

OVERVIEW OF DRUG REGULATORY AFFAIRS AND REGULATORY PROFESSIONAvailable online at www.ijdra.com**REVIEW ARTICLE****Badjatya Jitendra Kumar ***

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Corresponding Author's E-mail: jeetbadjatya@gmail.com*ABSTRACT**

Pharmaceutical drug regulatory affairs govern registration parameters of pharmaceutical products. It has a broad spectrum covering all aspects of documentation 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. Regulatory 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.

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.

RA as profession 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.

Regulatory Affairs professionals help the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labeling or in advertising.

Keywords: Regulatory Affairs professionals, Regulatory agencies, CDER, MHRA, MOH

Introduction

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices etc.

RA 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 judgments about medicines quality, safety and efficacy should be based on solid science.

Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). The success of regulatory strategy depends on interpretation, application, and communication within/ outside the companies.

Drug Regulatory Affairs

Regulatory Affairs is a new profession which is initiated from governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines. The companies manufacture and marketing these products must ensure that they supply Quality products to public for their health and welfare. Now most of the companies have specialist departments of Regulatory Affairs professionals.

Regulatory Affairs departments are growing within companies & is constantly evolving and growing and is the one which is least impacted during the Acquisition and Merger, and also during recession. Global harmonization in standards has led to consistent approach in regulatory submissions and hence its review.

This department is responsible for understanding the regulatory requirements for getting new /Generic products approved. They

know the commitments that company has made to the regulatory agencies where the product going to be approved. They also submit annual reports and supplements to the agencies.

This profession acts as the interface between the pharmaceutical industry and Drug Regulatory authorities across the world.

This department mainly involved in the registration of the drug products in respective countries prior to their marketing.

It can be of:-

- 1. Domestic Regulatory Affairs (DRA) - Country of origin
- 2. International Regulatory Affairs (IRA) – Other than country of origin

Regulatory Affairs communicates with one of the Centers e.g., Center for Drug Evaluation and Research (CDER) at the FDA headquarters, MHRA/ Countries Ministry of Health (MOH); Regulatory Affairs is a comparatively new profession which is initiated from governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines. The companies involved in discovery, testing, manufacture and marketing of Drug products should ensure that they supply the quality products that are safe & effective for public health and welfare. Most Pharma companies have specialist departments of Regulatory Affairs professionals – and those who don't, rely on the expert advice of independent regulatory consultants to meet their obligations.

The Regulatory Affairs department also takes part in the development of the product marketing concepts and is usually required to approve packaging and advertising before it is used commercially. Their Regulatory Affairs departments must be aware of the regulatory requirements in all the company's export markets.

The registration data prepared for one country frequently fail to meet the requirements for another. Therefore great care has to be taken in drawing up efficient and economical research and development programs whose results may be used as widely as possible. Different governments as an international effort are now trying to harmonize the regulatory

requirements for registration of products. Regulatory Affairs professionals, with knowledge of the Guidelines & regulations, are frequently called in to advice on such matters.

Importance of Drug Regulatory Affairs

In this Global competitive environment the reduction of the time taken by a product to reach the market is critical parameter and hence the company's success relies on that. The proper control maintain of its Regulatory Affairs activities is therefore of considerable economic importance for the company.

Wrong or inadequate reporting of data may prevent a timely positive evaluation of a marketing application. A new drug requires many millions of dollars to develop it and even a single day delay in bringing it to the market has considerable financial considerations. Even worse, failures to fully report all the required data or the product release of with incorrect labeling, may result in a product recall.

Regulation is a binding instruction issued by an agency that tells how to interpret and comply with a law. Failures to follow the regulations may end up in the "issued warning letter" section of the FDA website, which is not a good for a Pharma company.

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 maximize the cost-effective use of the company's resources.

The Regulatory Affairs department is the first point of contact between the Ministry of Health /Government departments and the company.

The Drug Regulatory Affairs Professional

It takes many years for bringing a new drug to the market; it is therefore essential that the process should be managed effectively from beginning to end in order to meet the regulatory requirements and permit a favorable evaluation of Quality, efficacy and safety in the shortest possible time. The drug regulatory affairs (DRA) professional plays an important role in each phase of this process, from developing effective regulatory strategies following the discovery of a new molecule up to the planning post-marketing activities.

The main role of the DRA professional within a pharmaceutical Industry is to secure approval of drug submissions from Health Therapeutic Products Program and to ensure regulatory compliance of marketed and investigational drugs with the Food and Drug Act and Regulations and Guidelines/Policies.

For this position, the DRA professional must possess a proficient scientific background and have a thorough knowledge of Domestic regulations as well as international regulations. Because the regulatory requirements are moving towards global and mutual recognition between different health authorities across the world, it is a major challenge for the DRA professional to keep & update policy and to determine how these changes in policies affects the regulatory approval process. Consequently, the importance of DRA in the development and approval of new drugs has increased significantly over the last decade.

The DRA professional must actively participate in discussions and coordinate team activities to obtain all the necessary documentation and then assess it for completeness and accuracy. Therefore, an effective DRA professional must exhibit the organizational and interpersonal skills of a "team player" and also be thorough and detail-oriented.

The scope of responsibilities is so wide and may vary significantly according to the organizational structure of the pharmaceutical company. The responsibilities of some DRA professionals may focus on Pharmacovigilance activities or on the electronic representation of data (electronic submissions). Other responsibilities may include product launch activities, DMF submission, formulary submissions, review of advertising materials and quality assurance. The primary function is the liaison between the Ministry of Health & Company.

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

Global Market is divided into:

- 1. Regulated Market:** US, EU (UK, Germany, France, Ireland, Sweden etc.), Japan, Canada, Australia, New Zealand, South Africa
- 2. Semi regulated Market: (ROW Countries):**
 - (a) **Asia** (Sri Lanka, India, Bangladesh,; **ASEAN:** 10 Countries group - Philippines, Vietnam Singapore, Malaysia, Thailand, Indonesia, Laos, Cambodia, Brunei Darussalam, Myanmar
 - (b) **African countries** (Algeria, Zambia, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Namibia, Nigeria, Sierra Leone, Tanzania, Zimbabwe etc.)
 - (c) **Middle East countries** (Gulf Co-operation Council countries i.e. Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE)
 - (d) **Latin America** (Mexico, Brazil, Panama, Peru, Guatemala, Argentina, Chile, Dominican Republic)
 - (e) **CIS** (common wealth of independent states): Russia, Ukraine, OFSUs (Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kirghizstan, Moldova, Tajikistan, Turkmenistan, Uzbekistan etc.)

Responsibility of Regulatory Affairs Professional's

1. Ensuring that their companies comply with all of the system policy and laws pertaining to their business.

2. Working with federal, state, and local regulatory agencies and staff on specific issues distressing their commerce. i.e. working with agencies as the Food and Drug Administration or European Medicines Agency (pharmaceuticals and medical devices)

3. Advising their companies on the regulatory aspects and climate that would affect proposed actions. i.e. describing the "regulatory climate" in the region of issues such as the endorsement of prescription drugs.

The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the countries where company wants to register their products.

Their advice at all stages both in terms of legal and technical requirements and restraints help companies save a lot of time and money in developing the product and marketing the same.

In an organization their prime responsibilities involves preparation and presentation of registration documents to regulatory agencies and carry out all following discussion to obtain and maintain marketing authorization (MA) for the products concerned.

They need to keep a track on ever changing legislation in all countries where the companies is looking to market their product.

It may take nearly 15 years to develop and launch a new pharmaceutical product and many problems may arise in the process of scientific development due to changing of regulatory environment.

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.

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