

IDRAC[®] US MODULE

A SINGLE, AUTHORITATIVE SOURCE OF US 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 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

REQUEST A TRIAL

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