

Regulatory Affairs in the Pharmacy

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Abstract: *The regulatory bodies are being established in various pharmaceutical industries across the globe which plays a vital role to meet the requirements of legal procedures related to drug development process in a country. The pharmaceutical industry is considered as the most highly regulated industries worldwide. The regulatory body ensures compliances in various legal and regulatory aspects of a drug. Countries possess their own regulatory authority, which is responsible for enforcing the rules and regulations and issue the guidelines to regulate drug development process, licensing, registration, manufacturing, marketing, labeling and the product life cycle of pharmaceutical products. In an ever-changing regulatory environment, the role of regulatory affairs personnel is essential to ensure compliance with legislation in all regions in which a company wishes to distribute its drug. This article describes the development of the drugs as it is a cumbersome process which includes several months of time, volunteers, and a huge financial investment majorly through the funding process, so it is strictly regulated as per the norms and regulations as given by those individual countries to carry out the drug development which was generally governed by the Drug Regulatory Affairs Personals.*

Keywords: Regulatory authority, legal procedures, guidelines, licensing.

I. INTRODUCTION

As the pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lies in executing the work by understanding the guidelines related to various activities carried out to give an assurance that the process is under regulation. Pharmaceutical Industry, being one of the highly regulated industries, is in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner. Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. A regulatory affair (RA) also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of regulatory affairs (RA) professionals. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents. Pharma regulatory affairs professionals play an essential role in ensuring all pharmaceutical products comply with regulations governing the industry.[4] Those working in pharma regulatory affairs jobs not only work in the initial application phase for a new or generic drug, but also in the licensing and marketing stages – making sure all operations and products meet required safety and efficacy standards. Professionals must combine knowledge of the business, legal and pharmaceutical industries to determine if regulations are being followed and in many cases form the link between pharma companies and regulatory authorities, such as the Food and Drugs Agency (FDA) and the European Union. Regulatory affairs jobs in the UK and further afield are generally within the pharmaceutical, chemicals, biotechnology, medical devices and cosmetics industries. Organisations such as the FDA also provide roles for those interested in working in the field. As biotechnology plays an increasing role within drug development and the pharmaceutical industry, growing numbers of biotech regulatory affairs positions are opening up. Inspection of biotechnology facilities requires a high level of technical knowledge due to the ever advancing systems being used.

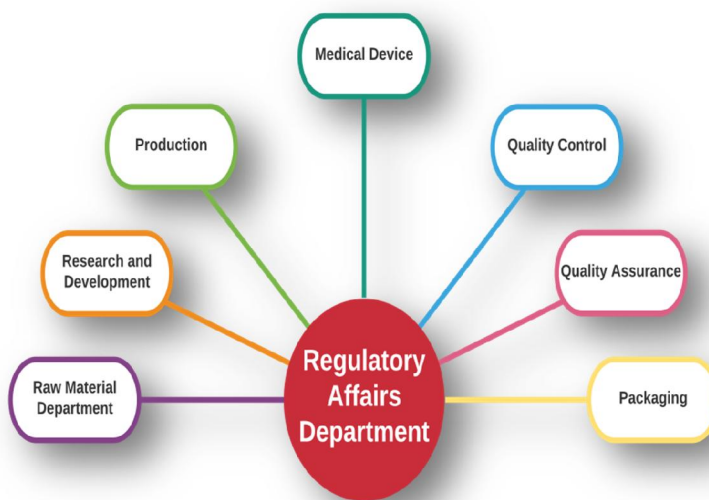


Fig. Pharmaceutical drug regulatory affairs

The person is responsible for knowing the regulatory requirements for getting new products approved. They know what commitments the company has made to the regulatory agencies where the product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine if and when the FDA must be notified. Regulatory Affairs is a comparatively new profession which has developed from the desire of 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 responsible for the discovery, 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. The Regulatory Affairs department will take 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 (RA) departments must be aware of the regulatory requirements in all the company's export markets. As an added complication, despite recent international efforts towards harmonization of requirements, the regulations laid down by different governments. 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. Regulatory Affairs professionals, with their detailed knowledge of the regulations and guidelines, are frequently called in to advice on such matters.

