

Global regulatory intelligence at your fingertips

IDRAC® full Japan module

A single, authoritative source of Japanese regulatory requirements

What you can do >>

- Access more than 800 key documents in English
- Speed up access to the information you need
- Track changes to documents
- Trace each step of new regulations
- Browse easily between documents
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- Facilitate better collaboration

When you can benefit >>

- Planning clinical trials
- Product registration and commercialization
- Market optimization

Unsurpassed breadth of coverage

IDRAC® from Thomson Scientific brings together everything you need to keep up with the ever-changing regulatory requirements in nearly 60 countries, replacing the onerous and time-consuming tasks of acquiring, compiling, indexing, cross-referencing, updating and analyzing this information. Tens of thousands of documents cover all aspects of drug development in each country or region, thematically organized for easy retrieval, with more added every day.

- > **Reference texts**, normally in the local language (with complementary translations into English for China, Japan, Taiwan, Thailand, South Korea and Vietnam)
- > Unique **explanatory documents** written in English by our team of experts to explain key processes and trends in each country

Every document includes a title, source, abstract, comprehensive and intuitive keywords in English, and extensive hyperlinks. A powerful search engine enables you to interrogate the entire database in seconds using full text, title, and keyword searches.

Several ways to retrieve information

- Simple search
- Advanced search
- Expert documents classified by subject
- Reference texts
- New texts
- Subjects



The Japan module

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 fulfill requests for translations of official documents.

What it covers

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.

Full list of available modules

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Outstanding flexibility and service

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As standard, every *IDRAC* subscription also includes free access to the international module, an extensive library of reference texts and explanatory documents covering international organizations such as ICH, WHO, PIC/S, and many others.

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