



A Review on Drug Regulatory Affairs in Pharmaceuticals Industry

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ABSTRACT

The Regulatory affairs in the pharmaceutical industry play a crucial role as the pharmaceutical sector is rising very rapidly and there is a want of regulatory affairs professionals to provide the current needs of industries for the global competition. Regulatory affairs (RA) professionals play vital roles in a pharmaceutical industry because it is concern about the healthcare product lifecycle, it provides strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. The pharmaceutical companies accountable for the discovery, testing, clinical trials, production, 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.

Keywords: Drug Regulatory Affairs (DRA), Lifecycle of healthcare products, medical devices, Agrochemicals, Cosmetics, Regulatory Affairs (RA), Academic research centers, Regulatory bodies.

INTRODUCTION

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices extra 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 otherworld's 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: good quality, safety, and effectiveness.

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 medical devices, Biologics and functional foods). The success of regulatory strategy interprets as.

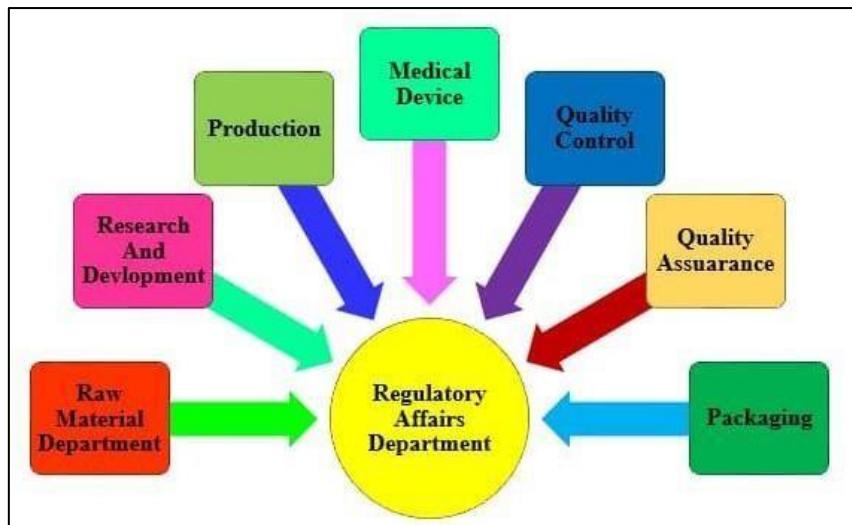


Fig no - 01



IMPORTANCE OF REGULATORY AFFAIR

The importance of the Regulatory Affairs function is that senior Regulatory Affairs professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies. 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. A new drug may have cost many millions of Euros or dollars, pounds, 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 labeling may easily result in the need for a product recall. Either occurrence may lead to the loss of several million units of sales, not to mention the resulting reduction in confidence of the investors, health professionals, and patients. The Regulatory Affairs department is very often the first point of contact between the government authorities and the company.

ROLES OF REGULATORY AFFAIRS PROFESSIONAL

The role of regulatory affairs professional is to act as organized and Ensure adherence and compliance with all the applicable CGMP, ICH, GCP, GLP guidelines regulations and laws.

They provide expertise and regulatory intelligence in translating regulatory requirements into practical, workable plans. A regulatory 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. the development stages, pharmaceutical companies have to follow the strict rule and guidelines to ensure the safety and efficacy of the drug in human the responsibilities of the regulatory affairs.

REGULATORY AFFAIRS DEPARTMENT

- Keep abreast of global laws, regulations and consumer trends.
- Keep abreast with a company's product lineup.
- Verify that a company's products comply with current laws.
- The responsibility of the regulatory affairs specialist is to be abreast of the always changing legislation in all of the nations in which the company hopes to market its products.
- In addition to offering technical and legal advice, they will collect, compile and evaluate the scientific evidence produced by their research and development colleague.

SCOPE OF REGULATORY AFFAIRS PROFESSION IN INDUSTRY

Regulatory affairs experts are employed in enterprises, government regulatory authorities, and academia. The diverse range of regulatory professionals' spans across these sectors:

- Pharmaceutical
- Medical devices
- In-vitro diagnostics
- Biologics and biotechnology
- Nutritional products
- Cosmetics
- Veterinary products

**REGULATORY BODIES IN THE WORLD**

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

Table 1: Different regulatory bodies of countries

COUNTRY	REGULATORY BODY
USA	FOOD AND DRUG ADMINISTRATION (FDA)
UK	MEDICINE AND HEALTHCARE PRODUCT REGULATORY AGENCY (MHRA)
AUSTRALIA	THERAPEUTIC GOODS ADMINISTRATION (TGA)
INDIA	CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)
CANADA	HEATH CANADA
EUROPE	EUROPEAN MEDICINES AGENCY (EMEA)
ITALY	ITALIAN PHARMACEUTICAL AGENCY
THIALAND	MINISTRY OF PUBLIC HEALTH
JAPAN	MINISTRY OF HEALTH, LABOUR & WELFARE (MHLW)

Role Of Regulatory Affairs In Research And Development

It should work together with Research and Development and marketing to develop novel drug product by using latest technologies a Regulatory Development Role of Regulatory Affairs in Quality Control and Quality Assurance In collaboration with QC and QA the Regulatory Authorities should submit the Dossier (documentation containing all details) which includes. Certificate of Analysis Stability studies Analytical Method Validation Process Validation Report Master Formula Record to Regulatory.