1.1 Institutions in India offering Regulatory Affairs

In India huge amount of colleges and universities throughout offer the course of regulatory affairs. The course material is also available in the form of online, distance learning and interactive CDs mode. Regulatory affairs position is in highest demand and fastest growing according to the findings from a recent survey on employment trends in the clinical trials. A pharmaceutical Regulatory affair (RA) is a vast area, which cannot be taught just with the help of books or the course materials. The issues related to the field are often updated so the professionals find it challenging to keep abreast with the recent modifications and inclusions. Importance of Regulatory Affairs In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs (RA) activities is therefore of considerable economic importance 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 labeling, may easily result in the need for a product recall may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients. 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 very often the first point of contact between the government authorities and the company. The attitudes and actions of the Regulatory Affairs (RA) professionals will condition the perceptions of the government officials to the company for better. The importance of the Regulatory Affairs function is such that senior Regulatory Affairs (RA) professionals are increasingly being appointed to boardroom positions, where they can advise upon and further influence the strategic decisions of their companies.

1.2 Responsibility of Regulatory Affairs Professional's

1. The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products.
2. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating.
3. They are responsible for the presentation of registration documents to regulatory agencies, and carry out all the subsequent negotiations necessary to maintain marketing authorization for the products concerned.
4. They give strategic and technical advice at the highest level in their companies, right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development program and the company as a whole. It may take anything up to 15 years to develop and launch a new pharmaceutical product and many problems may arise in the process of scientific development and because of a changing regulatory environment.
5. Regulatory affairs (RA) 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 labelling or in advertising.

1.3 Responsibilities of Regulatory Affairs Department

Keep in touch with international legislation, guidelines and customer practices

1. Keep up to the date with a company's product range.
2. Ensure that a company's products comply with the current regulations.
3. The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products.
4. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating.
5. Formulate regulatory strategy for all appropriate regulatory submissions for domestic, international and/or contract projects.
6. Coordinate, prepare and review all appropriate documents for example dossier and submit them to regulatory authorities within a specified time frame in conjugation with the organization.
7. Prepare and review of SOPs related to RA. Review of BMR, MFR, change control and other relevant documents.
8. Monitor the progress of all registration submission. Maintain approved applications and the record of registration fees paid against submission of DMF's and other documents.
9. Respond to queries as they arise, and ensure that registration/ approval are granted without delay.
10. Impart training to R&D, Pilot plant, ADI and RA. Team members on current regulatory requirements.
11. Advising their companies on the regulatory aspects and climate that would affect proposed activities. i.e. describing the "regulatory climate" around issues such as the promotion of prescription drugs and Sarbanes-Oxley compliance.
12. Manage review audit reports and compliance, regulatory and customer inspections.

13. 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 labelling or in advertising.
14. Have a duty to provide physicians and other healthcare professionals with accurate and complete information about the quality, safety and effectiveness of the product.

II. SCOPE OF REGULATORY AFFAIRS PROFESSIONAL IN INDUSTRIES

Regulatory affairs professionals are employed in industry, government regulatory authorities and academics. The wide range of regulatory professionals includes in these areas:

- Pharmaceuticals
- Medical devices
- In-vitro diagnostics
- Biologics and biotechnology
- Nutritional Products
- Cosmetics
- Veterinary Products

III. CONCLUSION

Regulatory Affairs department is constantly growing and is the one which is least impacted during the acquisition and merger, and also during recession. Regulatory Affairs departments are growing within pharmaceutical companies. Due to the changing resources needs to fulfil the regulatory requirements, some companies also choose to outsource to external service providers. In today's competitive environment the reduction of the time taken to reach the market is critical to a product and hence the company's success. The proper implementation of regulatory guidelines and laws will definitely improve the economic growth of the companies and also improves the safety of the people.

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