

IDRAC[®] REGULATORY ONLINE LEARNING

EXPERT PHARMACEUTICAL INDUSTRY TRAINING FROM THOMSON REUTERS



WHAT IT CAN HELP YOU DO

- Gain a solid grounding in global regulatory affairs
- Learn how the industry operates
- Stay on top of the ever-shifting regulatory landscape
- Develop and implement regulatory strategies
- Optimize your success in dealing with regulatory authorities
- Identify potential risks to approval

WHO CAN BENEFIT

- Regulatory affairs professionals
- Clinical trials managers
- Product registration managers
- Commercialization teams
- Market optimization teams

GET UP TO SPEED ON GLOBAL REGULATORY AFFAIRS

These modular online courses will bring you rapidly up to speed on global regulatory affairs, delivering an unparalleled depth of information and procedural knowledge to your desktop.

IDRAC[®] Regulatory Online Learning provides access to relevant IDRAC[®] documents, recognized by regulatory professionals the world over as the leading authority in respected industry information.

- Comprehensive — the 22 modules guide you through all relevant territories worldwide
- Accurate — designed and developed by our team of IDRAC experts, assisted by an international network of consultants and partners
- Up-to-date — continuously updated to reflect the very latest developments
- Driven by you — follow the entire course as a complete guide to regulatory affairs, or drop in to the module that interests you

INTRODUCTORY COURSES

- Introduction to the European Union Institutions and Regulatory Authority (EMA)
- Introduction to US Institutions and Regulatory Authority (FDA)
- Introduction to Japanese Institutions and Regulatory Authorities
- Overview of the CTD and the e-CTD
- Introduction to the International Conference on Harmonization (ICH)
- The Regulatory Development of a Drug
- Basics of Pharmacovigilance
- Basics of Clinical Trials



Example of course introduction screen.



Example of course summary.

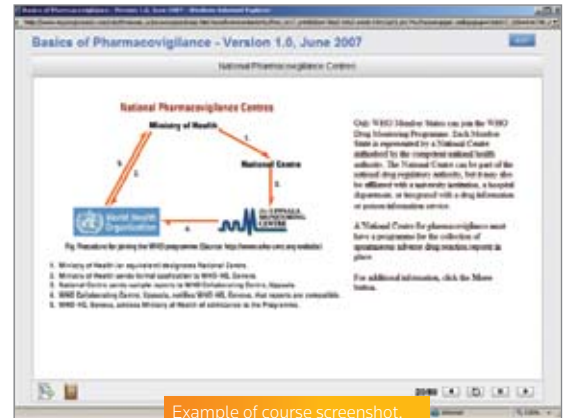


PRACTICAL COURSES

- How to Register Medicinal Products through the Centralised Procedure
- How to Register Medicinal Products through the Decentralised Procedure
- How to Register Medicinal Products through the Mutual Recognition Procedure
- How to Prepare for an FDA Advisory Committee Meeting
- How to Register a New Drug in the USA
- How to Maintain Marketing Approvals in Europe for Centrally Authorised Products
- How to deal with a Pharmacovigilance Inspection

STRATEGIC COURSES

- Regulatory Provisions for Expediting the Access to Innovative Medicines in the United States and Europe
- Access to Unapproved Drugs through Compassionate Use
- Regulatory Requirements for the Conduct of Clinical Trials in Europe
- Orphan Drugs in the USA, European Union and Japan
- Regulatory Requirements for the Conduct of Clinical Trials in the USA (INDs)
- Meeting Opportunities with Agencies
- Risk Management



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