



Review Article

REGULATORY AFFAIRS IN THE PHARMACY CURRICULUM

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(Received: August 12, 2013; Accepted: September 20, 2013)

ABSTRACT

Indian 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. A regulatory affair is a somewhat 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, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines. The pharmaceutical companies responsible 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. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries. The present article discusses the regulatory education and its need, learning resources, courses available, syllabus contents, and job opportunities in regulatory affairs.

Keywords: Regulatory affairs, Pharmaceutical industries, Pharmacy College, Regulatory education.

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 [1]. 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.[2] 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.[3] Figure 1 shows the various role of DRA department.

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.[5] 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.[6] Table 1 shows the various major regulatory authorities of different country.

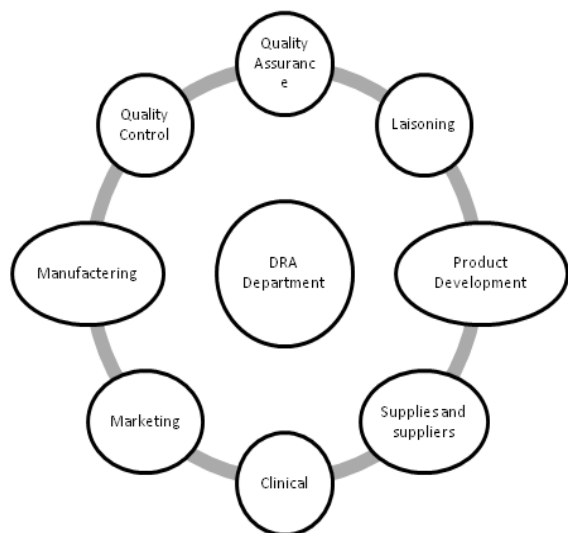


Figure 1. Various Role of DRA Department

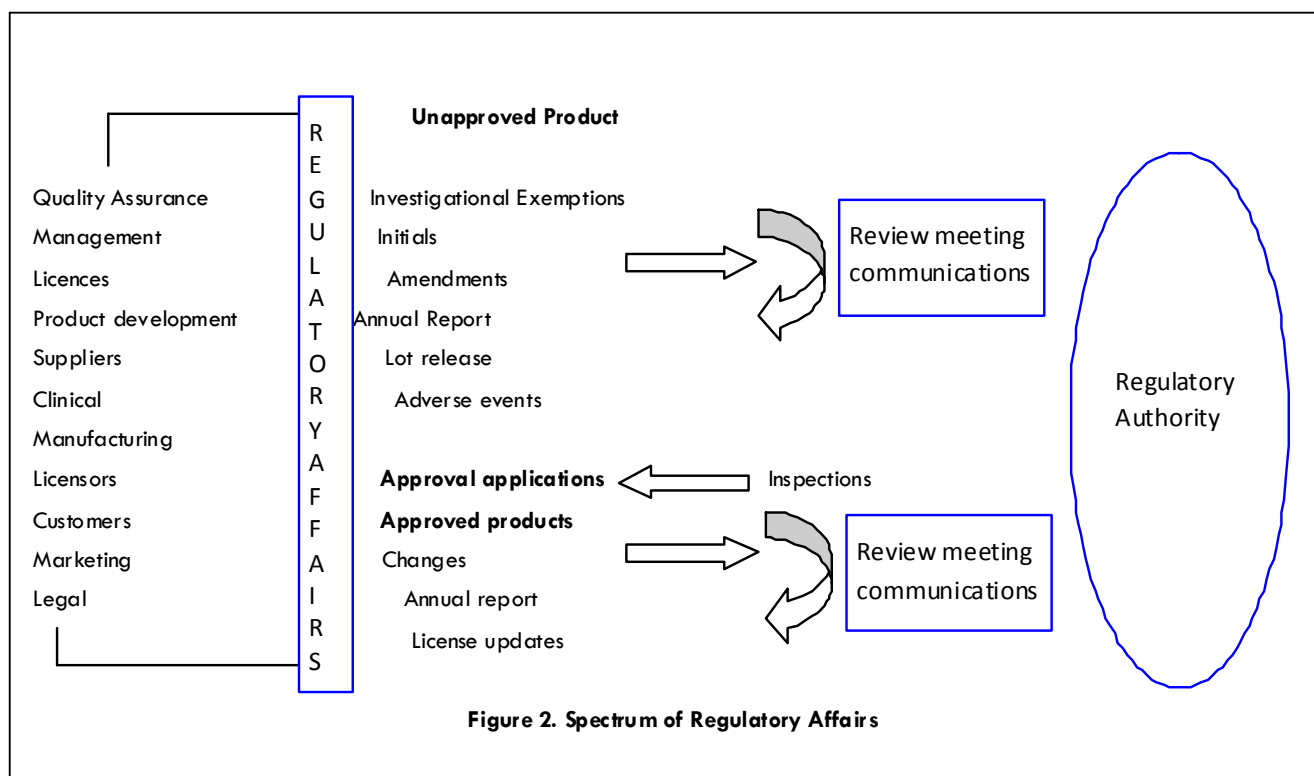
Pharmaceutical Drug Regulatory Affairs:

