SSRG International Journal of Pharmacy and Biomedical Engineering
ISSN: 2394 – 2576 / doi: 10.14445/23942576/IJPBE-V3I1P101
Volume3 Issue 1, 1-2, Jan- Apr 2016

Regulatory Affairs and its Role in Pharmaceutical Industry

P. Praneeth
M.Pharmacy (Pharmaceutical Management and Regulatory Affairs) PG Student,
Sri Sivani College Of Pharmacy, Srikakulam, India

Abstract *- Regulatory affairs in the pharmaceutical industry play an important 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. A regulatory affair is a profession which acts as the interface between pharmaceutical industries and government authorities across the world. The goal of the regulatory affairs professional is the protection of human health, ensuring safety, efficacy, and quality of drugs, ensuring appropriateness and accuracy of product information. This present article discusses the evolution of Regulatory Affairs, its role in the pharmaceutical industry and its involvement for the implementation of regulatory guidelines which improve the growth of the industry.*

Keywords - *Regulatory Affairs, Pharmaceutical industries, world regulatory bodies.*

I. INTRODUCTION

A regulatory affair (RA) is a profession which acts as the interface between the pharmaceutical industry and drug regulatory authorities across the world. It is mainly involved in the registration of drug products in the respective countries prior to their marketing. The current Pharmaceutical Industry is well organized, systematic and compliant to international regulatory standards for the manufacturing of Chemical and Biological drugs for human and veterinary consumption as well as medical devices, traditional herbal products and cosmetics. The Regulatory Affairs department is an important part of the organizational structure of pharmaceutical companies. Internally it liaises at the interface of drug development, manufacturing, marketing and clinical research. Regulatory Affairs is actively involved in every stage of development of new medicine and the post-marketing activities with authorized medicinal products.

II. ROLES OF REGULATORY AFFAIRS PROFESSIONAL

The role of regulatory affairs professional is to act as liaison with regulatory agencies. Preparation of organized and Ensure adherence and compliance with all the applicable CGMP, ICH, GCP, GLP guidelines regulations and laws. They are providing 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. Throughout the development stages, pharmaceutical companies have to follow the strict rule and guidelines to ensure the safety and efficacy of the drug in humans.

III. EVOLUTION OF REGULATORY AFFAIRS

During the 1950s, many tragedies happened due to the misjudgement of the personnel during manufacture and some intentional addition of adulteration of substances into the pharmaceutical product, which has lead to the death of the patients. After so many incidents, the regulatory bodies introduced the new laws and guidelines which improve the quality, safety and efficacy of the products. This has also resulted in stricter norms for Marketing Authorization (MA) and Good Manufacturing Practices (GMPs).

IV. REGULATORY BODIES IN THE WORLD

Country	Regulatory Body
USA	Food and Drug Administration (FDA)
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
India	Central Drug Standard Control Organization (CDSCO)
Canada	Health Canada
Europe	European Medicines Agency (EMEA)
Japan	Ministry of Health, Labour & Welfare(MHLW)

Table 1: Different regulatory bodies in the world

V. INVOLVEMENT OF REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSTRY

Fig.1. Involvement of Regulatory Affairs in the Pharmaceutical Industry

Regulatory Affairs professionals give strategic and technical advice to R&D, Production, QC department etc.; right from the beginning of the development of a product, making an important contribution both commercially and scientifically to the success of a development programme and company as a whole.

It takes 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. Regulatory professionals help the company to avoid problems caused by irrelevant records, inappropriate scientific thinking or poor presentation of data.

VI. 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

VII. 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 the pharmaceutical companies and worldwide regulatory bodies such as USFDA and the European Union, etc.

VIII. CONCLUSION

Regulatory Affairs department is continually evolving and growing and is the one which is least impacted during the acquisition and merger, and also during the recession. Regulatory Affairs departments are growing within companies. Due to the changing resources necessary to fulfil 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 and hence the company's success. The proper implementation of regulatory guidelines and laws will improve the economic growth of the company and also improves the safety of the people.

REFERENCES

[1] Regulatory affairs from Wikipedia, the free encyclopaedia modified on 21 st January available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
[2] Douglas J Pisano and David S. Mantus. "Text book of FDA Regulatory Affairs- A Guide for Prescription Drugs, Medical Devices, and Biologics" Second Edition.
[3] www.centerwatch.com
[4] www.regulatoryone.com
[5] Sachin C Itkar, Dr. Ns Vyawahare, "Drug Regulatory Affairs", Third edition (2015).
[6] "Need For the Introduction of Regulatory Affairs in the Pharmacy Curriculum" *Health Administrator Vol: XIX Number 1: 51-52.*