REVIEW ON REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSRTIES

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Abstract: Regulatory affairs (RA) plays very important roles in pharmaceutical industrial department which have the responsibility for obtaining approval for new products arriving in the market and ensures that approval is maintained for as long as the company wants to keep the product for marketing & it also provide calculated and operational ways and assist for working within regulations to accelerate the development and delivery of safe and effective healthcare products for every particular person all over the world. It behaves as the link between the regulatory authority and the project team, and is the passage for communication with the regulatory authority as it move forwards, target to providing that project plan correctly predicts what the regulatory authority will require before approving the product. The role of regulatory affairs is to develop and carry out a regulatory strategy to make sure that the collective efforts of the drug development team results in product that is going to approve by global regulators. Regulatory Affairs have so many career choice for the graduate students from a scientific background who are interested for the communication and team work, are complacent with multi tasking and who have enthusiastic response to expand their knowledge in the pharmaceutical world. Regulatory Affairs is a gratifying, mentally invigorating and highly considered profession within pharmaceuticalfield.

Keywords: Regulatory authorities, Regulatory agencies, Pharmacy schedule,Pharmacy policy, Worldwide regulatory agencies.

Introduction:A new molecule can cost several millions of rupees or dollars to progress and any blunder causes greater impact on company's status. As medicines play a vital role in human's life there must be regulations for medicines ensuring Quality, Safety and Efficacy of drugs. The regulatory affairs professional is the only one who is completely responsible for holding products in compliance and maintaining all the records. One of the vital activities of the regulatory specialist is to ensure that the all the information regarding medicines has been correctly established to the patient covering labeling also. Even a small mistake in any of the activities related to regulatory can make the product to be recall in addition to loss of several millions of the money.[1] The current Pharmaceutical Industry is well organized, systematic and compliant to international regulatory standards for manufacturing of Chemical and Biological drugs for human and veterinary consumption as well as medical devices, traditional herbal products and cosmetics.[2] Drug development to materialistically is highly controlled. Every drug before acquire market approval must undergo meticulous inspection and clinical trials to make sure its safety, efficacy and quality. These standards are bring by regulatory authorities of their corresponding countries like as FDA in US and DCA in India etc. Regulation influences all strands of the pharmaceutical world, from maverick pioneers and pharmaceutical companies to regulatory and managerial bodies and patients also.

Regulatory department is pivotal interface between company, products and regulatory authorities whose positive or negative vantage point to strengthen the discernment of the regulatory authority into the industry, for good or for bad. So, the better the scientific exactitude, the greater will be the chances for a product to come to the market within the expected time.

Objectives of the Regulatory Affairs: The present study describes a brief review of various regulatory bodies of major developed and developing countries around the world and the scope and challenges of such pharmaceutical regulatory organizations in delivery of safe and effective healthcare products.

1. Roles of Regulatory Affairs Professional in Health Authorities as well as Pharmaceutical Industry.
2. PharmaceuticalLegislations.
3. ClinicalTrials.

What is regulatory affairs?