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.[7] 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

Table1. Major Regulatory Authorities of Different Country

Country	Regulatory Authority
India	Central Drugs Standard Control Organization Drug controller general of India (DCGI)
US	Food and Drug Administration (US FDA)
UK	Medicines and Health care products regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
Japan	Japanese Ministry of health, Labour and Welfare (MHLW)
Canada	Health Canada
Brazil	Agency Nacional degradation Vigilancia Sanitaria (ANVISA)
South Africa	Medicines Control Council (MCC)
Europe	European Directorate for Quality of Medicines (EDQM) European Medicines Evaluation agencies (EMA)

when the FDA must be notified.[8] 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.[9] 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.[10] 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.[11]



Regulatory Affairs Education:

The person indulging 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 drafted.[12] 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).[13] 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 relevant information. [14] In general, the curriculum 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 full-time courses available for the subject.[15] 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.[16]

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.[17] 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[18]. 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.[19]

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.[20] 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.[21]

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.[22]

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. [23]

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.[24]

Recent Advancements

Recently, the Govt. of India has constituted a few autonomous bodies to gauge the standards of profession of Pharmacy & grade the colleges accordingly so that the students, parents, employers and funding agencies have a valid & reliable rating of the various Pharmacy colleges in the country.[25]

These are:

- (1) National Board of Accreditation (NBA) under the aegis of All India Council for Technical Education.
- (2) National Assessment and Accreditation Council (NAAC) by the University Grants Commission.

The Drug Regulatory Affairs Professional

The pharmaceutical research and development process of bringing a new drug to the market takes many years; it is therefore essential that the process be managed effectively from beginning to end in order to meet the regulatory requirements and permit a favorable evaluation of efficacy and safety in the shortest possible time.[26] The drug regulatory affairs (DRA) professional plays an important role in every phase of this process, from developing regulatory

strategies following the discovery of a new chemical entity to planning post-marketing activities.

The main responsibility of the DRA professional within a pharmaceutical company is to secure approval of drug submissions from Health Therapeutic Products Program (TPP) and to ensure regulatory compliance of marketed and investigational drugs with the Food and Drug Act and Regulations and TPP Guidelines/Policies.[27]

In this position, the DRA professional must possess a proficient scientific background (B.Sc, M.Sc., Ph.D., M.D. B. Pharm, M.Pharm or Pharm.D.) and have acquired a thorough knowledge of Indian regulations as well as international regulations.[28] Because the regulatory environment is evolving rapidly toward global harmonization (several ICH guidelines have now been adopted by TPP) and mutual recognition between different health authorities across the world, it is a major challenge for the DRA professional to keep abreast of policy changes and determine how these changes affect the approval process. Consequently, the importance of DRA in the development and approval of new drugs has increased significantly over the last decade.[29]

Whether a submission is filed to the TPP for the conduct of a clinical trial (Investigational New Drug Submission, or IND), for the approval to market a new drug (New Drug Submission, or NDS), for a new indication or dosage form for a marketed drug (Supplemental NDS, or S/NDS), or for the maintenance of a marketed drug's regulatory status, the submission's preparation entails the close collaboration of a multidisciplinary team.[30] The DRA professional must actively participate in discussions and coordinate team activities to obtain all the necessary documentation as per the current TPP policies and then assess it for completeness and accuracy. Therefore, the effective DRA professional must exhibit the organizational and interpersonal skills of a "team player" and also be thorough and detail-oriented.[31]

The scope of responsibilities is wide and may vary significantly according to the organizational structure of the pharmaceutical company. The responsibilities of some DRA professionals may focus exclusively on pharmacovigilance activities or on the electronic representation of information (electronic submissions).[32] The common point, however, is that the DRA professional is the primary liaison between the sponsor and the TPP. In this capacity, the individual must

possess excellent writing and communication skills and be an effective negotiator. This is to ensure that the requests or comments generated during the submissions review process are promptly and satisfactorily answered and to negotiate the most favorable labeling (Product Monograph) consistent with the sponsor's business objectives.[33]

In line with today's growing technological developments, knowledge of several computer applications is essential to effectively fulfill the job requirements. DRA is a dynamic, rewarding field that embraces 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.[34]

Responsibility of Regulatory Affairs Professional's

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. 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.[35]

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. 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.[36]

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.[37] 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.[38]

List of responsibilities of Regulatory Affairs Department

1. Keep in touch with international legislation, guidelines and customer practices
2. Keep up to the date with a company's product range

3. Ensure that a company's products comply with the current regulations.

4. 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. 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.[39]

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 conjunction with the organization.

