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Symbiosis of regulatory affairs and drug development to deliver high quality, safe and effective medicines

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Regulatory Affairs plays a crucial role in the pharmaceutical and biotechnological industry and is involved in all stages of drug development, drug approval and life cycle maintenance of the product after approval. The Drug Discovery and Development cell in the industry is obligated to follow the strict regulations and guidelines issued by health authorities to develop the safe and effective medicines. Regulatory Affairs acts as an interface between the industry and the health authorities and provides strategic advice to ensure regulatory compliance at all stages. The drug development process is changed drastically from the last 2 decades due to new technological advancement in the science. With this advancement, the role of Regulatory Affairs is also broadened and strengthened. The Drug Discovery/Development and Regulatory Affairs have joined hands in the modern process of drug development for interpretation and application of regulations with a goal to provide high quality, safe and effective medicines to the patients.

Biography

Guriqbal Singh is a pharmacy postgraduate (M. Pharm) with around 11 years of experience in the pharmaceutical industry. He has versatile experience in the field of regulatory affairs and CMC, covering the entire life cycle, encompassing new chemical entities, generics and biosimilars. His career has led him to specialise increasingly in management of complex global projects. He has experience in submission of clinical trial applications (CTAs), abbreviated new drug applications, ANDSs), complex variations, renewals, and post approval commitments.

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