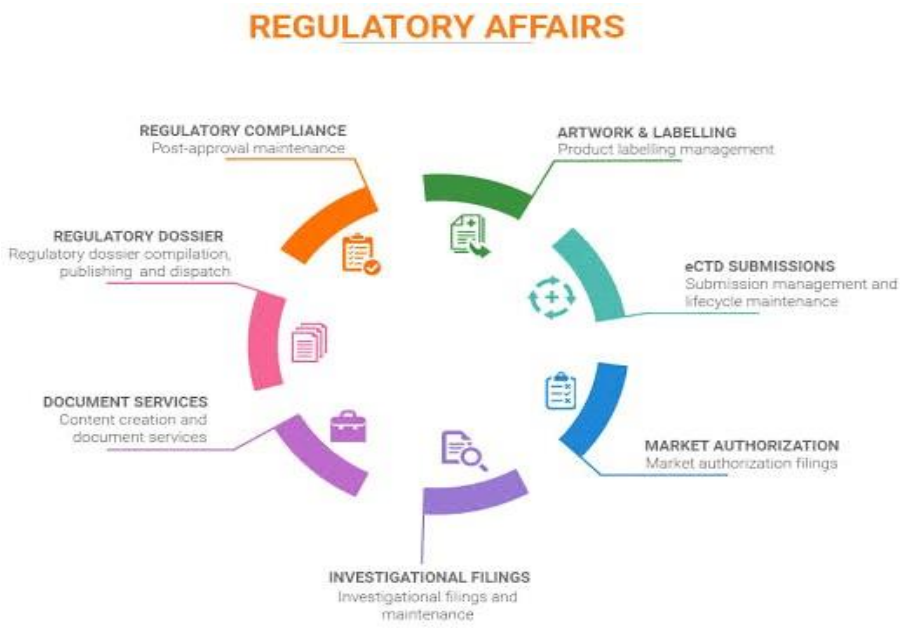

Fig1: What is regulatory affairs[17]

Regulatory affairs is a comparatively new profession which developed from the desire of governments to protect a public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines.

REGULATORY AFFAIRS in the pharmaceutical industry may be defined as "the interface between the pharmaceutical company and the regulatory agencies across the world."[3]

Evolution of regulatory affairs: In 1950's generation, many tragedies came about due to the misinterpretation of the employees during manufacture & some purposive addition of contaminated substances into the pharmaceutical product which has move forward to the execution of the patients. After so many occurrences, the regulatory bodies launched the new laws and guidelines which are going to ameliorate the quality, safety and efficacy of the products. This is again developed into severe standards for Marketing Authorization (MA) and Good Manufacturing Practices (GMPs). That is the tragedies of **SULPHANILAMIDE ELIXIR, VACCINE TRAGEDY & THALIDOMIDETRAGEDY.**

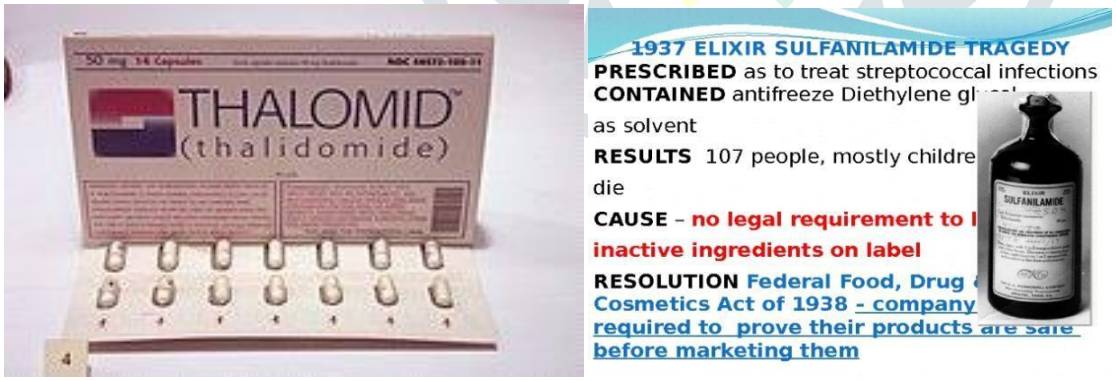

Fig2: THALIDOMIDE AND SULFANILAMIDE TRAGRDY[4]

FDA launched in 1906 as Bureau of chemistry, served simply to police claims made about food and drugs ingredients. At that time no formal government approval required to market new drugs. The disasters provoked a public outcry that led to the passage of the 1983 Food Drug & Cosmetics Act, which gave the FDA power to monitor the safety of new drug.

