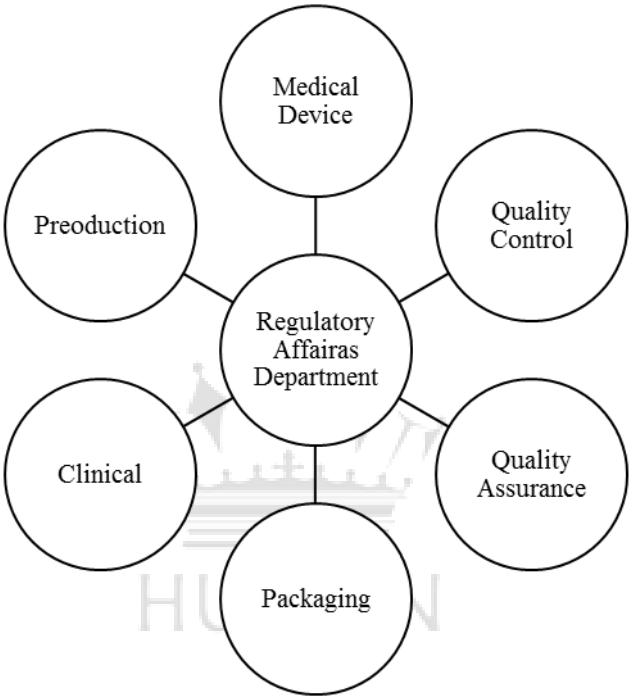


Figure No. 2: Role of Regulatory Affairs

In today's competitive environment the reduction of time taken to reach the market is critical to products and hence the Company's success. The proper conduct of its Regulatory activities is therefore of considerable economic importance for the company. A new drug might also have a value of many tens of millions of Euros or dollars, pounds, to enhance and even a three-month extend in bringing it to the market has sizeable monetary issues and even worse screw-ups to completely record all the on-hand facts or launch of the product being incorrect, labeling might also without problems result in the want for a product recall both incidences may additionally lead to the loss of various hundreds of thousands of units of sales. Not to mention the resulting reduction in confidence of the investors, health professionals, and

patients. The regulatory affairs department is very often the first point of contact between the government authorities and the company. [9,10]

The key role of Regulatory Affairs (RA) professionals is broader than registration products. They advise the company both strategically and technically at the highest level. Their role begins right from the development of the product to make, marketing, and post-marketing strategies. Their advice at all stages both in term 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 regulations the world health organization guidelines on health matters and world trade organization on trade regulations between nations is followed. [11,12]

Regulatory Bodies in the World

Every country has its very own regulatory authority which is accountable to implement the regulations and policies and problem tips for drug development, licensing, registration, manufacturing, advertising and marketing, and labeling of pharmaceutical products. The regulatory bodies are given in table 1. [13,14]

Table No. 1: Regulatory Bodies in the World

Sr no.	Country Name	Regulatory Body
1	USA	Food And Drug Administration (FDA)
2	UK	Medicine and Healthcare Products Regulatory Agency (MHRA)
3	Australia	Therapeutic Goods Administration (TGA)
4	India	Central Drug Standard Control Organization (CDSCO)
5	Canada	Health Canada
6	Europe	European Medicines Agency (EMEA)
7	Japan	Ministry Of Health, Labor Welfare (MHLW)
8	Ukraine	Ministry Of Health
9	China	State Food And Drug Administration
10	Germany	Federal Institute For Drugs and Medical Device

Pharmaceutical drug Regulatory Affairs

This branch is accountable for understanding the regulatory necessities for getting new products approved. They recognize what commitments the organization has made to the regulatory corporations in the place the product has been approved. They additionally post annual reviews and dietary supplements to the agencies. Regulatory Affairs usually communicates with one of the facilities at the FDA headquarters as an alternative to the FDA's nearby district offices. However, they need to recognize and consider adjustments to drug manufacturing and check out things to do to decide if and when the FDA have to be notified the organizations accountable for the discovery, testing, manufacture, and advertising of this merchandise additionally prefer to make certain that they grant merchandise that is protected and make a worthwhile. Contribution to public fitness and welfare. [15,16]

