COVUE

Medical Devices Import in Japan

Medical Devices are regulated in Japan by the Pharmaceuticals and Medical Device Agency (PMDA).

First Shipment with COVUE

- Approval process and timelines are based on several factors including, Product, Medical Device Class (1,2,3,4,5), known device or new to the market, manufacturing plant registration, and plant audits.
- Pricing is determined by Medical Device Class (1,2,3,4,5).
- Average Approval Time:

  Class 1: 120 Days
  Class 2: 6-12 Months
  Class 3: 9+ Months
  Class 4 & 5: 12+ Months

Note:

- Only a Japanese company licensed for Import, Sales & Marketing of Medical Devices can legally import the product on behalf of the foreign seller.
- Whoever handles the Japan import application will control the product rights, regardless of the contractual agreement between the importer and the license holder.
- Regulated products cannot be shipped directly. They must arrive at the facility of the license holder where the products are registered.
- The products must undergo a compliance IQC inspection.
- PMDA is the agency responsible for medical devices.

Why Choose COVUE?

Our license permits our clients omni-channel access to the Japanese market.

Our Sales & Marketing license umbrellas all sellers and resellers in Japan.

We never lock your product rights under compliance. If at any time you wish to change, please contact us, and we will unregister your products.

Application Requirements:

- Manufacturing plant information
- Product claims
- Trial data submission (where applicable)
- Factory inspection (where applicable)

Steps

1. Submit your product information to COVUE compliance for pre-application review
2. Register your company under COVUE's license
3. Document work for product standards (in Japanese, performed by COVUE)
4. Open an import application (notification) with PMDA
5. Product label creation and registration
6. Plant audit (where applicable)
7. Create shipping invoice from the COVUE IOR account
8. Ship to COVUE for IQC inspection* (required)
9. Ship to the final destination

*Note: *Japan law requires all PMDA-regulated products to be received at the licensed IOR facility for IQC inspections. The process takes 48-72 hours.*

For more information, click here.

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