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OVERVIEW OF DRUG REGULATORY AFFAIRS AND REGULATORY PROFESSION

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ABSTRACT

A regulatory affair is a slightly new profession which has developed from the desire of governments to defend public health. The areas where government controlling the safety and efficacy of products are pharmaceuticals, medical device, veterinary medicines, pesticides, agrochemicals, cosmetics and complementary medicines. The companies responsible for the finding, testing, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. armaceutical drug regulatory affairs govern registration parameters of pharmaceutical products. It has a comprehensive band covering all aspects of certification and marketing in legalized form. The pharmaceutical industry is highly regulated industries in our country. Regulatory affairs professionals are need of present market scenario to cater to link pharmaceutical industries and worldwide regulatory agencies. Regula tory Affairs (RA), is a profession within synchronized various industries, such as pharmaceuticals, medical devices and biotechnological industries. Regulatory Affairs also has a very specific meaning within the pharmaceutical industries.

KEYWORD: Regulatory Affairs professionals, Regulatory agencies.

INTRODUCTION

A regulatory affair (RA) is a profession which acts as the interface between the pharmaceutical industry and drug regulatory authorities across the world. It is mainly involved in the registration of drug products in the respective countries. The modern Pharmaceutical enterprise is well prepared, systematic and compliant to international regulatory standards for manufacturing of biological and Chemical tablets for human and veterinary intake in addition to scientific gadgets, conventional herbal merchandise and cosmetics. Strict GMPs are being accompanied for blood and its by-product in addition to controlled production for classic herbal drug treatments, Food, Cosmetics, and dietary products which became in any other case otherwise a century before. Each regulatory gadget had challenged certain occasions which brought about modern-day well-defined managed regulatory agenda. This has resulted into systematic manufacturing and advertising of secure, efficacious and qualitative pills. With the boom of enterprise, the legislation from each area have come to be increasingly complex and created a need for regulatory specialists.

Regulatory Affairs profession at its heart is all about Collecting, Analyzing and Communicating the Risks and Benefits of health care products to regulatory agencies and public all over the world. A science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of regulated products All medicines must meet three criteria: be of good quality, safe and effective. The decisions about medicines quality, safety and efficacy should be based on solid science.

ROLES OF REGULATORY AFFAIRS PROFESSIONAL

I. Ensuring that their companies comply with all of the system policy and law pertaining and laws pertaining to their business.
II. Working with federal, state and local regulatory agencies and working with agencies as the food and Drug Administration European medicines Agency
III. Advising their companies on the regulatory Aspects and climate that would affect proposed actions. i.e. describing the Regulatory Climate in the region of issue such as the endorsement of prescription drugs.
IV. The Regulatory Affairs department is an important part of the organizational structure of pharmaceutical companies.
V. Preparation of organized and Ensure adherence and compliance with all the applicable CGMP, ICH, GCP, GLP guidelines regulations and laws.

VI. They are providing expertise and regulatory intelligence in translating regulatory requirements into practical, workable plans.

VII. gulatory affair plays a crucial role in the industry and is involved in all stages of drug development and also after drug approval and marketing. Pharmaceutical companies use all the data that has been observed during the discovery and development stages to register the drug and thus market the drug.

