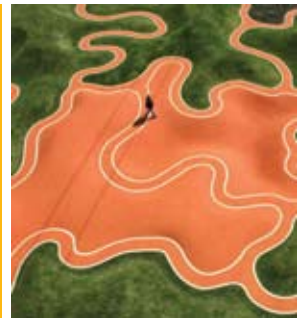


# IDRAC<sup>®</sup> INTERNATIONAL MODULE

A SINGLE, AUTHORITATIVE SOURCE OF INTERNATIONAL 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 international module contains a wide-ranging collection of reference texts and explanatory documents written by local experts and based on *IDRAC* proprietary specifications. They include detailed information on the major international and regional organizations involved with legislating medicinal products around the world.

The international module covers:

- World Health Organization (WHO)
- International Conference on Harmonization (ICH)
- Pharmaceutical Inspection Cooperation Scheme (PIC/S)
- Council for International Organization of Medical Sciences (CIOMS)
- Organization for Economic Cooperation & Development (OECD)
- European Department for the Quality of Medicines & Healthcare (EDQM)
- New Collaboration Agreement of Drug Regulatory Authorities in EU Associated Countries (nCADREAC)

For each of these organizations, the international module includes a full description, including its structure and the role it performs, practical information on interacting with it, and links to key resources.

The international module also includes an extensive library of official texts, including:

- **WHO:** key guidelines for the manufacturing of vaccines (WHO Technical Report Series), the WHO Pharmaceutical Newsletters, the ATC classification
- **ICH:** all Guidelines classified according to their topic (Quality, Safety, Efficacy, Multidisciplinary) in a user-friendly table that highlights the history of every guideline and provides hyperlinks to the corresponding Japan, EU and US implementing texts
- **PIC/S:** key guidelines, recommendations and SOP on Good Manufacturing Practice and Quality Assurance
- **CIOMS:** all the reports issued by the Working Groups which relate to pharmacovigilance or clinical trials
- **OECD:** Environment Monographs from the Series on Good Laboratory Practice
- **EDQM:** key documents on Batch Release, Certification, Quality Assurance Activities, the Technical Guides for the Elaboration of Monographs

## REQUEST A TRIAL

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