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Regulatory Affairs: Dependence and Overview in the Pharmaceutical Industry by Cdsco

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The aim of this study is to provide a comprehensive overview of the role and dependence of the pharmaceutical industry on regulatory affairs, with a specific focus on the Central Drugs Standard Control Organization (CDSCO) in India.The objective is to understand the regulatory framework established by CDSCO, highlight its significance in drug approval and quality assurance, and evaluate how regulatory affairs serve as a critical link between the pharmaceutical industry and regulatory authorities to ensure compliance, safety and efficacy of pharmaceutical products.This study involves an in-depth analysis of CDSCO's regulatory pathways, including the drug approval process, import/export regulations, clinical trial oversight, post-marketing surveillance, and licensing procedures. It also examines the interaction between regulatory affairs professionals and CDSCO in the preparation, submission, and management of regulatory documents. Key regulatory guidelines, forms and timelines are reviewed to assess their impact on the pharmaceutical product lifecycle from development to commercialization. Regulatory affairs play a pivotal role in the pharmaceutical industry by ensuring that all processes align with national regulatory standards laid down by CDSCO. The pharmaceutical sector heavily depends on regulatory compliance to gain market authorization, maintain product safety and achieve global competitiveness. A well-established regulatory framework like that of CDSCO not only supports public health but also promotes innovation and ethical standards within the industry.

Biography

Tejeswari has her own experience in valuation and passion for ML and data. The research team built this model after many years of experience in research, evaluation, work in both hospitals and scientific laboratories. This approach meets all the requirements for precise, specific, sensitive diagnostics.

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