

eCTDmanager™ in the EXTEDOcloud

The most comprehensive eCTD management software solution in the cloud

eCTDmanager provides you with a complete regulatory dossier management and assembly solution. Its scalable, all-in-one submission management capabilities meet the requirements for both electronic submissions, such as eCTD and NeeS, and paper submissions.

As well as traditional on-premise deployments, eCTDmanager is available in the cloud. Cloud-based deployments (or SaaS platforms) are now becoming the standard deployment model around the globe and the life sciences industry is catching-up fast. A cloud-based approach is ideal for growing businesses, or those with less sophisticated IT infrastructure or technical knowledge. It also fits more established organizations that are looking to outsource their IT and reduce the total cost of ownership (TCO) associated with software applications.

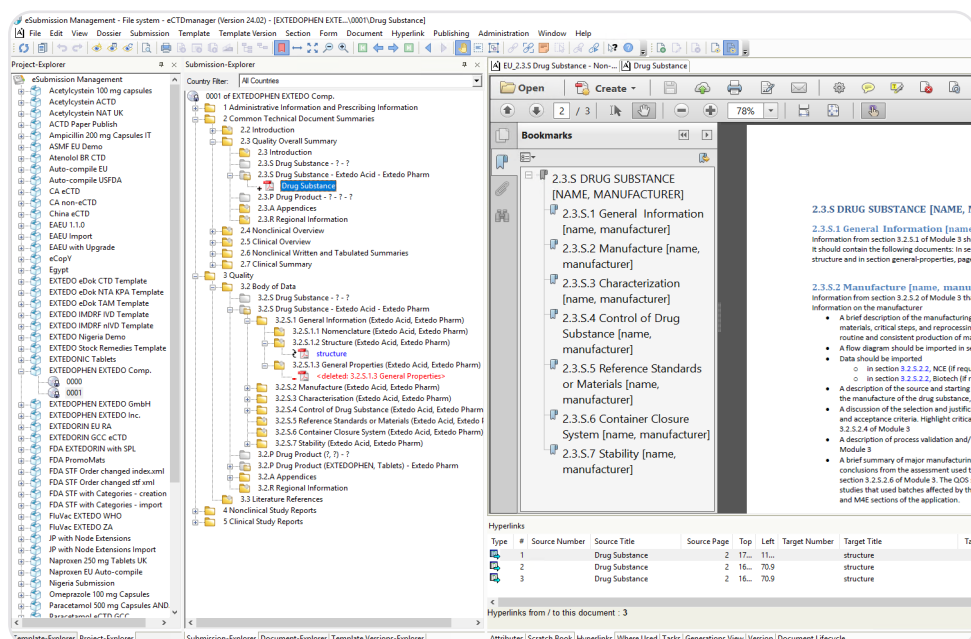
Benefits

- Reduced cost associated with shared validation
- Reduction of maintenance and support overheads
- No specialist IT skills required
- Faster implementation and on-boarding
- Regular, managed operational cost
- Highly available and secure infrastructure

Significantly reduce your total cost of ownership

Cloud instances of eCTDmanager can be quickly established and ready for use within a matter of hours, saving you vast amounts of time and effort at the start of your project – all

Intuitive user interface: handling of pharmaceutical submissions without the knowledge of XML-technology



The screenshot displays the eCTDmanager software interface. On the left, a 'Project-Explorer' shows a tree view of various submission templates and documents. The main area is divided into two panes: 'Submission-Explorer' and 'Document-Explorer'. The 'Submission-Explorer' shows a hierarchical view of a submission, including sections like 'Administrative Information and Prescribing Information', 'Quality Overall Summary', and 'Body of Data'. The 'Document-Explorer' shows the content of a selected document, '2.3.S DRUG SUBSTANCE', with a table of contents and a list of hyperlinks. The table of contents includes sections like '2.3.S.1 General Information', '2.3.S.2 Manufacture', '2.3.S.3 Characterization', '2.3.S.4 Control of Drug Substance', '2.3.S.5 Reference Standards or Materials', '2.3.S.6 Container Closure System', and '2.3.S.7 Stability'. The document viewer shows the content of the selected section, '2.3.S.1 General Information', with a list of hyperlinks and a table of contents.

| Type | # | Source Number | Source Title | Source Page | Top | Left | Target Number | Target Title | Target |
|------|---|---------------|----------------|-------------|------|------|---------------|--------------|--------|
| | 1 | | Drug Substance | 2 | 17.0 | 11.0 | | structure | |
| | 2 | | Drug Substance | 2 | 16.0 | 70.9 | | structure | |
| | 3 | | Drug Substance | 2 | 16.0 | 70.9 | | structure | |



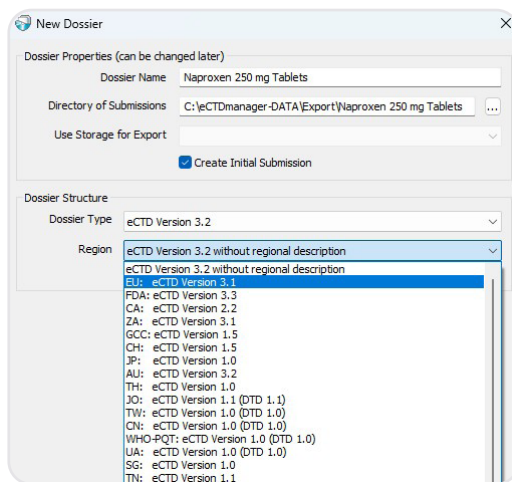
you need is an internet connection. EXTEDO's hosted solutions also cut away the cost of capital intensive hardware.

With the EXTEDOcloud, we take care of your routine back-ups, system maintenance and periodic upgrades. This eliminates the need to monitor for patches and upgrades and ensures that you always have the most up-to-date application version for your region and business requirements. There is also no need to have dedicated IT or other support staff available to perform upgrades and keep the software running.

On average, our estimates have shown that customers deploying their RIMS solution through the EXTEDOcloud save around 30% year-on-year in comparison to those customers using on-premise deployments.

Always validated and compliant

Through our shared validation approach the EXTEDOcloud reduces the time and cost involved in validating your eCTDmanager instance. Within your cloud environment, EXTEDO ensures that your solution is Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) validated. Where required, we can provide validation



New dossier dialog

Additional EXTEDOpulse Hubs in the cloud include:

- Safety Management Hub
- Registration Management Hub
- Submission Management
- Document Management Hub
- Quality Management Hub

scripts and documentation for your records. The resulting system is validated under FDA 21 CFR Part 11 and EU GMP Annex 11 Volume 4.

About the EXTEDOcloud

The EXTEDOcloud is the leading SaaS environment for Regulatory Information Management Systems (RIMS). Our software delivery model provides a centrally hosted solution that enables individual customers to connect to their personal tenant within the cloud environment.

Our platform architecture enables us to keep data for each customer physically separated, but at the same time share costs associated within hosting and maintenance. Each application within the cloud is ready-to-use on deployment. No further software installation is required and only customer specific data and the users need to be configured.

Like you, security is of the highest priority and the protection and integrity of your data is paramount to us. Access to each individual instance is available only to users on whitelisted IP addresses and regular penetration tests are conducted by a third-party to ensure no loopholes are left unchecked.

If you have additional questions or are interested in learning more about the EXTEDOcloud, contact your regional EXTEDO sales executive for further information.

For further information contact your local EXTEDO representative:

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