Review Article

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Recent Regulatory Initiatives at the Indian Central Drugs Standards Control Organization (CDSCO)

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ABSTRACT

The Government of India, through the CDSCO office, has been trying to engage with the drug industry and other stakeholders through its inclusive approach for instituting measures, through administrative orders, in helping remove regulatory bottle necks, and thereby improve ease of doing business. Some of the measures which have been instituted include facilitating the conduct of trials; rationalizing and simplifying various formats of applications; doing away with pre-inspection of manufacturing sites for grant of test license; potentially reducing approval timelines for different kinds of regulatory submissions by making the submission process online etc. These measures have helped to remove the constraints which have been plaguing the industry. At the same time CDSCO has been building in enough checks and balances within the system to monitor quality, safety and compliance. Emphasis has been laid on quality standards being followed by manufacturing firms with a view to bringing the GMP standards at par with the WHO guidelines. There are plans which include scrapping the need to renew manufacturing licenses at the end of five years etc for which industry and other stakeholder's opinion is being sought.

KEYWORDS: CDSCO; Clinical Trial; Manufacturing; Regulation; Guideline; India.