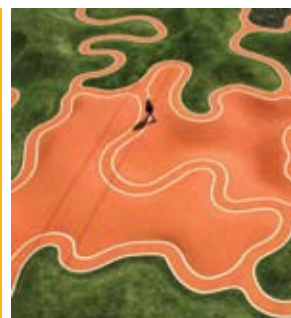


# IDRAC<sup>®</sup> JAPAN MODULE

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
- Receive configurable email alerts
- Facilitate better collaboration

## WHEN YOU CAN BENEFIT

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

## 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.

## Scientific Head Offices

### Americas

Philadelphia +1 800 336 4474  
+1 215 386 0100

### Europe, Middle East and Africa

London +44 20 7433 4000

### Asia Pacific

Singapore +65 6411 6888  
Tokyo +81 3 5218 6500

For a complete office list visit:

[scientific.thomsonreuters.com/contact](http://scientific.thomsonreuters.com/contact)

## GET A QUOTATION

Contact us today to request a no obligation quotation or visit [scientific.thomsonreuters.com](http://scientific.thomsonreuters.com)

