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Regulatory Affairs in Pharmaceutical Industry

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Abstract

Regulatory Affairs in pharmaceutical industries is a one of the most critical job. Regulatory Affairs is mainly concerned about the lifecycle of healthcare product and it gives tactical, strategic and operation advice to work within regulation to develop safe and effective healthcare product around the World. The work of Regulatory Affairs to nurture and implementing a strategy to guarantee the collective efforts of the drug development team, so that the drug get approval from global regulatory authorities. Regulatory Affairs is a catchy career choice for graduate student from scientific background. Regulatory Affairs is a multi-tasking job. This job is suitable for those people who enjoys communicating with people, enjoys team work and want to expand their knowledge in pharmaceutical sector. Regulatory Affairs is a very rewarding job. A person who want pursue their job in Regulatory Affairs should have knowledge about ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use).

Keywords: Regulatory Bodies; Pharmaceutical Industries; Regulatory Affairs

Abbreviations: USFDA: United States Food and Drug Administration; MHRA: Medicines and Healthcare products Regulatory Agency; CDSCO: Central Drugs Standards Organization; NDA: New Application for Drugs; ANDA: New Short Application for Drugs; CTD: A Standard Technical Document; ICH: International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use; EMEA: European Medicines Testing Centers; MHRA: Management and Healthcare Agency; MCC: Medicines Control Council; FDA: Food and Drug Administration.

Introduction

The pharmaceutical industries around the world are advancing and increasingly competitive. The battle for survival lies in completing the task by maintaining and understanding the many work-related guidelines to ensure that the work is subject to regulation [1]. Administrative issues also known as Government News. Work related to regulatory industries such as pharmaceuticals and medical equipment etc. The Management Issues function involves the Collection, Analysis and Communication of the Benefits and Risks of a health-related product to regulatory bodies and agencies and the community around the World [2]. Regulatory Affair is a link between the pharmaceutical industry and the drug regulatory authorities around the world. Regulatory Affairs is heavily involved in each phase of new drug development and post-marketing surveillance. It is an important part of the organizational structure of the pharmaceutical industry [3].

Administrative News History

Major risks have made people realize that laws and regulations are essential to the safety and effectiveness of drugs. The other incidents are as follows

- More than 100 people died in the USA in 1937 with elixir sulfanilamide manufactured using DEG. Following this incident in 1938 the Federal Food and Cosmetic action in the USA was approved.
- Pregnant women using thalidomide to treat morning sickness caused paralysis in more than 10,000 babies between 1950-1960. After the incident "The Kefauver-Harris Amendment in the USA was passed. It is a 1962 amendment to the Federal Food and Cosmetic act [4].

Clinical Research

In the US
IND- New Research Case
E-EU
CTA / CTX-Clinical Trial Authorization / Release of Clinical Trial
Marketing authorization:
In the US
NDA- New Application for Drugs
ANDA- New Short Application for Drugs
Application for a BLA-Biologic license
CTD- A Standard Technical Document

The Role of Management Issues

Managing staff works with Research and Development staff to create a safe and effective product. With a new product to add more revenue to a company's lower revenues, market downtime equals revenue and profit margins. Implementing clinical trial strategies, gaining immediate approval from controlling managers. Control issues can accelerate the development of new drugs and reduce costly errors.

Product registration is not the only role for regulatory affairs staff, advising companies on technology and strategies. Work begins with product development, product marketing and post marketing. They help companies save a lot of money by providing legal and technical advice. Countries that do not have their own regulatory bodies are required to follow the guidelines of the World Health Organization in the event of health issues and the World Trade Organization when regulating trade between countries. Regulatory issues are the link between pharmaceutical companies and regulatory authorities around the world such as the USFDA, MHRA, CDSCO [5].

The Role of Management Issues in the various departments [6]:

Governing bodies in different countries [7]:

- Country Management Authorities
- India CDSCO Central Drugs Standards Organization
- Europe EMEA European Medicines Testing Centers
- UK MHRA Product Management and Healthcare Agency
- Australia TGA Therapeutic Goods Administration
- Japan MHLW Japan Department of Health, Labor, and Welfare
- Canada HC Health Canada
- Brazil south Africa MCC Medicines Control Council
- USA FDA Food and Drug Administration

Effective drug control requires a variety of functions:

- Assurance of safety, efficiency, quality.
- Buildings, customization, personal authorization.
- Production and distribution channel testing.
- Monitor adverse drug reactions.
- Quality control.
- Drug promotion and advertising control.

Drug control consists of:

- Drug laws
- Drug control centers
- Drug control boards
- Quality control
- Drug Information Center [8]

Activities of Pharma Regulatory Affairs in India

Asia has emerged as a strong region for the development of the pharmaceutical industry in recent years. India is becoming a popular destination for clinical testing and research and development. The growth of the pharmaceutical industry is expanding the scope of the pharmaceutical industry in India. There are many regulatory issues in Mumbai [9,10].

Conclusion

Our country is at a crossroads between the developing world and the developed world. In the field of regulatory issues always follows the best model to deliver a safe and effective product. Management issues are an innovative, creative and rewarding career. Most companies, perhaps an international pharmaceutical company or small companies with a regulatory department. With the advent of new laws and regulations, regulatory issues are growing day by day. To meet regulatory requirements, some companies select an external regulatory service provider. Regulatory issues are the link between the pharmaceutical industry and regulatory bodies around the world. They contribute to the financial well-being of the pharmaceutical organization by providing technical and legal advice. Proper conduct of regulatory

issues is very important for chemical companies.

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