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Role of Regulatory Affairs in the Production of Pharmaceutical Products in All over the World

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ABSTRACT

INTRODUCTION: Regulatory affairs has been a very important department in the pharmaceutical Company during the last few years. Currently, this department helps safeguard the products' life cycle and guide the company on regional and global laws/regulations set forth by different regulatory authorities. **ROLE:** Regulatory affairs (RA) professionals play critical roles. People who work in regulatory affairs negotiate the interaction between the regulators, the regulated and the market to get high standard products to the market and to keep them there preventing substandard products from being marketed. They give strategic and technical advice at the highest level in their companies, from the beginning of the development of a product, making a major contribution both commercially and scientifically to the success of a company as a whole. In today's competitive environment the reduction of the time taken to reach the market is critical to the company's success. **CONCLUSION:** The proper implementation of regulatory guidelines and laws will improve the economic growth of the industry and also improve the safety of the people.

INTRODUCTION:

All companies, whether they are multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of regulatory Affairs. The success of a regulatory strategy is less dependent on the regulations than on how they are interpreted and connected within companies and to outside constituents. Regulatory affairs have been the very prime department in pharmaceutical Companies during the last few years in Asia and other countries. Currently, this department helps to guard the product life cycle and lead the company on regional and global laws/regulations set forth by different regulatory authorities. Principally, this consists of data proving that the drug has quality, efficacy and safety properties suitable for the intended use, additional administrative documents, samples of the finished product, and reagents necessary to perform analyses of the product. Therefore, they are the vehicle in a country through which drug sponsors formally propose that the regulatory agencies approve a new pharmaceutical for sale and marketing.

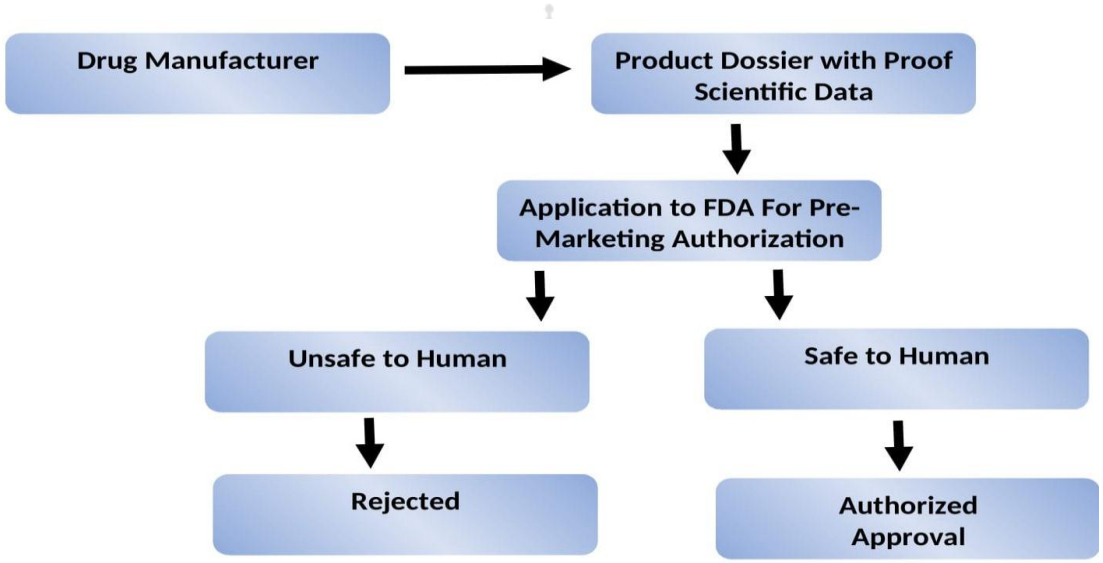

Figure 1: Pre-Marketing approval for the new drug.

HISTORICAL OVERVIEW OF REGULATORY AFFAIRS:

During the 1950s, multiple tragedies i.e. sulphanilamide elixir, vaccine tragedy, and thalidomide tragedy have resulted in a substantial increase of legislation for drug product quality, safety, and efficacy. This has also resulted in stricter norms for Marketing Authorization (MA) and Good Manufacturing Practices (GMPs).

ROLE OF REGULATORY AFFAIRS IN A PHARMACEUTICAL INDUSTRY:

Regulatory Affairs (RA) professionals concerned with the healthcare product lifecycle, it provides strategic, and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals all over the world. The role of regulatory affairs is to develop and execute a regulatory strategy to ensure that the collective efforts of the drug development team result in a product that is approval by global regulators but is also differentiated from the competition in some way and also to ensure that the company's activities, from non-clinical research through to advertising and promotion, are conducted following the regulations and guidelines established by regulatory authorities. Regulatory Affairs (RA) professionals play critical roles. People who work in regulatory affairs negotiate the interaction between the regulators, the regulated and the market to get high standard products to the market and to keep them there preventing substandard products from being marketed. They give strategic and technical advice at the highest level in their companies, from the beginning of the development of a product, making a major contribution both commercially and scientifically to the success of a company as a whole. In today's competitive environment the reduction of the time taken to reach the market is critical to the company's success.