Authorities for approval. Role of Regulatory Affairs in licensing: Regulatory Affairs should all the supporting documents to Regulatory Authorities for licensing/approval. Functions of Regulatory Affairs Department Regulatory Affairs is a new profession created by governments to protect public health by regulating the safety and efficacy of products in specific sectors. Regulatory Affairs departments are growing, changing, and becoming larger within businesses. They are also the ones that are least affected by mergers and acquisitions, as well as by recessions. Due to global standardization, regulatory submissions, and, consequently, reviews are now handled consistently.

This section is in charge of comprehending the regulatory requirements for obtaining new/generic products approved. They are aware of the pledges made by the corporation to the regulatory agencies where the product will be approved. They also provide the agencies with annual reports and supplements. This profession serves as a liaison between the pharmaceutical sector and drug regulatory authorities worldwide. This department is primarily responsible for registering drug items in their respective nations prior to marketing.

It may be of the following types:

1. Origin country under Domestic Regulatory Affairs (DRA)
2. Other than country of origin: International Regulatory Affairs (IRA).

RESPONSIBILITY OF REGULATORY AFFAIRS PROFESSIONALS

In the current competitive world, the role of Regulatory Affairs is to minimize the approval time for the drug product is beneficial commercially in pharmaceutical companies. the responsibilities of the regulatory affair department.

Regulatory Affairs Department

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- The responsibility of the regulatory affairs specialist is to be abreast of the always changing legislation in all of the nations in which the company hopes to market its products.
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SKILLS FOR THE FUTURE REGULATORY AFFAIRS WORKFORCE

These developments in healthcare, medicine, and the pharmaceutical and medical device industry will impact the regulatory affairs team. The traditional heavy ‘task’ based workload will evolve with digital solutions and automation to require broader strategic leadership skills. It is therefore vital that regulatory professionals are equipped with the skills, knowledge, and minds to develop themselves in order to advance their professional lives.

REGULATORY EDUCATION

The personnel in the regulatory affairs should have a good knowledge of all documents related to the respective country guidelines. Regulatory affairs personnel should be well known about the WHO, ICH, GMP, and other regulatory documents which have to be revised and submitted. These people are the primary communication barrier between pharmaceutical companies and worldwide regulatory bodies such as USFDA and the European Union, etc.

NEED OF REGULATORY AFFAIRS

Drug development and commercialization are highly regulated paths to drug registration. Marketing approval is paved with good intension but can be complicated things change constantly. Regulatory bodies deal in the area of regulatory law, secondary legislation, administrative law and rulemaking (codifying and enforcing rules and regulation and imposing supervision or oversight for the benefit of public at large). The existence of independent regulatory agencies is justified by complexity of certain regulatory and supervisory tasks that require expertise, the need for rapid implementation of public authority in certain sectors and drawbacks of political interferences. India is growing very rapidly in pharmaceutical sector; there is need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are linked between pharmaceutical industries and worldwide regulatory agencies.

They are required to be well versed in the regulations, laws, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirement of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries.

AIM: A Review on Drug Regulatory Affairs in Pharmaceutical Industry.

OBJECTIVES: 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. The main objective of regulatory affairs is to provide the basis for the assurance of high quality of food products which can increase consumer interest in ensuring efficacy, quality, and safety.

1. Roles of Regulatory Affairs Professional in Health Authorities as well as Pharmaceutical Industry.
2. Pharmaceutical Legislations.
3. Clinical Trials.
4. Indian Pharmaceutical Industry & Drug Regulations development in different Era.
5. Major Rules and Act of India.
6. Drug Regulatory Affairs and Global, Regional and National Regulatory Network.



CHALLENGES TO REGULATORY AFFAIRS PROFESSION

- Regulatory affairs include complete dynamics:
- Multi-dimensional
- Knowledge in science and technology
- Prolific communication skill
- Deal with people with diverse background, skills, culture, and personalities
- Deal with conflicting loyalties, motivations, social and ethical, responsibilities
- Case in point: submission of a dossier During submission of a dossier a regulatory affair would be:
 - Guided by various regulatory guidance
 - Receiving input from various department within the firm about process capabilities and product attribute specification
 - Receiving advice from peers about easy way to get approvals
 - Receiving motivation from management through incentives to achieve speedy approvals.

MEGATRENDS

Understanding changes in global megatrends can help regulatory affairs professionals navigate the future impacts on their roles. Megatrends are global trends that may unfold over several years and have the potential to have substantial transformative impacts on society.

The Australian Commonwealth Scientific and Industrial Research Organization (CSIRO) has recently updated their global megatrend list to include the following: adapting to a changing environment; leaner cleaner and greener; unlocking the health imperative; geopolitical shifts; diving into digital; increasingly autonomous and unlocking the human dimension. Such megatrends may impact the future of medicine, therapeutic product development and the way that regulatory professionals perform their work.

Climate change concerns are impacting manufacturing with an emphasis on sustainable processes, reduced environmental impact, and a move toward a circular manufacturing economy.

Geopolitical uncertainty is being reflected by the increasing drive of governments to manufacture critical pharmaceutical products locally, after the COVID-19 pandemic highlighted risks to supply chains.

The COVID-19 pandemic has highlighted the risks of infectious diseases, which are likely to increase climate change.

CONCLUSION

Many in the Regulatory Affairs Profession believe the New Approach to regulation Will eventually be adopted for all healthcare products as it represents the best model for delivering new healthcare advances to market in a reasonable time with acceptable safety. Regulatory Affairs department is constantly evolving and growing and is the one which is least impacted during the Acquisition and Merger, and also during recession. Regulatory Affairs departments are growing within companies. Due to the changing resources necessary to fulfill the regulatory requirements, some companies also choose to outsource or out task regulatory affairs to external service providers. In today's competitive environment, the reduction of the time taken to reach the market is critical to a product's success and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance.



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