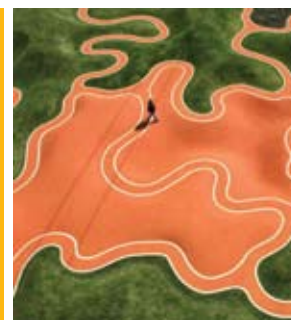


IDRAC[®] EU MODULE

A SINGLE, AUTHORITATIVE SOURCE OF EU REGULATORY REQUIREMENTS



WHAT YOU CAN DO

- Access key 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 EU module covers all European Union Authority legislation. Local experts explain key processes and trends, while documents explain the specific national requirements faced by companies operating in this complex regulatory environment.

The EU module includes a full description and practical information on:

- Authorities/organizations
- Legal framework
- 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
- IDRAC comparative tables
- EU committees and Working Group overview
- Overview of EU legislative proposals

It also includes:

- 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 the following main topics:
 - EU rules implementation follow-up (eg. Bolar Provision, Sunset Clause, eCTD, Directive 2004/27/EC)
 - Fees (mutual recognition and decentralized procedures, clinical trial applications, variations etc)
 - Pharmacovigilance (pre- and post-marketing surveillance)
 - Authorities (medicines agencies, CHMP members, EU membership etc)
- **Legal and regulatory rulings** from the European Parliament, Council and Commission, the Court of Justice, the Heads of Medicines Agency, the EMEA (European Medicines Agency) and its Scientific Committees (CHMP, COMP, HMPC and PDCO) and Working Groups.
- Overview of EU legislation proposals explanatory document, summarizing future changes in EU legislation.
- EU Committees and Working Group overview explanatory document, 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.

THE MODULE COMPRISES REGULATORY INFORMATION FOR THE FOLLOWING COUNTRIES:

- 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
- Spain
- Slovakia
- Slovenia
- Sweden
- Switzerland
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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
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