

IDRAC[®] JAPAN MODULE

A SINGLE, AUTHORITATIVE SOURCE OF JAPANESE REGULATORY REQUIREMENTS



WHAT SETS IDRAC APART?

- An unrivaled depth of global information
- Covers both established and emerging economies
- Unique, proprietary regulatory intelligence
- Compiled by Thomson Reuters regulatory experts
- Every entry is curated manually

HOW YOU CAN BENEFIT

- Optimize your regulatory strategy and minimize your risk
- Save time and cost
- Get your product to the market on time and keep it there
- Gain a competitive advantage

UNSURPASSED DEPTH OF COVERAGE

The Japan module was designed for non-Japanese professionals who want to understand the Japanese system. It facilitates easier communication with Japanese colleagues by helping to explain the Japanese marketplace.

The module contains 59 explanatory documents written by local experts, as well as more than 500 key reference texts. The module also contains Japanese legal documents translated into English that cannot be found elsewhere.

The module has translations that are not available anywhere else and are offered in electronic format. We can also fulfil requests for translations of official documents.

As the Japanese system is reorganized following the Revision of the Pharmaceutical Affairs Law, which was passed by the Diet on July 25, 2002, the module will keep you up-to-date with:

- The switch from manufacturing approval to marketing approval
- The merger of Kiko (Organization for Pharmaceutical Safety and Research), PMDEC (Pharmaceutical and Medical Devices Evaluation Centre), and JAAMD (Japan Association for the Advancement of Medical Equipment) into PMDA (Pharmaceuticals and Medical Devices Agency)
- Changes to Japan's In Country Caretaker system
- The enhancement of safety measures for biological products
- The adoption of the Common Technical Document

Additionally, the module includes explanatory documents on how to market medical devices, as well as drug approval and evaluation reports. These include discussions on the drugs being reviewed and provide an insight into the mind of the investigator.

REQUEST A TRIAL

Contact us today to take an IDRAC trial and see for yourself how it will improve your regulatory affairs intelligence. Contact us at scientific.thomsonreuters.com/contact

