

UNDERSTANDING THE JAPANESE MEDICAL DEVICE APPROVAL PROCESS



Home to several medical device companies, Japan is one of the largest markets in the world. But despite the country's own advances in technology and pharmaceuticals, many of the medical devices marketed in Japan are manufactured by foreign firms. In fact, Japan is among the most lucrative of markets for international manufacturers.

In order to enter the Japanese market, medical devices are required to undergo regulatory approval based on the Pharmaceutical and Medical Device Act (PMD Act). Enforced in 2014, the new regulations include provisions for medical devices, which had previously been treated in much the same way as pharmaceutical products.

While certain elements of the update streamlined the country's device laws, the regulations can often be challenging for foreign manufacturers. Language barriers and a complex registration process may be intimidating at first glance, but with patience and expert guidance, the Japanese regulatory process can be easily negotiated.



WHAT ARE THE MAJOR ISSUES?

To sell a medical device in Japan, manufacturers are required to comply with the Japanese Pharmaceutical and Medical Device Act (PMD Act) and registration process. Registration is overseen by the Pharmaceuticals and Medical Devices Agency (PMDA), a regulatory agency of the Ministry of Health, Labour and Welfare (MHLW). These bodies work together to review new product safety, develop comprehensive regulations and monitor post market safety.

However, as few of the regulatory documents are published in English, complying with these rules can be difficult for foreign firms.

Additionally, registering a medical device in Japan can be time-consuming and expensive, with the approvals process usually taking anywhere between one to three years to complete, depending on the classification of the device. Japanese regulators have also been known to request local clinical trials, which can be a costly process for manufacturers.

The Japanese market should only be pursued after determining that there is a significant demand for a product. Fortunately, this is often the case for many manufacturers.

Due to a large aging population, the demand for medical devices in Japan is significant. So despite these hurdles, gaining medical device approval in Japan is often well worth the time and expenses involved.

EXPERT GUIDANCE

As regulatory requirements vary widely around the world, taking a medical device to any international market can be a challenging process and requires an in-depth understanding of how to become fully compliant.

NSF International offers a series of country-specific medical device training courses, featuring instructions on each jurisdiction's legal and regulatory framework, premarket pathways and requirements, as well as post-market regulations.

NSF is a trusted provider of auditing and risk management solutions for human health and the environment. We were also the first to launch a comprehensive set of online training modules covering global medical device regulatory requirements for all five countries participating in the Medical Device Single Audit Program (MDSAP), which includes Japan.



The MDSAP course equips manufacturers to:

- > Identify the legal and regulatory framework for manufacturing, marketing and distributing medical devices
- > Distinguish how medical devices are classified
- > Identify the premarket pathway and requirements for bringing a product or device to market
- > Recognize post market requirements, including quality audits guidelines

What Does It Take to Bring a Product to Market In Japan?

Register for the NSF International eLearning course, [Medical Device Regulatory Requirements - Japan](#) to gain a comprehensive overview of Japan's medical device regulatory framework.

Have more questions? Contact healthsciences@nsf.org.

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