Journal of Developing Drugs
ISSN: 2329-6631
OPEN ACCESS Freely available online
Editorial

Heart of the Pharmaceutical Industry: The Regulatory Body

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EDITORIAL

The drug regulation is bounded by the regulatory body which plays a vital role in the journey of product from laboratory to the pharmacy shop. Though it is a challenging phase, it helps to protect the public health by constant monitoring and controlling the safety and efficacy of the healthcare products like pharmaceuticals, medical devices, veterinary medicine and agro based chemicals etc. The main objective of the regulatory body or the regulatory affairs is to ensure the availability of the safety and efficacy of the healthcare products over the worldwide. As we know, it is the government's responsibility for safeguarding the health of the public and therefore, certain rules and regulations are needed. Every company has the regulatory department to keep a track over the legislation to sustain the rules and norms evenly to every pharmaceutical company. It also includes the collection as well as the analysis of the legal, scientific requirements for the particular country to obtain and maintain the marketing authorization of the healthcare products.

The regulatory body encompasses the variety of the disciplines as well as the responsibilities which generally starts at times starting from the drug development or product development till it reaches to the market. A new pharmaceutical product must and should undergo the clinical studies or clinical-trails which it need to have the list of standard ranges to meet the criteria. No new drug can enter market without the new drug approval from the regulatory body or regulatory authority. There are many regulatory bodies such as United States Food and Drug Administration (USFDA), Medicine and Health care Regulatory Authority (MHRA), Therapeutic Goods and Administration (TGA), Central Drug Standard Control Organization (CDSCO) etc. In order to serve the intellectual property rights, the innovator company applies for the patent which has the period of almost 20 years. The regulatory departments in the pharmaceutical company plays an important role in helping the coordination between the scientific endeavors with that of the regulatory demands throughout the product life and help the companies or the industries to meet all the regulations and guidelines and to obtain in turn for maximizing the profits.

In order to sustain the track of ever-changing legislation and amendments with respect to the existing rules and norms, all the countries are distributed with the even frame work of rules. It plays an important role in overall developmental process of the drugs ranging from the strategic decisions like design and timing of the clinical studies. This helps an individual company to avoid the problems that occur if the records are kept inappropriate way. Therefore, the regulatory body plays a key role in pharmaceutical field. Also, this can be regulated by the certain set of rules called as ICH guidelines. ICH stands for International Council for Harmonization of technical requirements. This is a unique body that brings the regulatory body and pharmaceutical industry to discuss and develop the required amendments for attaining the safe product for the human use. Also, these guidelines helps to safeguard the rights, safety and welfare of the human objects and minimize the human exposure to the exposure to the investigational products to minimize the suffering by the human, maximize the product quality and speed up the marketing of new drugs by the application of the trending techniques and technologies.

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Received: October 16, 2021; **Accepted:** October 30, 2021; **Published:** November 6, 2021

Citation: Peter J (2021) Heart of the Pharmaceutical Industry: The Regulatory Body. J Develop Drugs 10:e161