Drug Development Process and Clinical Trial

The innovator company synthesis a New Chemical Entity (NCE) or New Biological Entity (NBE) which can probably be a cure for a disease. The synthesis of NCE/NBE takes place in the preclinical testing period. The innovator company after the synthesis of an NCE/NBE files an Investigational New Drug (IND) application and requests the FDA to grant permission to conduct clinical trials. Clinical trials today have become one of the most important aspects of modern medical research and drug development.[17]

After studying the IND application, FDA grants permission to conduct clinical trials which involve studies in phases like phase1, phase 2, and phase 3. The innovator company files New Drug Application (NDA) and requests the FDA to grant permission to commercialize the product after studying the application, FDA grants permission to launch the new drug in the market the company continues clinical trials of the same molecule in phase 4 called product surveillance studies. Not every compound that is tested in the laboratory is marketed but before is marketed it has undergone several stages of development called drug development. The development of a new drug is a complex and costly process the cost for the development of biopharmaceuticals is higher than those specified earlier. About 10,000 NCE investigated to potentially treat disease, only 250 might make it to the animal testing and these approximately 5-10 would qualify for testing in humans, which means 1-2 of the original 10,000 NCE results in a marketable product. [18,19]

There are five important steps including many phases and stages each of them.

The five steps are:-

1) Step 1: Discovery and Development
2) Step 2: Preclinical Research
3) Step 3: Clinical Development
4) Step 4: FDA Review
5) Step 5: FDA post-market safety monitoring.

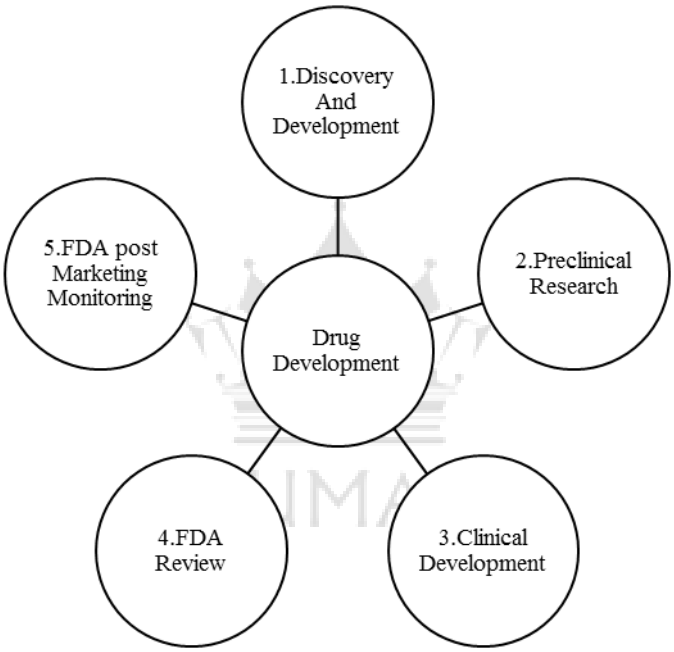


Figure No. 3: Drug Development Process

Step 1: Discovery and Development

Drug discovery efforts address a biological target that has shown to play a role in the development of the disease or starts from a molecule with interesting biological activities. The drug discovery process involves the identification of candidate drugs in their synthesis, characterization, screening, and assay for therapeutic efficacy.

