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Introduction to Regulatory Affairs

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A B S T R A C T

Regulatory affairs is having important role in pharmaceutical industries having responsibilities to obtain approval for new products arriving in the market and ensures that approval is maintained till the period that drug product is in market and provide ways to working within regulations for safety and efficacy, Regulatory affairs links regulatory authorities of various countries and organisation. The role of Regulatory Affairs is to develop and carry out regulatory strategy to make sure that collective efforts of drug development team results in product that is going to approve by Regulatory authorities. Various countries having different regulatory authorities which having stringent rules and regulations. The ultimate Aim is Quality, safety and efficacy. Regulatory affairs has many career choice for graduate students from scientific background who are interested in teamwork, communications. Regulatory affairs is gratifying, highly considered profession in pharmaceutical field.

Keywords: Regulatory authority, agencies, Authority

INTRODUCTION:

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. 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.The Medical devices is demanding sector nowadays.Drug development to materialistically is highly controlled Every drug before acquire market approval must undergo 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 CDSCO in India etc. Regulation influences all strands of the pharmaceutical world pharmaceutical companies to regulatory and managerial bodies and patients also. Regulatory department is interface between company and regulatory authorities whose positive or negative point to strengthen the perception. 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 in expected period.

Objectives of the Regulatory Affairs:

This 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. Pharmaceuticall. lagislations.
3. Clinical Trials

What is regulatory affairs"

Regulatory affairs is a 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 be defined as "the interface between the pharmaceutical company and the regulatory agencies across the world."(5)

Evolution of regulatory affairs:

In 1950's generation, many tragedies came about due to the unstringent regulations 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). The tragedies like Thalidomide,Diphtheria occur .In case of Thalidomide it is sleeping pill and it is teratogenic so due to this birth defects were seen in babies.(15)

The roles of regulatory affairs professional is to act as

1. .To audit on constantly changing constitution.
2. Adapted documents to regulatory agencies.
3. To give tactical and practical advice to R&D, Production, QCDepartment
4. Providing prowess and regulatory perception in interpreting regulatory necessities into practical viable plans.
5. A regulatory affair plays a pivotal role in the industry and is intricated in all stages of drug development. (2)

Scope of regulatory affairs in pharmaceutical industry:

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 countries! 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. It is valued at $ 8.0 billion approximately and ranks 4th in

terms of volume and 13th in terms of value globally. 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.. It has opened up new vistas of employment for a large number of trained professionals.."(3)

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 provided for basic principles to conduct medical experiments on human beings followed by Declaration of Helsinki (1964), Belmont Report of USA" (1978) and WHO GCP (1995) and ICH GCP 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 in 1972.

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 asset 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.

Recent developments:

Beginning of the 1980 the European Union erupted 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 device regulation, 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)

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 the century.

2) The European Model for medical device has mostly take on by the Global Harmonization Task Force as long as the intercontinental arrangement revolution.

3) Besides regulatory affairs professional, they are habitually in control for tracing alters in regulatory guide lines as they may happen Forther purpose of this ,they should take hold of the ingenuity to maintain latest on alterations in regulations. For example, they have to check the PDA Web site and read professional journals.

4) They can study about recently introduced guidelines from individual sources like peers, print liberated from regulatory authorities and be present at convocations.

5) All alterations in regulations necessarily registered in the way demanded by the company. Changes must alsobe clarify and commune to suitable persons in the company

6) Management be allowed at that time regulate what alterations in company approaches and action may be needed remain in submission

7) They are also incorporated with harmonising and executing the alterations which claims for greatly responsiveness 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 and scientifically(7,8)

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

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" and World Trade Organization on trade regulations between nations is followed.(10)

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 relently developed high tech and regulatory progresses to speed up the time to market. Accompanied by new prodults assumed to add on notable dutcomes 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."(12)

Responsibilities.

