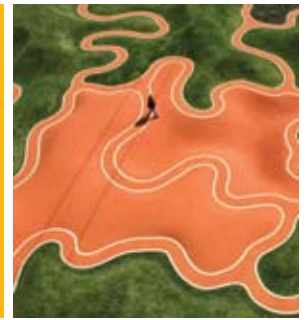


IDRAC[®] MEDICAL DEVICE COVERAGE

AUTHORITATIVE, GLOBAL REGULATORY REQUIREMENTS ON MEDICAL DEVICES



WHAT SETS IDRAC APART?

- An unrivaled depth of global information
- Covers both established and emerging economies
- 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

MINIMIZE YOUR REGULATORY RISK AND GAIN COMPETITIVE ADVANTAGE

IDRAC[®] from Thomson Reuters helps you get your product to market without delay, and ensure it stays there.

IDRAC equips your organization to stay fully up to date with the ever-changing requirements of governments and regulatory authorities around the world. Only *IDRAC* has the global reach, depth of analysis and local expert knowledge to keep you informed of every regulation that could affect your product.

This is why *IDRAC* is the solution the world's most demanding pharmaceutical companies rely on to guide their regulatory decisions, day after day.

SAVE TIME AND COST WITH RELIABLE, IMPARTIAL KNOWLEDGE

IDRAC saves you the things most precious to your organization—time and cost. Complying with the regulatory demands of every potential market is an onerous and time-consuming task. Get it wrong and you might delay your product's entry into your target marketplace.

IDRAC has built its enviable reputation on providing reliable, impartial knowledge the moment it's available, backed up by accurate, expert analysis and the world's finest customer support.

It ensures you're aware of every relevant piece of legislation, saving you the effort of acquiring, compiling, indexing, cross-referencing, updating and analyzing the regulatory information vital to your business.

UNSURPASSED DEPTH OF COVERAGE

For each country or region, the documents in *IDRAC* are thematically organized for easy retrieval, with more added every day.

- **Reference texts**, normally in the local language (with complementary translations into English for China, Japan and South Korea)
- **Unique explanatory documents** written in English by our team of experts to explain key processes and trends in each country.

FAST, POWERFUL DOCUMENT RETRIEVAL AND BROWSING

Navigating the regulatory knowledge in *IDRAC* is quick and simple. Every document is classified by subject and region. A powerful search engine enables you to interrogate the entire database in seconds using full text, title, and keyword searches.

Extensive hyperlinking makes it easy to browse through documents, following citations from explanatory documents to the original reference texts, widening your enquiry into associated regulations, and ensuring you're always kept informed of the full picture.

Since each document has its own unique URL, you can bookmark and share document addresses in your browser and in emails—instantly retrieving the correct information, the moment you need it.

OUTSTANDING SERVICE AND SUPPORT

Training is provided by qualified instructors who can visit your site at your convenience or host virtual training sessions online. You will also receive comprehensive customer service through easy-to-follow product manuals, and dedicated telephone and email helpdesk support.

BUILD THE COVERAGE THAT SUITS YOU

IDRAC is a flexible, modular system, enabling you to build the coverage that suits you by subscribing only to the countries and regions relevant to your organization.

Each user can choose to receive the *IDRAC* Weekly Alert, bringing the very latest developments in global regulations straight to their desktop. They can also create their own email alerts and saved queries, configured to their needs.

With the *IDRAC*[®] Notes commenting feature, your users can create comments and attach them to *IDRAC* documents. This enables you to share within your organization special internal knowledge side by side with the relevant *IDRAC* information.

AVAILABLE MODULES

- Australia
- Canada
- China
- Europe
- France
- Germany
- India
- Japan
- The Netherlands
- South Korea
- UK
- US



EU MODULE

Reference texts cover:

- The Medical Device Directive
- The Active Implantable Medical Devices Directive
- The In Vitro Diagnostics Directive
- MEDDEV guidelines

The module also contains information on other directives such as the EU Waste Electrical and Electronic Equipment Directive 2002/96/EC, Directive 2005/50/EC on Reclassification of Hip, Knee and Shoulder Joint Replacements, and Directive 2003/32/EC for Devices Manufactured Utilising Tissues of Animal Origin.

Expert Reports cover:

- How to market medical devices
 - Definition
 - Legal framework including European Directives, Classification, Essential Requirements, Competent Authorities, Notified Bodies
 - Requirements for design and compliance including Preclinical Assessment
 - Clinical evaluation
 - Labeling requirements, including CE marking
 - Post-marketing requirements
 - Fees
 - Pricing and reimbursement
 - Advertising
 - International aspects (GHTE, GMDN, MRAs, PECAS)
 - A brief overview of human tissue engineered products
 - REACH, GHS
 - Checklists for essential requirements and technical file
- How to market combination products
- How to market advanced therapy products

US MODULE

Reference texts cover:

- Major acts within the scope of *IDRAC*, including Medical Device User Fee and Modernization Act (MDUFMA) and the Food and Drug Administration Amendments Act of 2007
- Code of Federal Regulations 21 CFR Parts 800 to 898 (2005–present) – CFR is updated in blue text as Final Rules become effective and the amended text remains in blue for one year
- Federal Register – all proposed and final rules affecting the CFR, including the Center for Devices and Radiological Health (CDRH) guidances
- CDRH guidances (2005–present) related to therapeutic use.
- EIRs, FDA 483 and Correspondence, FDA Enforcement Reports
- Major EIRs dealing with medical devices (since June 2002)

Major forms likely to be used by regulatory affairs departments in medical device companies are provided in ready-to-use Microsoft® Word format.

Expert Reports cover:

- How to market medical devices
 - Definition
 - Legal framework
 - Requirements for registration format and content of applications
 - Fees
 - Clinical research
 - Labeling requirements
 - Post-marketing requirements
 - Pricing and reimbursement
 - Advertising
 - Federal pre-emption
 - International aspects
- How to market combination products
- How to market advanced therapy products

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