Stages of Drug Discovery

1. Target Identification
2. Target Validation
3. Lead Identification
4. Lead Optimization
5. Pre-Clinical Safety
6. Clinical trials

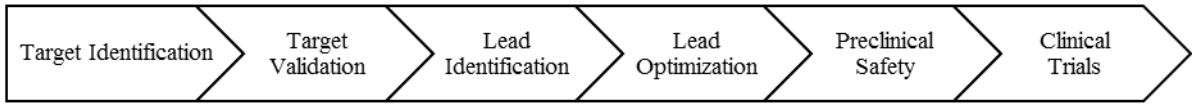


Figure No. 4: Stages of Drug Discovery

Step 2: Preclinical Research

The preclinical research step comprises studies on animals to find out various parameters for a potential drug candidate under the process of development during this stage a sponsor evaluates the drug's toxic and pharmacological effects through in-vitro and in-vivo laboratory animal testing. At the preclinical research step, the US FDA's minimum requirement is that a sponsor should develop a pharmacological profile of the drug; determine its acute toxicity in at least two species of animal and conduct short-term toxicity studies ranging from 2 weeks to 3 months, depending on the proposed duration of use of the candidate drug in the proposed clinical studies.[20]

Step 3: Clinical Development

The clinical development step involves the development of potential drug candidates comprised of pharmaceutical clinical trials which are commonly conducted in 4 phases.

Phase 0: This is an exploratory phase of a clinical trial that expedite the development of a promising drug by establishing early on whether the agent behaves in human subjects as anticipated from preclinical studies.

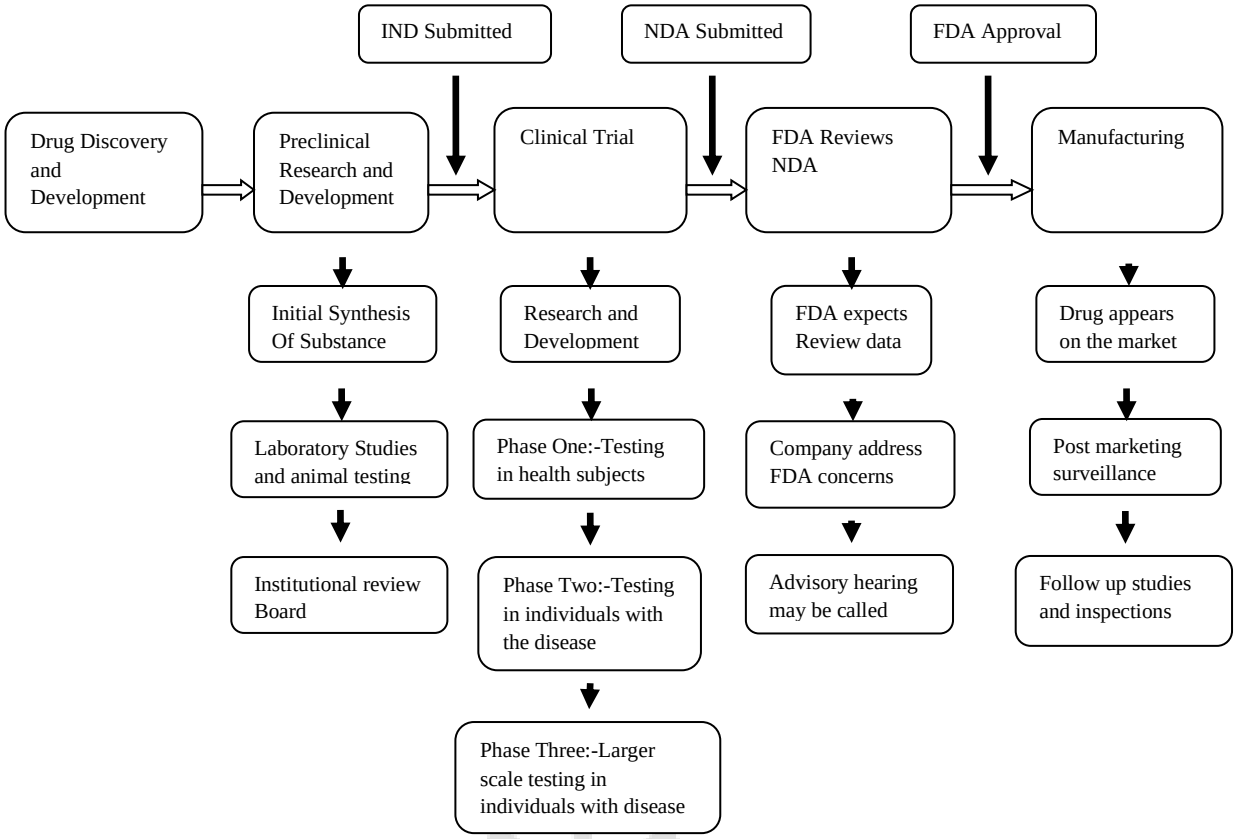
Phase 1: Studies in phase 1 are carried out on a small number of healthy volunteers usually 20 to 100 with the disease or condition and the study requires several months. The purpose of studies in this phase is to identify the metabolic and pharmacological effects of the drug in humans and to determine the side effects associated with increasing doses mainly by determining the safety profile. During phase1sufficient information about the dose of the drug ranging studies so that doses for clinical use can be adjusted approximately 70% of drugs tested in this stage move to the next phase.