1. Certify that their companies outline accompanied all of the regulations and legislations related to their business,

2. Working with confederate, state and provincial regulatory agencies and staff on particular problems influencing their business

3. Counsel companies on the regulatory features and region that would influence their suggested activities

4. 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.(14)

The major challenges of these regulatory bodies are:

1) To promote public health and protect the public from harmful and dubious drugs,

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. (12)

Major Regulatory Agencies worldwide

Ever country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue guides for drug development, licensing, registration, manufacturing, marketing and labeling of pharmaceutical products,"[12]

COUNTRY	**NAME OF REGULATORY AUTHORITY**
USA	Food and Drug Administration(FDA)
UK	Medicines and Healthcare products Regulatory Agency (MHRA)
Australia	Therapautic Goods Administration
Canada	Health Canada
Europe	European Medical Agency
Denmark	Danish ,edicines Agency
New Zeland	Medsafe Medicines and Medical Devices Safety Authority
Netharlands	Medicines Evaluation Board
Sweden	Medical Products Agency
Ireland	Irish Medicines Board
Ukraine	Ministry of Health
Thailand	Ministry of Public Health
Japan	Ministry of Health labour and Welfare (MHLW)
Brazil	Agencia Nacional de Vigilonica Sanitaria (ANVISA)
South Africa	Medicines control council
Pakistan	Drugs control organization

INTERNATIONAL ORGANIZATIONS

1. World Health Organization (WHO)
2. World Trade Organization (WTO)
3. International Conference on Harmonization (ICH)

4. World Intellectual Property Organization (WIPO)

Conclusion

In today's competitive environment the reduction of the time taken to reach the market is vital to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic significance for the company.

Inadequate reporting of data may prevent a timely positive evaluation of a marketing application. A new drug may have cost many millions of pounds, Euros or dollars to develop and even a three-month delay in bringing it to the market has considerable financial considerations. Even worse, failures to fully report all the available data or the release of product bearing incorrect labelling, may easily result in the need for a product recall.

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, helping to maximise the cost-effective use of the company's resources. The Regulatory Affairs department is very often the first point of contact between the government authorities and the company. Officials respond much better to a company whose representatives are scientifically accurate and knowledgeable than to one in which these qualities are absent.

References

1) Regulatory Affairs overview, by Dolits Shah & Mayur Mistry
2) Roles of Regulatory Affairs in Pharmaceutical Instasty, by Y. Bri Hanka, V. Shamila Raddy
3) Regulatory affairs professional society www.raps.org
4) Trails of war criminals before Nuremberg Military Tribunals under control council Law No.10
5) Williams JR.Bulletin of World Health Organization 2008:86
6) The Belmont Report, Office of the Secretary, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.7
7) Guidelines for Good Clinical Practices (GCP) for trials on pharmaceutical products, WHO Technical Report series, No:850,1995
8) Good Clinical Practices, Central Drugs Standard Control Organization, Directorate General of Health Services,Ministry of Health & Family Welfare, Govt. of India, 2001
9) World Health Organization guidelines on health matters-www.who.int/entity/er World Trade Organization on trade regulations between nations-http://www.wto.org
10) World Trade Organization on trade regulations between nations- http://www.wto.org
11) Regulatory Affairs from wikipedia, the free encyclopedia, http//en.wikipedia.org/wiki/Regulatory Affairs
12) Pharmaceutical Regulatory Agencies and Organizations around the World: Scope and Challenges in Development, by Geetanjali Sengar, Pranab Tripathy, Drug Regulatory Affairs Dept.
13) Regulatory Affairs Profession: Integral to the healthcare product lifecycle, @2007 R. A. Professionals Society.
14) https://www.medpace.com/capabilities/regulatory-affairs/
15) Kim, J. H., & Scialli, A. R. (2011). Thalidomide: the tragedy of birth defects and the effective treatment of disease. *Toxicological sciences : an official journal of the Society of Toxicology*, *122*(1), 1–6. https://doi.org/10.1093/toxsci/kfr088