

REGULATORY INTELLIGENCE - NEED OF THE HOUR

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ABSTRACT

The pharma industry is characterized by a long R&D cycle with an acute need for speed to market. Regulatory agencies have increased scrutiny leading to fewer innovative drugs & increased costs in clinical trials. Considering the current dynamic regulatory landscape along with other challenges, Regulatory Intelligence (RI) has become a key function in the industry. Regulatory professionals have to deal with abundant data from varied sources, analyze and evaluate the required necessary information from that. The analyses and evaluation of all the available information has to be interpreted to buildup future regulatory strategies. The objectives of RI are to identify competitive advantages in the sectors of Regulatory Affairs, Business development, Sales and Marketing, CMC, Manufacturing, Toxicology, Preclinical phases, Drug development stages and many more. Successful RI drives successful global business. Importance and advantages of RI have been articulated here to demonstrate the need of the hour for the industry to focus on Regulatory Intelligence.

Key Words: *Pharma industry, Regulatory agencies, Regulatory Affairs, Regulatory Intelligence*