Phase 2: Phase 2 includes the early controlled clinical studies conducted to obtain some preliminary data on the effectiveness (efficacy) of the potential drug for a particular indication or indication in patients with the disease or condition testing in this phase help to determine the common short-term side effects and risks associated with the drug under testing these studies are typically well-controlled closely monitored and performed on larger groups of patients usually involving 20-300 the length of study vary from several months to 2 years and approximately 33 % of drugs tested as this phase move to the next phase.

Phase3: Phases3 are expanded, controlled and uncontrolled trials the purpose of study at this phase is to gather additional information about the effectiveness and monitoring of adverse reactions phase 3 includes several hundred to several thousand people usually 300 to 3,000 who have the disease or condition to obtain approval from the US FDA it is typically expected that there must be at least two successful phase-3 clinical trials. The length of study varies from 1-4 years. [21,22]

Step 4: FDA Review

Once the new drug is formulated for its best efficacy and safety, and the results from clinical trials are available, it's advanced for FDA review at this time FDA Review and approves, or does not approve. [23, 24]



Step 5: FDA Post-Market safety monitoring.

This step is also known as Post Marketing Surveillance (PMS) and it is carried out once the candidate drug is approved as a drug and marketed as a medicinal product. This phase aims to find out the drug safety profile in a large patient pool across the world and to establish its Safety profile it is estimated that the success rate of drugs making to market from the laboratory is very less the post-launch safety monitoring helps to detect rare or long term adverse effects of the drugs over a large patient population and time scale than was possible during a clinical trial usually, several thousand volunteers who have the disease or condition are involved in this phase of the trials.[25,26]

Regulatory Affairs in R &D

The Regulatory Affairs personnel work hand in hand with advertising and R & D to develop innovative products that take advantage of new technological and regulatory developments to speed up time to market with new products expected to add great revenues to the company's bottom lines using adaptive clinical trial strategies acquiring quick approval from regulatory authorities and avoiding pitfalls in the method can accelerate the development of new products and help to reduce high-priced errors and time lags.[27,28]

CONCLUSION

Regulatory Affairs (RA) is a profession that acts as interference between the pharmaceutical enterprise and drug regulatory authorities across the world. It is mainly concerned with the registration of drug products in the respective countries before their marketing. The Regulatory Affairs branch is continually evolving and growing and is the one that is least impacted at some stage in the assembly and addition. Regulatory Affairs departments are growing inside companies. The proper implementation of regulatory guidelines and legal guidelines will improve the economic boom of the company and also improves the security of the people. Regulatory Affairs departments are getting larger inside the companies. Due to the altering resource necessary to fulfill the regulatory requirements, some agencies also choose to outsource or out assignment regulatory affairs to external service providers.

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