



Japan

## The regulatory System and Requirements in Japan for Medical Devices The New Pharmaceutical Affairs Law

*To market products in an industry, it is necessary to comply with the applicable laws and regulations.*

*The medical device industry in the EU, the USA and Japan is very competitive in the global market where numerous manufacturers export their products to other countries. It is necessary to take into consideration that the EU, the USA and Japan are also places which have strict laws and regulations regarding medical devices. Japan's new Pharmaceutical Affairs Law (hereinafter referred to as PAL) has been effective since April 2005. One of the purposes of this amendment is to make it more harmonized with the regulatory framework, which is currently being discussed at the meetings of the Global Harmonization Task Force. While there are some similarities between PAL in Japan and MDD in the EU, there are significant differences as well. In this textbook, those features of PAL are explained, and presentation slides are shown at the top of each page with additional comments below.*

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