Roles of regulatory affairs in pharmaceutical industry: The roles of regulatory affairs professional is to act as cooperation with regulatory agencies:

1. To audit on constantly changingconstitution.
2. Adapted documents to regulatoryagencies.
3. To give tactical and practical advice to R&D, Production, QCDepartment.
4. Preparation of well ordered and Ensure fidelity and complaisance with all the applicable CGMP, ICH, GCP, GLP guidelines regulations andlaws.

5. Providing prowess and regulatory perception in interpreting regulatory necessities into practical viableplans.
6. A regulatory affair plays a pivotal role in the industry and is intricated in all stages of drug development and also after drug approval andmarketing.

Scope of regulatory affairs in pharmaceutical industry: The regulation of medical products has been expanding since early 20th century. Regulatory agencies are being established in an ever increasing number of countries across the globe. Those that have established are reorganizing their systems and attempting to harmonize with organizations of other countries1 . The pharmaceutical, biotechnology and medical devices are among the most highly regulated industries in the world. Regulatory affairs (RA) professionals are employed in pharmaceutical industry, government, academic research and clinical institutions. The Indian Pharmaceutical industry is one of the fastest growing industries in India, with a compounded annual growth rate (CAGR) of over 13 % in last 5 years and it is expected to grow at a higher rate in coming 10 years. It is valued at $ 8.0 billion approximately and ranks 4th in terms of volume and 13th in terms of value globally.[5] All companies engaged in R&D worth its salt has an individual RA department to aid them in new product development. The clinical research industry, which provides opportunities for RA professionals, is also growing at an unparalleled rate. It has opened up new vistas of employment for a large number of trained professionals. The clinical trials market worldwide is worth over USD 52 billion. A study by Ernst and Young indicates that the total market value of Clinical Research activities performed in India is expected to grow to around USD 1.5-2 billion. There is expected to be a huge demand for qualified RA personnel in clinical research.[6]

International Regulatory Environment: Good Manufacturing Practices has been in practice from Old Testament times (Laws of Kashrut). The Nuremberg Code, 1947 on Permissible Medical Experiments[7] provided for basic principles to conduct medical experiments on human beings followed by Declaration of Helsinki (1964)[8] , Belmont Report of USA[9] (1978) and WHO GCP[10] (1995) and ICH GCP[11] in 1996. In 1959, Canada instituted its QUAD regulations, which is the first recognizable drug GMP of modern era. It was followed by GMPs of USA in 1963 and that of UK in1972.

Future developments: In the Regulatory Affairs Profession count on the make overtures to regulation will ultimately be acquired for all healthcare products as it constitutes the best model for delivering new healthcare proceeds to market in a appropriate time with justifiable safety. Regulatory Affairs departments are enlarging within the bounds companies. Due to the changing assets it is essential to attain the regulatory necessities, some companies also go for to redistribute or out task regulatory affairs to exterior amenity supplier. Regulatory Affairs department is persistently extending and enlarging and is the one which is slightly influenced during the investment and alliance, and besides throughout downturn. Global harmonization in excellence has led to reconcilable solicits in regulatory capitulation and hence itsreview.

Recent developments: Beginning of the 1980 the European Unionerupted to systematized the regulation of healthcare products in the member states. The postulation of regulating medicines was genuine in most member countries besides indistinguishable rules to the US model, but many countries did not have at all notable medical deviceregulation. coexistently the EU had been evolving the notion of New Approach Directives where at most extensive notion were registered into the law and the large amplitude of the technological allocate authorized to abidance with acceptable standards (which are more easily upgradable).

