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Need for India to evolve as an SRA

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India is evolving as a significant player in clinical research and pharmaceutical field.



Drugs are materials recognized by an official Pharmacopeia and Formulary which are approved for use to treat, cure or prevent a disease or disorder. With drugs being a vital element for saving lives, the regulation of drugs and medicine is crucial to the health and safety of the public. Ensuring that a medicine is high quality is achieved by checking the efficacy, quality and safety of the drug. The medicines are prepared, stored, manufactured and shipped according to health and safety guidelines of professional and experienced chemists and pharmacists. The production and use of poor quality drugs or harmful medicines can have adverse repercussions such as organ failure, exacerbation of the ailment, and sometimes fatality. In order to protect public health and also maintain the confidence of the people in the health systems and the pharma industry, there needs to be a comprehensive set of regulations to ensure that accurate information is available and no spurious drugs can enter the existing drug system.

India, being a large contributor to the pharma industry, needs to have regulations imposed upon the pharmaceutical activities. They are crucial not only due to essential and stringent regulatory requirements for manufacturing of products such as Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) but also due to the obligation on regulatory bodies to make sure that a healthy supply of safe and quality drugs is provided to the public, at affordable rates. The regulatory authorities of the country are responsible to ensure the implementation of the various rules to regulate the drug market. The process of drug approval has to go through many stages including formal administrative requirements for marketing authorization and conducting clinical trials and surveillance of post-marketing studies. In order to prove the efficacy and safety of the proposed drug molecule in Indian population, it has to conduct clinical trials in accordance with the guidelines specified in Schedule Y and submit the report in stated format to the authority.

The Stringent Regulatory Authorities (SRAs) provide critical expertise for the evaluation of finished pharmaceutical products (FPPs) and active pharmaceutical ingredients (APIs) for prequalification. The process of scrutiny includes participating in the WHO Prequalification Team (PQTm) assessment sessions that take place every two months in Copenhagen, Denmark. The WHO shares its expertise and work with PQTm to resolve technical pharmaceutical issues relating to dossier assessment. This is followed by participating in the WHO inspections of manufacturing sites, contract research organizations and quality control laboratories. This stage helps the team to ensure that its inspection standards and approaches are completely aligned with current practices working with PQTm so as to develop the prequalification guidance that will help the manufacturers understand and meet the stated prequalification requirements. Most importantly, enable the low- and middle-income country medicine regulators to facilitate understanding of WHO prequalification requirements and enhance their expertise in applying international standards for assessment and inspection.

India is evolving as a significant player in clinical research and pharmaceutical field. The progressive growth and development in regulatory framework is a case in point as to how the pharmaceutical industry is modernizing under the rationale of scientific knowledge and public health.

In India, the new drug approval is now lined with the rules influencing the approval of these products in order to safeguard the health of the population. This is constituted under the role of statutory regulatory authorities to ensure that pharmaceutical companies comply with regulations. The drug approval process can be understood as an optimized procedure by which a new drug molecule is formally approved by the drug authority for a person or an organization that is interested in launching a drug product for commercialization. Though an overlook of Indian pharmaceutical Industry shows a complicated regulatory structure wherein pharmaceuticals companies come under the purview of the Ministry of Chemicals & Fertilizers. The Central Drugs Standard Control Organization (CDSCO) is headed by the DCGI that comes under the Ministry of Health and Family Welfare and there is a separate agency for monitoring food products that is the Food Safety and Standards Authority of India.

Owing to India’s growth, accomplishments and the potential it holds as an emerging pharma leader, the country needs to step ahead of the back foot from being an observer in the International Council for Harmonisation (ICH) and transpire as a member so as to reinforce its audits and develop its pharma market.

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