

## Review Article

# Need of Regulatory Affairs Knowledge in Pharmaceutical Industry

Anup Rajan\*, Nagasamy Venkatesh D

Department of Pharmaceutics, JSS College of Pharmacy, JSS University, Rocklands, Ootacamund, Tamil Nadu, India

\***Corresponding author:** Anup R Pharmaceutical Regulatory Affairs Group, Dept. of Pharmaceutics, JSS College of Pharmacy, JSS University, Rocklands, Ootacamund, Tamil Nadu, India; E-mail: anuprajan7@gmail.com

**Citation:** Anup R (2016) Need of Regulatory Affairs Knowledge in Pharmaceutical Industry. J Pharma Pharma Sci 02: 114. DOI:10.29011/2574-7711.100014

**Received Date:** 26 December, 2016; **Accepted Date:** 21 February, 2017; **Published Date:** 28 February, 2017

### Abstract

Indian pharmaceutical sector is rising very rapidly and there is a need 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 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, and guidance of the regulatory agencies. There is a growing need to incorporate the current requirements of pharmaceutical 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 Profession; Drug Regulatory Affairs; Regulatory Authority; Pharmaceutical Industry

### Introduction

The pharmaceutical industries throughout the world are moving ahead towards becoming more and more competitive, these are realizing that the real battle of survival lie 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 Professionals. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within com-

panies and to outside constituents [3]. 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 field are generally within the pharmaceutical, chemicals, biotechnology, medical devices and Cosmetics industries. Organizations 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].

---

## 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 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 guideline-a frequently called in to advice on such matters [11].

## Major Regulatory Authorities of Different Country

1. India-CDSCO (Central Drugs Standard Control Organization)
2. US - USFDA (United States Food and Drug Administration)
3. Japan-Japanese ministry of health Labor and welfare (MHLW)
4. UK-Medicine and health care products Regulatory Agency (MHRA)
5. Australia-Therapeutic Goods Administration (TGA)
6. Canada-Health Canada
7. South Africa-Medicine Control Council (MCC)

8. Brazil-ANVISA

9. Europe-European Medicine Evolution Agency (EMA)

## 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 [12]. 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 [13]. 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 [14].

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 [15]. 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 [16]. 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 [17]. 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 activi-

ties or on the electronic representation of information (electronic submissions) [18].

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 [19]. 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 [20].

## 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 [21]. 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 [22].

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 [23]. 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 labeling or in advertising [24].

## List of responsibilities of Regulatory Affairs Department

1. Keep in touch with international legislation, guidelines a 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 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 [25].
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 [26].
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 [27].
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 [28].
14. Regulatory Affairs professionals help the company avoid problems caused by badly kept record 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.
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 [29].

## 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.

## References

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified [online] 7th April.
2. International regulatory affair updates [online] 2005.
3. Douglas Pisano J, David Mantus S (2008) Text book of FDA Regulatory Affairs A Guide for Prescription Drugs Medical Devices, and Biologics'. 2nd edition.
4. Topra brought (2011) by dimension associates.
5. Douglas Pisano J, David Mantus S (2008) Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
6. Science career brought (2011) by American association.
7. Topra brought by dimension associates.
8. Training Needs in Regulatory Science (2001) for the Biopharmaceutical Industry," Nature jobs Biotechnology 19: 1187-1188.
9. Careers in Regulatory Affairs (2002) from Practitioner to professional," Nature jobs Biotechnology 20: 409-41.
10. Regulatory Affairs Management.
11. Recent Advancements.
12. Srivastava DA. Country level report on the pharmaceutical sector in India'. Report commissioned by DFID, UK
13. Central Drugs Standards Control Organization.
14. [http://www.medindia.net/indian\\_health\\_act/drugs-andcosmetics-act-1940-introduction.htm](http://www.medindia.net/indian_health_act/drugs-andcosmetics-act-1940-introduction.htm)
15. [www.vakilno1.com/bareacts/drugsandcosmeticsact/drugsandcosmeticsact.htm](http://www.vakilno1.com/bareacts/drugsandcosmeticsact/drugsandcosmeticsact.htm)
16. <http://www.dancewithshadows.com/pillscribe/cgmpregulations-in-india-to-be-diluted/>
17. <http://www.prescriptiondrug-info.com/topics/drug-andcosmetic-act/>
18. Jain NK, Pharmaceutical Product Development" edition 3rd, CBS publishers
19. Sharma PP "how to practice GMPs" 5th edition, Vandana publication Pvt. Ltd Delhi
20. WHO (2003) Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-seventh Report. Geneva, World Health Organization.
21. Guide to good storage practices for pharmaceuticals (2003) WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-seventh Report. Geneva, World Health Organization.
22. WHO (2004) Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-eighth Report. Geneva, World Health Organization.
23. Good trade and distribution practices for pharmaceutical starting materials (2004) WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-eighth Report. Geneva, World Health Organization.
24. Quality Assurance of Pharmaceuticals (1997) A compendium of guidelines and related materials, Volume 1. Geneva, World Health Organization.
25. Quality Assurance of Pharmaceuticals (2004) A compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2 (updated version). Geneva, World Health Organization.
26. Marketing Authorization of Pharmaceutical Products (1999) with Special Reference to Multisource (Generic) Products-A Manual for a Drug Regulatory Authority. Geneva, World Health Organization.
27. A Model Quality Assurance System for Prequalification (2003) Procurement, Storage and Distribution of Pharmaceutical Products. Geneva, World Health Organization.
28. Managing Drug Supply (1997) the selection, procurement, distribution, and use of pharmaceuticals. Management Sciences for Health in collaboration with World Health Organization. 2nd Ed. Connecticut, USA. Kumarian Press.
29. Guidelines on Good Distribution Practice of Medicinal Products (1992) for Human Use (94/C63/03). European Agency for Evaluation of Medicinal Products