

# IDRAC<sup>®</sup> TAIWAN MODULE

A SINGLE, AUTHORITATIVE SOURCE OF TAIWANESE 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 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.

## REQUEST A TRIAL

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