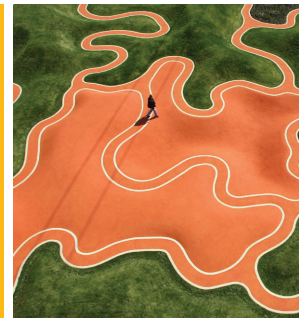


# IDRAC LATIN AMERICA MODULE

A SINGLE, AUTHORITATIVE SOURCE OF LATIN AMERICAN 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

## WHEN 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 Latin America module contains regulatory summaries for each country, written by local experts and based on IDRAC® proprietary specifications. It covers regulatory information for Argentina, Brazil, Chile, Colombia, Mexico, Peru, and Venezuela, as well as the Southern Common Market MERCOSUR, including:

- The organization and functions of the health authorities in Argentina, Brazil, Chile, Colombia, Mexico, Peru, and Venezuela (ANMAT, ANVISA, ISP, INVIMA, SSA, MINSA, and MPPS 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 follow for the registration of medicinal products in Argentina (depending on medicinal product country of origin) and in Brazil, Chile, Colombia, Mexico, Peru, and Venezuela (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 these countries

- 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 documents section of the Latin America module is organized around country-specific legislative documents, such as laws and decrees, and specific country documents such as resolutions and dispositions in Argentina, orders and resolutions in Brazil, resolutions and circulars in Chile, resolutions and agreements in Colombia, official forms and agreements in Mexico, resolutions and regulations in Peru, and circulars and official forms in Venezuela. Ready-to-use forms are also available for these modules.

The MERCOSUR regulatory summaries section is organized into tables, listing the corresponding Brazilian and Argentinean implementing text for each GMC Resolution. The MERCOSUR regulatory summaries additionally provide basic information on the objectives, structure, and functions of the Southern Common Market and mainly focuses on the Health Area.

## HEALTHCARE & SCIENCE REGIONAL OFFICES

### North America

Philadelphia +1 800 336 4474  
+1 215 386 0100

### Latin America

Brazil +55 11 8370 9845  
Other countries +1 215 823 5674

### Europe, Middle East and Africa

London +44 20 7433 4000

### Asia Pacific

Singapore +65 6775 5088  
Tokyo +81 3 5218 6500

For a complete office list visit:

[science.thomsonreuters.com/contact](http://science.thomsonreuters.com/contact)

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