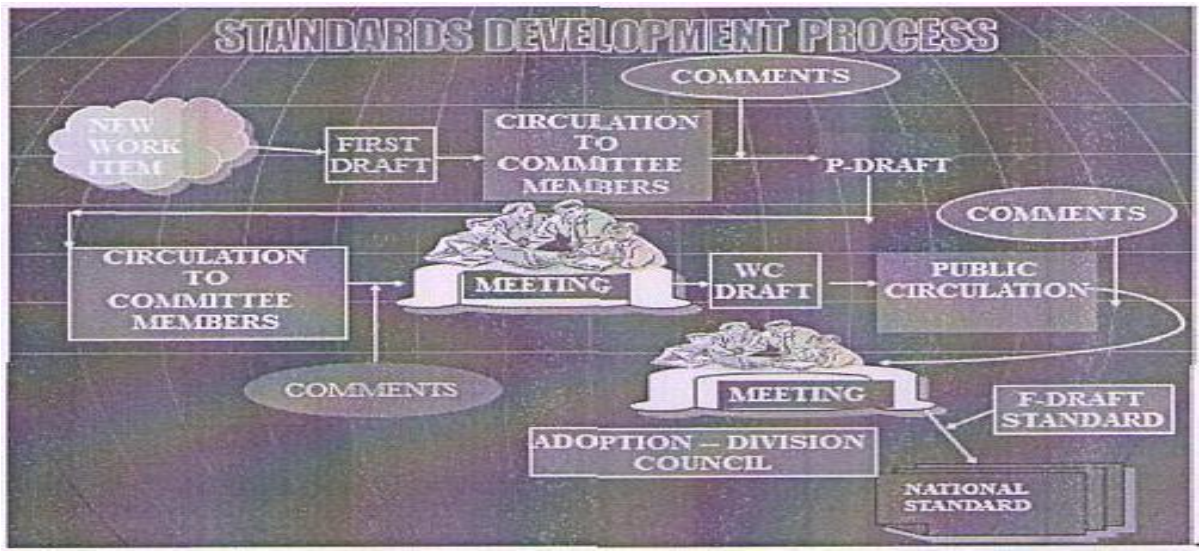

Fig3: Standard development process

1) The Europeans pulled the revolutionary strategies of petition the New Approach Directive to Medical Devices and beyond performing so assembled the initial notable abstracts promote in healthcare regulation being almost thecentury.
2) The European Model for medical device has mostly take on by the Global Harmonization Task Forceas long as the intercontinental arrangementrevolution.
3) Besides regulatory affairs professional, they are habitually in control for tracing alters in regulatory guide lines as they mayhappen.
4) Forthepurposeofthis,theyshouldtakeholdoftheingenuitytomaintainlatestonallalterations in regulations. For example, they have to check the PDA Web site and read professional journals.
5) They can study about recently introduced guidelines from individual sources like peers, print liberated from regulatory authorities and be present atconvocations.
6) All alterationsin regulations necessarily registered in the way demanded by the company. Changes must alsobe clarify and commune to suitable persons in the company.
7) Management be allowed at that time regulate what alterations in company approaches and actionmaybeneededtoremaininsubmission.
8) They are also incorporated with harmonizing and executing the alterations which claims for greatly responsivenessso that alterations proposed are fluently received by the company's management and the regulatory bodies. They have a vital endowment to make in company's victory both economically andscientifically.

Involvement of regulatory affairs in pharmaceutical industry: 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.

Fig4: RA Profession: Integral to the healthcare products lifecycle[16]

Regulatory Affairs in Product Management: The key role of RA professional is broader than registration of products, they advise companies both 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 on regulations the World Health Organization guidelines on health matters[12] and World Trade Organization on trade regulations between nations is followed.[13]

Regulatory Affairs in R&D: The regulatory affairs staff work in an association with marketing and R&D to develop, original products that take authority of recently developed high-tech and regulatory progresses to speed up the time to market. Accompanied by new products assumed to add on notable outcomes to the company's core, slight drop in time to market equalize to major material obtain in outcome and yield. Recruiting modifiable clinical trial planned, relinquishing fast approval by regulatory authorities and eschewing hazards in processes can speed up development of new products and suggest to lessen expensive mistakes and time lags.[9]

Responsibilities: The responsibilities of RA staff in extensive can be encapsulated into three

1) Certifythattheircompaniesoutlineaccompaniedalloftheregulationsand legislations related to theirbusiness,
2) Working with confederate, state and provincial regulatory agencies and staff on particular problems influencing theirbusiness.
3) Counsel companies on the regulatory features and region that would influence their suggestedactivities.

