

IDRAC[®] SOP LIBRARY

EASILY CREATE, COMPLETE, MAINTAIN AND UPDATE YOUR STANDARD OPERATING PROCEDURES



WHAT IT GIVES YOU

- Improved compliance and auditability
- Better-managed revisions and updates
- Up-to-date SOPs
- Intuitive templates to create new documents

WHO CAN BENEFIT

- Clinical operations
- Medical writing departments
- Regulatory departments
- Established pharmaceutical companies that are updating existing SOPs
- Start-up pharmaceutical companies
- SME pharmaceutical innovators

MANAGE YOUR SOPS MORE EFFICIENTLY

A single change in regulation can impact your Standard Operating Procedure (SOP). This means that simply developing a SOP will not necessarily result in improved compliance.

IDRAC[®] SOP Library from Thomson Scientific can improve your SOP performance by helping to automate the way you manage and maintain these vital documents. It covers everything you need:

- Electronic templates compliant with the latest regulations and ready to be customized with your company's specificities.
- Cross-references to the relevant international regulations governing each SOP. These references are constantly monitored and kept up-to-date; any change is reflected in the affected SOP.
- Advanced editing and alerting features that notify you when a change affects your SOP.
- Complete, easy-to-follow user guide.

IDRAC SOP Library is supported by the Thomson Pharmaceutical Services team. Our skilled Regulatory Affairs Certified specialists have participated in the design and preparation of more than 125 regulatory submissions, spanning even the most complex therapeutic areas, including submissions to the FDA, EMEA and other ICH parties.

As standard, every IDRAC subscription also includes free access to an extensive library of reference texts and explanatory documents covering international organizations such as ICH, WHO, PIC/S, and many others.

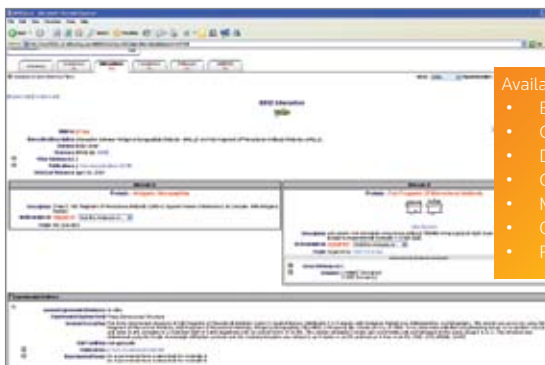
IDRAC INTEGRATION

If you also subscribe to other modules of *IDRAC*, you can instantly access regulatory reports and guidelines that provide information and intelligence on a wide range of regulatory issues in nearly 60 countries and regions.

Tens of thousands of documents cover all aspects of drug development in each country or region, thematically organized for easy retrieval, with more added every day.

A powerful search engine enables you to interrogate the entire database in seconds using full text, title, and keyword searches.

IDRAC's enhanced alerting will notify you of any specific regulatory change affecting your SOP. Through extensive, integrated hyperlinks to the *IDRAC* database, you will be able to access any amendments and new regulatory documents.



Available topic areas

- Biostatistics
- Clinical Operations
- Data Management
- General Administration
- Medical Writing
- Quality Assurance
- Regulatory Affairs

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