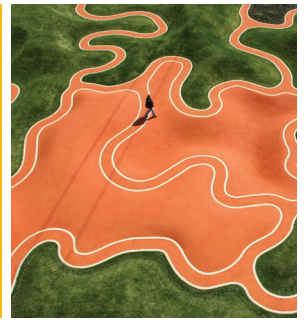


IDRAC[®] EU MODULE

A SINGLE, AUTHORITATIVE SOURCE OF EU 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 EU module provides you with all relevant European Union Reference Texts, with key-added value English Abstracts.

The EU module includes fully detailed Regulatory Summaries, reviewed on a continuous basis on:

- Authorities/organizations
- Legal definitions and marketing requirements
- Prescription and supply requirements
- Prescription and supply requirements
- Format and content of applications
- Assembly and submission of applications
- Marketing authorization procedures
- Fees
- Product information
- Clinical research
- Quality assurance
- Pharmacovigilance and risk management
- Import/export
- Advertising/promotion
- Pricing and reimbursement
- Intellectual property
- Environmental framework

These Regulatory Summaries, reviewed on a continuous basis, contain links to all relevant reference texts cited throughout the summary.

In addition to Reference Texts and Regulatory Summaries, our IDRAC Editorial regulatory experts provide you with Regulatory Intelligence Reports, based on a unique in-house expertise in terms of analysis and manual curation.

For example::

- A **'how to market'** section for generics, medical devices and combination products, herbal products, orphan drugs, advanced therapy products and drugs for pediatric use.
- **Comparative tables** that enable you to make easy comparisons between EU member states on topics such as (latest additions):
 - PIL User Testing
 - Compassionate Use
 - National Public Assessment Reports
 - Implementation of the EU Directive 2004/23/EC
 - Braille labelling
 - Bolar Provision
- **Amended versions** for all main legislative reference texts.
- **Guidelines Matrix** that enables you to quickly and easily link to all versions of a guideline.
- **Overview of EU legislation proposals** summarizing future changes in EU legislation.
- **EU Committees and Working Group overview** providing detailed information on the tasks, rules of procedures, work plan, composition, membership and meeting schedule of all the committees and working groups within the EMEA.

These Regulatory Intelligence reports are reviewed on a continuous basis.

INDIVIDUAL EUROPEAN COUNTRIES

As for the EU module, these provide you with all relevant Reference Texts, with key-added value English Abstracts.

Regulatory Summaries are provided by Local regulatory consultants and reviewed on a continuous basis. These highlight the specific national requirements faced by companies operating in this increasingly complex regulatory environment.

THE INDIVIDUAL EUROPEAN COUNTRIES COVERED IN ADDITION TO "EU" ARE:

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Russian Federation
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Turkey
- Ukraine
- United Kingdom

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