SCOPE OF REGULATORY AFFAIRS PROFESSIONAL IN INDUSTRIES:

- Regulatory affairs professionals are employed in industry, government regulatory authorities, and academics.

- Wide range of regulatory professionals includes in these areas: Pharmaceuticals, Medical Devices, In vitro diagnostics, Biologics, biotechnology, Nutritional Products, and Cosmetics.

DMF (Drug Master File)

Drug Master File is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes, manufacturing, processing, packaging, and storing of one or more human drugs. The information in the DMF used to support the following,

– Investigational New Drug Application (IND),

– New Drug Application (NDA),

– Abbreviated New Drug Application (ANDA),

– Export Application

TYPES OF DMFs:

Type I: Manufacturing Site, Facilities, Operating Procedures, and Personnel.

Type II: Drug Substance, Drug Substance Intermediate, and Material Used in drug preparations, or Drug Product

Type III: Packaging Material.

Type IV: Excipient, Colorant, Flavor, or Essence

Type V: FDA Accepted Reference Information

DOSSIER: A document containing detailed records on a particular person or subject. Any preparation of pharmaceutical product for human use experience the process of reviewing and assessing the dossier of a pharmaceutical product which contains detailed information about administrative, quality, non-clinical and clinical data and the permission permit by the regulatory agencies of a country intending to support its marketing is called as" the Marketing approval" or" registration Marketing authorization" or "Product Licensing". This process is governed by the Drug Regulatory Authority of a particular country and process is called NDA in the USA, MAA in EU and other countries as simply registration Dossier. There are two formats for dossier preparation i.e. ICH-CTD and ACTD. ICH-CTD followed by ICH countries as well as developing countries whereas ACTD is followed by ASEAN countries. ACTD act as a bridge between the regulatory requirements of developed and developing countries. Also, if both guidelines of CTD and ACTD can be harmonized then the variation between both guidelines can be minimized.

Evolution of CTD: Effort over the past 2 decades by ICH of technical requirements for "registration of pharmaceutical for human use" have an outcome in a uni-field dossier for drug applications.

COMMON TECHNICAL DOCUMENT (CTD): CTD is a set of identification for application dossier for the registration of Medicines and designed to be used across Europe, Japan, and the United States. CTD was developed by the European Medicines Agency (EMA,

Europe), the Food and Drug Administration (FDA, U.S.), and the Ministry of Health, Labor and Welfare (Japan). The CTD is maintained by the International Conference on Harmonization for Registration of Pharmaceuticals for Human Use. The agreement to assemble all the quality, safety, and efficacy information in a common format have revolutionized the regulatory review processes.

General Consideration

★ CTD is only a harmonized format for submission of information to relevant regulatory authorities.

★ Template for presenting data in the dossier.

★ A guideline that merely indicates an appropriate format for the data that have been acquired.

★ CTD is not a statement of data for the application of data.

★ A guideline that intends to indicate what studies are required.

★ Define the content.

★ CTD should have clear and unequivocal information.

★ Have a style & font size that is large enough to be effortlessly readable.

Follow the ICH guidelines for:

- Document pagination and segregation.
- Submission requirements for CTD.
- Contained all abbreviations that are used & be listed at the end of the dossier.
- Give proper information about the source of the bulk drug(s) for manufacturing finished formulation.

CTD MODULES:

•The documents, either for a marketing application, an investigational application, or a related submission, should be organized based on the following five modules.

• Module 1 have administrative information and prescribing information.

• Module 2 have CTD summary documents.

• Module 3 have information on quality.

• Module 4 have the nonclinical study reports.

• Module 5 have a clinical study.

Regulation & regulatory bodies of CTD

1. The regulation under Drugs and marketing.

2. Every country has its regulatory authority, which Cosmetics Act & Rules 122A, 122B, and 122D and further Appendix I, IA, and VI of Schedule Y, describe the information required for approval of an application to import or manufacture of a new drug for.

3. Is responsible to enforce the rules and regulations and issue guidelines for drug development, licensing, manufacturing, marketing, and labeling of pharmaceutical products.

