

IDRAC[®] CHINA MODULE

A SINGLE, AUTHORITATIVE SOURCE OF CHINESE REGULATORY REQUIREMENTS



WHAT YOU CAN DO

- Access 49 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 China module contains 49 explanatory documents, written by a local expert and based on *IDRAC* proprietary specifications, covering:

- The organization and function of authorities, the State Food and Drug Administration (SFDA), and the Ministry of Health (MOH)
- What is regulated by the China Drug Administration Law
- The types of business licenses and applications required for registration of medicinal products in China
- The data required in the Chinese approval application for clinical trials and registration
- The step-by-step review procedure of Chinese clinical trials and approval, as well as marketing authorization approval
- How medicinal products are advertised and promoted in China
- Fees, pricing, and reimbursement
- Wholesale and marketing medicinal products in China
- How Chinese guidelines including GMP, GLP, GCP, GRP, and GSP are regulated
- The Chinese ADR monitoring and reporting system

In addition, the China module includes English translations of official regulatory documents, including:

- The China Drug Administration Law
- Regulations for Implementation of Drug Administration Law
- Chinese Good Manufacturing Practice
- Chinese Good Clinical Practice
- SFDA Orders (Technical Guideline for Pharmaceuticals)

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