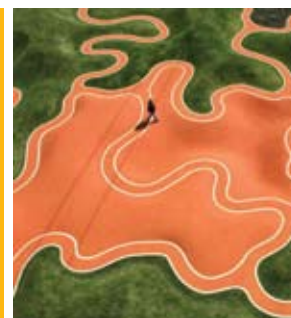


IDRAC[®] LATIN AMERICA MODULE

A SINGLE, AUTHORITATIVE SOURCE OF LATIN AMERICAN REGULATORY REQUIREMENTS



WHAT YOU CAN DO

- Access 50 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 Latin America module contains 50 explanatory documents per country, written by local experts and based on *IDRAC* proprietary specifications. It covers regulatory information for Argentina, Brazil, Mexico, and Mercosur, including:

- The organization and functions of the health authorities in Argentina, Brazil, and Mexico (ANMAT, ANVISA, and SSA, respectively)
- The medicinal products regulated by national drug laws and decrees, with exhaustive discussions on locally-defined categories of medicinal products and their prescription status
- The types of business licenses and applications required for the registration of medicinal products
- The dossier format and procedure to be followed for the registration of medicinal products in Argentina (depending on medicinal product country of origin) and in Brazil and Mexico (depending on the category of the product)
- How to put clinical trials in place in these countries, including the documentation required, the authorities and committees involved, and the approval and notification processes
- The steps to be followed for importing medicines into Latin American countries or exporting from them

- Local fees and advertising requirements
- Healthcare policies and consequences, including the role of generics and local manufacturing
- Quality assurance information, such as following good practices and conducting inspections
- How patents, copyrights, and trademarks are handled in the Latin American countries
- The ADR monitoring and reporting system

The reference texts section of the Latin America module is organized around country-specific legislative documents, such as laws and decrees, as well as specific country documents such as resolutions and dispositions in Argentina, order and resolutions in Brazil, and official norms and agreements in Mexico. Ready-to-use forms are also available for the three modules.

The Mercosur explanatory texts section is organized into tables listing the corresponding Brazilian and Argentinean implementing text for each GMC Resolution. The Mercosur explanatory document additionally provides basic information on the objectives, structure, and functions of the Southern Common Market and mainly focuses on the Health Area.

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