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Approval, Manufacture and Marketing Regulations of Medical Devices in Regulated Markets.

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A medical device is an instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body. This Article mainly deals with the approval process of medical device in regulated markets of USA, Europe, India, Canada and Australia. The comparison of approval process of medical devices is very beneficial for medical device industries. This work will give clear and detailed information regarding the classification of medical devices and their approval process in regulated countries. Medical devices have become more important in the health care sector. It is mostly used for diagnosis and prevention of public health. There are more than 8000 generic medical device groups, where some medical devices contain drugs. This increases the demand for better regulatory frameworks to ensure that products entering in the market are safe as well as efficient. One of the major issues for companies developing and producing medical devices is to be updated on the bases of regulatory requirements and to implement them in the process. This is particularly true in developing countries, where assessments of health technology are rare and where little regulatory controls exist to prevent the importation or use of substandard devices. So regulation of medical device is a vital need in Pharmaceutical Sector. The better regulatory frameworks to ensure that products entering the market are safe and efficient

Keywords: Medical device, Regulation, Classification rules, Australia, India, CDSCO, TGA.

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