

IDRAC[®] TAIWAN MODULE

A SINGLE, AUTHORITATIVE SOURCE OF TAIWANESE REGULATORY REQUIREMENTS



WHAT YOU CAN DO

- Access 48 explanatory documents
- 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 Taiwan module contains 48 explanatory documents, written by local experts and based on *IDRAC* proprietary specifications, covering:

- The organization and function of authorities, the Department of Health (DOH), and affiliated agencies
- What is regulated by The Pharmaceuticals and Pharmaceutical Companies Law (Taiwanese Pharmaceutical Affairs Law)
- Regulations that control medicinal products relating to manufacturing, exports, and imports
- Data required for Taiwanese registration
- The registration process of NDA
- How medicinal products are advertised and promoted in Taiwan
- Fees, pricing, and reimbursement
- Quality assurance issues such as GMP, GLP, GCP, and GRP
- The Taiwanese ADR monitoring and reporting system

Additionally, the Taiwan module includes a comprehensive set of reference texts including English translations of official regulatory documents such as:

- The Pharmaceuticals and Pharmaceutical Companies Law (Taiwanese Pharmaceutical Affairs Law)
- Enforcement rules for The Pharmaceuticals and Pharmaceutical Companies Law
- Taiwanese Good Manufacturing Practice
- Taiwanese Good Clinical Practice

IDRAC provides more Chinese-English translations than any other source. *IDRAC* English translations are completed by translators qualified in the pharmaceutical field who undergo quality assurance checks by native English speakers.

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

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