

IDRAC[®] US MODULE

A SINGLE, AUTHORITATIVE SOURCE OF US REGULATORY REQUIREMENTS



WHAT YOU CAN DO

- Access 46 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 US module contains 46 explanatory documents written by local experts and based on IDRAC proprietary specifications. They include detailed information on the US market authorization process, with links to key resources.

The US module covers:

- Ethical drugs (brand name and generic)
- Over-the-counter drugs (followed from brand to OTC switch only)
- Biological therapies
- Medical devices
- Combination products
- The Code of Federal Regulations (CFR), updated weekly. This is updated in blue text as Final Rules become effective. The amended text remains in blue for one year
- FDA drug and biological advisory committee and workshop meetings, with links to *IDRAC AdComm Bulletin*, *IDRAC AdComm Profiles*, *IDRAC AdComm Voting*, and *FDA Workshop Bulletin*

- The Guidance Bulletin, providing an overview of FDA CDER and Office of the Commissioner guidance documents including the history of its development. The Guidance Bulletin features new text, including links to public comments to the FDA and a line-by-line comparison to previously released versions of the FDA Guidance
- Compliance Information. The US module contains over 3,700 compliance related documents including:
 - 1,000 Establishment Inspection Reports (EIR)
 - 2,300 Compliance Letters [Warning Letters, Untitled Letters (from FDA's Division of Drug Marketing, Advertising and Communications), NIDPOE (Notice of Initiation of Disqualification Proceedings and Opportunity to Explain) and NOOH (Notice of Opportunity for Hearing) letters], FDA Forms 483s, Compliance Manuals and Inspection Guides

Scientific Head Offices

Americas

Philadelphia +1 800 336 4474
+1 215 386 0100

Europe, Middle East and Africa

London +44 20 7433 4000

Asia Pacific

Singapore +65 6411 6888
Tokyo +81 3 5218 6500

For a complete office list visit:

scientific.thomsonreuters.com/contact

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