4. More or less all the independent countries of the world have their regulatory authorities.

ORGANIZATION OF ASEAN CTD (ACTD) FORMAT:

ACTD is a guideline for the preparation of well-structured CTD applications that would be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals products. Four parts of ACTD are:

- Part I: Table of Contents, Administrative Data, and Product Information

- Part II: Quality Document

- Part III: Nonclinical Document

- Part IV: Clinical Document.

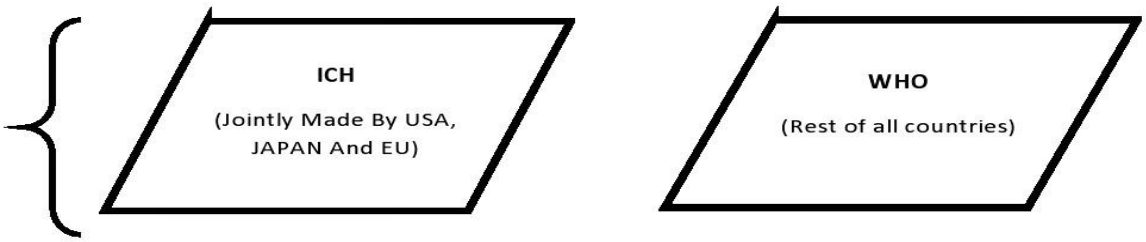

Figure 1: National Regulatory framework.

Figure 2: Global Regulatory Network.

Regulatory Environment in Different Countries:

The regulatory environment in different countries of the world is different according to their rules and regulation of regulatory bodies.

Table No. 1: List of countries and their Regulatory Authority (ICH-CTD)

Country	**Regulatory Authority**
Australia	Therapeutic Goods Administration (TGA)
Argentina	National administration of Drugs, Food & Medical Technology (ANMAT)
Armenia	Drug & Medical Technology Centre, Ministry of Health
Austria	Federal Ministry for Health
Brazil	National Agency for Sanitary Vigilancia (ANVISA)
Belgium	Federal public services (FPS) Health
Canada	Health Canada
China	State Food and Drug Administration (SFDA)
Colombia	National Institute of Food and Drug Monitoring (INVIMA)
Denmark	Danish Medicines Agency
Egypt	Ministry of Health & population
Europe	European Medicines Agency (EMEA)
Fiji	Ministry of Health
France	French Agency for Sanitary Safety of Health Products, Ministry of Health

Germany	Federal Institute for Drugs and Medical Devices
India	Central Drug Standard Control Organization (CDSCO)
Pakistan	Drug regulatory authority in Pakistan
Italy	Italian Pharmaceutical Agency
Japan	Ministry of Health, Labour & Welfare (MHLW)
Malaysia	National Pharmaceutical Control Bureau, Ministry of Health
Russia	Ministry of Health and Social Development
Greece	National Organization for Medicines (EOF)
Hong Kong	Department of Health: Pharmaceutical Services
Hungary	National Institute for Pharmacy
Ireland	Irish Medicines Board
Maldives	Ministry of Health and Family
Mauritius	Ministry of Health and Quality of Life
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)
Romania	National Medicines Agency (ANM)
Singapore	Center for Pharmaceutical Administration Health Sciences Authority
Spain	Medicines and Health Product Agency (AEMPS)
Zimbabwe	Medicine Control Authority of Zimbabwe (MCAZ)
USA	Food and Drug Administration (FDA)
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
Thailand	Ministry of Health and Social Welfare
South Africa	Medicines Control Council (MCC)
Switzerland	Swiss Agency for Therapeutic Products (SWISSMEDIC)
Jordan	Ministry of Health
South Korea	Food and Drug Administration
Taiwan	Department of Health
Nepal	Ministry of Health and Population
Kenya	Ministry of Health
New Zealand	Medicines and Medical Devices Safety Authority (MEDSAFE)
Norway	Norwegian Medicines agency
Indonesia	National Agency of Drug & Food Control

CONCLUSION:

This study shows that regulatory affairs is very important for all pharmaceutical companies around the world. The main focus of the regulatory affairs department is to give safe and effective medicine to people around the world. In this study, we show the responsibility of regulatory affairs professionals. Drug regulatory agencies of various countries give the rules which must be followed by pharmaceutical companies. A regulatory affair is also important for research and development, product management, Clinical trial, and marketing authorization. All pharmaceutical companies have their regulatory affairs department. Regulatory Affairs is also a good profession for Post Graduate in Pharmacy with pharmaceutical Administration and Management or Regulatory Affairs specialization will be the preferred qualification to qualify for as a RA professional. To become a good regulatory affairs officer executive, some special skills are needed like sound knowledge about regulatory affairs and drug laws, and good communication skills. Regulatory Affairs is an intellectually stimulating and highly regarded profession within pharmaceutical companies.

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