

Regulatory Affairs in the Pharmacy

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Abstract: *The regulatory bodies are being established in various pharmaceutical industries across the globe which plays a vital role to meet the requirements of legal procedures related to drug development process in a country. The pharmaceutical industry is considered as the most highly regulated industries worldwide. The regulatory body ensures compliances in various legal and regulatory aspects of a drug. Countries possess their own regulatory authority, which is responsible for enforcing the rules and regulations and issue the guidelines to regulate drug development process, licensing, registration, manufacturing, marketing, labeling and the product life cycle of pharmaceutical products. In an ever-changing regulatory environment, the role of regulatory affairs personnel is essential to ensure compliance with legislation in all regions in which a company wishes to distribute its drug. This article describes the development of the drugs as it is a cumbersome process which includes several months of time, volunteers, and a huge financial investment majorly through the funding process, so it is strictly regulated as per the norms and regulations as given by those individual countries to carry out the drug development which was generally governed by the Drug Regulatory Affairs Personnel.*

Keywords: Regulatory authority, legal procedures, guidelines, licensing.

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