7. Prepare and review of SOPs related to RA. Review of BMR, MFR, change control and other relevant documents.[40]

8. Monitor the progress of all registration submission.

9. Maintain approved applications and the record of registration fees paid against submission of DMF's and other documents.

10. Respond to queries as they arise, and ensure that registration/ approval are granted without delay.[41]

11. Impart training to R&D, Pilot plant, ADI and RA. Team members on current regulatory requirements.

12. 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.

13. Manage review audit reports and compliance, regulatory and customer inspections.[42]

14. 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.

15. Have a duty to provide physicians and other healthcare professionals with accurate and complete information about the quality, safety and effectiveness of the product.

Pharma regulatory affairs jobs: Professionals working in pharmaceutical regulatory affairs roles will be required to

handle a number of different tasks; from keeping on top of the latest developments within the industry to writing product labels and patent information. As well as collecting and collating large amounts of information and preparing licensing submissions, pharma regulatory affairs jobs also include liaising with doctors and scientists, conducting clinical trials and negotiating with regulatory authorities. Workers may also be tasked with undertaking and managing regulatory inspections within the company and reviewing practices when required to meet with new or updated regulatory requirements.[43] Opportunities for regulatory affairs consultants offer professionals the chance to work in a number of fields, which requires high levels of knowledge of multiple industries. Jobs in pharma regulatory affairs generally require a background in the applicable industry, business knowledge, great oral and written communication, good attention to detail and strong IT skills. The international scope of many companies working within the pharmaceutical industry mean that a second language is generally desirable, as it previous work experience within a clinical or pharma setting.

Pharma regulatory affairs jobs in India

Asia has emerged as a strong growth region for the pharmaceutical industry in recent years, in particular India which is fast becoming a preferred location for clinical trials and research and development activities. The creation of a new product patent system in 2005 was a driver of this growth, which is expected to increase as the domestic market in India further opens up.[44] This growth has also helped facilitate an increasing number of pharma regulatory affairs jobs in India. A number of companies have set up in the most populous city in the country, creating a number of regulatory affairs jobs in Mumbai. Figures from a companies and markets.com report show that by the year 2012 the market for clinical trials in India is expected to grow to \$630 million (£404 million), helped by the fact that the cost of conducting research in the country is sometimes less than half that in more developed nations.[45] The United Arab Emirates (UAE) is another country looking to expand its appeal to the pharmaceutical industry, increasing the number of pharma regulatory affairs jobs in Dubai. A report by RNCOS suggests that compound annual growth of 17 per cent will take place between 2010 and 2013 and that the UAE is

ripe for investment for pharmaceutical manufacturing operations.

Makes a Good Regulatory Affair Professional

Most regulatory professionals are graduates in a scientific discipline, commonly life sciences or pharmacy, although increasingly biotechnology based degrees are valuable. Some choose to have an additional legal qualification. The ability to tackle data in a wide range of scientific areas and to quickly grasp new concepts and complex technical information is vital. Analyzing issues and presenting both written and oral evidence before a panel of experts such as scientists, pharmacists, doctors and lawyers who run the government agencies require considerable understanding of both legal and scientific matters.[46]

A high degree of sensitivity is required when proposing and executing the strategy and tactics needed to obtain marketing approval in a way which will satisfy the authorities and serve the best needs of the company. Considerable care must be exercised if the best possible case is to be presented to the authorities for the company. It must be done without obscuring the facts, enabling the authorities to arrive at a proper and rightful conclusion regarding safety, efficacy and quality of the product under application. Regulatory professionals must always exercise considerable judgment in the practice of their role. Integrity and the ability to inspire trust and confidence are valuable attributes. Project management skills help to achieve the challenging goals they are set.[47] They can work as part of multi-disciplinary teams and lead them when necessary. They can work under pressure and inspire and motivate others to do the same.

Need of Regulatory Affairs in the Pharmacy Curriculum

The pharmaceutical biotechnology and medical device research and development industries are among the most highly regulated industries in the country. As India is growing very rapidly in pharmaceutical sector, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition.

Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. They are required to be well versed in the laws, regulations, guidelines and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical industries in the standard

curriculum of pharmacy colleges to prepare the students with the latest developments to serve the industries. The present article discusses the regulatory education and its need, learning resources, courses available, syllabus contents, and job opportunities in regulatory affairs.[48]

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, which are capable of handling issues related to regulatory affairs in a comprehensive manner.[49]

Conclusion

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. Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory affairs professionals and Regulatory affairs department is constantly evolving the one which is least impacted during the acquisition and merger, and also during recession. 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 and hence within the company's for their success and growth. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company.

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How to cite this article:

Kumar S., Panwar R., Singh U., A review on "Regulatory affairs in the pharmacy curriculum ", *Int. J. Res. Dev. Pharm. L. Sci.*, 2013, 2(6), pp. 690-698.