In a marketing arrangements their main responsibilities concerns construction and presentation of registration data to regulatory agencies and convey out all communication to acquire and continue marketing authorization (MA) for the products united. They need to keep track on almost altering laws in all countries where the companies is focusing to market their product. They play a crucial part in making easier the economical development of new health products and mechanization via product circuition.

Regulatory affairs education:

INDIA OFFERING REGULATORY AFFAIRS AS ONE OF THE SUBJECTS IN PG COURSE

In India, there are only two universities

1) Guru Jambheshwar University,Haryana.[14]
2) Manipal College of Pharmaceutical Sciences,Manipal.[14]

Challenges: The major challenges of these regulatory bodies are:

1) To promote public health and protect the public from harmful and dubiousdrugs,
2) To establish proper legalization covering all products with a medicinal claim and all relevant pharmaceutical activities, whether carried out by the public or the privatesector.
3) To increase worldwide regulatory growth to ensure safety of people.[15].**Major Regulatory Agencies WorldWide:**

Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue guidelines for drug development, licensing, registration, manufacturing, marketing and labeling of pharmaceutical products.[15]

Table No.: 1[15]

Country	Name of Regulatory Authority
USA	Food and Drug Administration (FDA)
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
India	Central Drug Standard Control Organization (CDSCO)
Canada	Health Canada
Europe	European Medicines Agency (EMEA)
Denmark	Danish Medicines Agency
Costa Rica	Ministry of Health
New Zealand	Medsafe - Medicines and Medical Devices Safety Authority
Sweden	Medical Products Agency (MPA)
Netherlands	Medicines Evaluation Board
Ireland	Irish Medicines Board
Italy	Italian Pharmaceutical Agency
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)
Ukraine	Ministry of Health
Singapore	Centre for Pharmaceutical Administration Health Sciences Authority
Hong Kong	Department of Health: Pharmaceutical Services
Paraguay	Ministry of Health
Sweden	Medical Products Agency (MPA)

Thailand	Ministry of Public Health
China	State Food and Drug Administration
Germany	Federal Institute for Drugs and Medical Devices
Malaysia	National Pharmaceutical Control Bureau,Ministry of Health
Pakistan	Drugs Control Organization, Ministry of Health
South Africa	Medicines Control Council
Sri Lanka	SPC,Ministry of Health
Switzerland	Swissmedic , Swiss Agency for Therapeutic Products
Uganda	Uganda National Council for Science and Technology (UNCST)
Brazil	Agencia Nacional de Vigiloncia Sanitaria (ANVISA)
Japan	Ministry of Health, Labour & Welfare(MHLW)
INTERNATIONAL ORGANIZATIONS	
World Health Organization (WHO)	
Pan American Health Organization (PAHO)	
World Trade Organization (WTO)	
International Conference on Harmonization (ICH)	
World Intellectual Property Organization (WIPO)	

Conclusion: Numerous in the Regulatory Affairs occupation convinced by the eventually newly extended approaches to regulation will usually be embraced accompanied with all healthcare products as it appears to the best model for bringing new healthcare developments to market in a rational time along with tolerablewelfare.

Regulatory Affairs department is persistently progressing and enlarging and is the one which is least influenced throughout the accession and amalgamation, and also throughout downturn. Regulatory Affairs departments are getting larger inside t he companies.

Because of the altering assets obligatory to a cc o mp l i s h the regulatory necessities, some companies also select to redistribute or out task regulatory affairs to extrinsic amenity supplier. Among this in present days ruthless habitat the depletion of the time taken to get into the market is condemnatory to a product's and consequently the company's triumph. The genuine management of its Regulatory Affairs pursuit is for that reason commercial significance besides the company.

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