Objective of regulatory affairs

I. Major Regulations of USA.

II. How and why the pharmaceutical industry and drug regulations have developed in USA.

III. Framework of EU and its regulatory.

IV. "The Rules Governing Medicinal Products in the European Union".

V. Pharmaceutical Legislations of EU.

VI. Indian Pharmaceutical Industry & Drug Regulations development in different Era.

VII. Types of Marketing Authorization Procedure in EU Market.

VIII. Major Rules and Act of India.

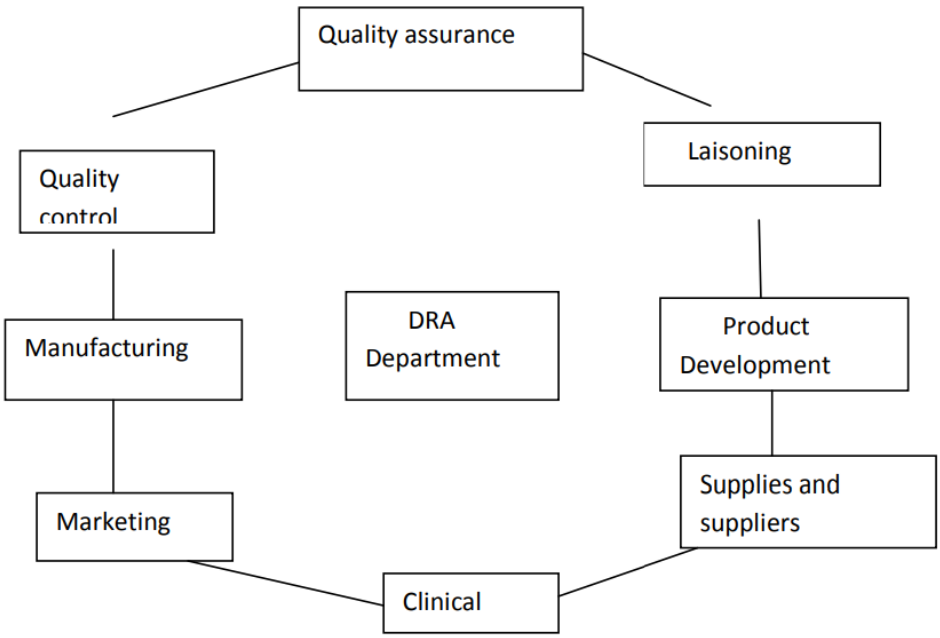

Figure 1: Various Role of DRA Department.

REGULATORY BODIES IN THE WORLD.

Table 1: Different regulatory bodies in the world.

Country	Regulatory Body.
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)
Japan	Ministry of Health, Labour & Welfare(MHLW)
Thailand	Ministry of Public Health
Italy	Italian Pharmaceutical Agency

Skills & Attributes required for making a good RA Skills

- Influence IT Literate.
- Work independently.
- Persuade Accuracy.
- An effective negotiator.
- Present Quality.
- Excellent writing and communication skills.
- Listen actively.
- Interpret and consolidate data.
- Strong follow-ups and convincing ability.
- Technical sound knowledge**.**

Emerging Trends Affecting Regulatory Strategy

- Strong growth in Emerging Markets
- Acquisition and licensing opportunities
- Biologics and Biosimilars market expansion
- Aging populations
- New product development strategies
- Rare diseases
- Quality aspects in entire supply chain
- ICH Expansion
- Collaboration among regulatory agencies**.**

Regulatory Affairs Education: The person spoiling in the regulatory affairs must be familiar with all the guidelines, guidance and regulatory documents. He should have thorough understanding of a particular regulatory document which has been recruited. Such people are the primary communication link between the company and worldwide regulatory agencies such as USFDA (United States Food and Drug Administration) and European Union of Drug Regulatory Affairs (EUDRA). A number of organizations such as the Regulatory Affairs Professional Society (RAPS), the Drug Information Association (DIA), the Food and Drug Law Institute (FDLI) and international organizations such as the European Society of Regulatory Affairs play a vital role in providing applicable information. In general, the program comprises of introductory foundation that outlines the health care product research, development process and the regulatory oversight of the complex processes. There are both part-time and fulltime courses available for the subject. Part-time courses are suitable for the professional who will come across these terms occasionally where as full-time course is meant for the professional who intends to make his career in the regulatory affairs.

CONCLUSION

DRA is a dynamic, rewarding field that includes both scientific and legal aspects of drug development. DRA professionals are dedicated individuals who take pride in their contribution to improving the health and quality of life of peoples. Regulatory Affairs department is continually developing and growing and is the one which is least obstructed during the merger and acquisition and also during the recession. Regulatory Affairs departments are growing within companies. Due to the changing resources necessary to fulfil the regulatory requirements, some companies also choose to outsource or out task regulatory affairs to external service providers. In today competitive environment, the decrease of the time taken to reach the market is serious to a product and hence the company's success. The proper implementation of regulatory guidelines and laws will improve the economic growth of the company and also improves the safety of the people.

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