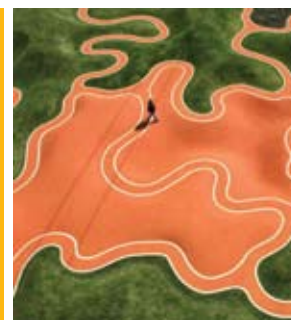


# IDRAC<sup>®</sup> INDIA MODULE

A SINGLE, AUTHORITATIVE SOURCE OF INDIAN REGULATORY REQUIREMENTS



## WHAT YOU CAN DO

- Access 40 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 India module contains 40 explanatory documents written by local experts and based on *IDRAC* proprietary specifications, covering all topics relevant to pharmaceutical industry activities in India, including:

- The organization and function of the Medicines Agency (CDSCO)
- What is regulated by the Drugs and Cosmetics Act 1940 and the Drugs and Cosmetics Rules 1945, along with all amendments
- The types of business licenses and applications required for registration of medicinal products in India
- The data required for the approval of clinical trials in India
- The step-by-step procedure for the conduct of clinical trials in India
- How medicinal products are imported into and exported from India
- Fees, pricing, and reimbursement
- Applicable GMP and GCP guidelines
- The Indian pharmacovigilance system
- Generics and medical devices applications.

Additionally, the India module includes reference texts covering the Constitution of India, acts, rules, policies, guidelines and notifications from 1940 onwards, as well as relevant forms.

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