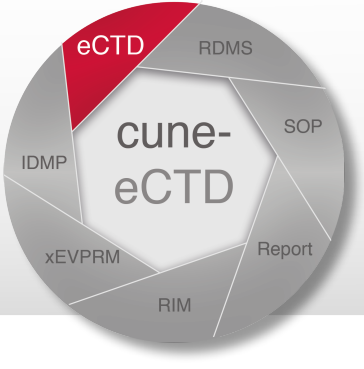
cunesoft
compliance delivered

Advantages:

- Save 30-50% in license costs
- Reduce maintenance costs
- Cut submission time
- Improve audit preparation time



- **Creates** eCTDs to compile submissions for FDA, EMA, Swiss Medic, Health Canada and other authorities working with this format.
- **Uploads** existing regulatory submissions into the system and allows corresponding new sequences to be created.
- **Complies** with country specific regulatory requirements based upon geographies identified for individual submissions.
- **Manages** the complexity of multiple sequences with the eCTD lifecycle management function.
- **Controls** the compilation and publication of eCTDs by designating varying levels of access to defined users.
- **Utilizes** additional, unique functions such as “auto-compile” to reduce dossier compilation times from hours to minutes.
- **Publishes** incrementally (i.e. draft versions) to allow users to verify eCTD compliance. Allows incremental publishing as often as needed.
- **Ensures** users exercise control over the entire lifecycle using the eCTD viewer for delta, sequence and cumulative views.
- **Integrates** with other Cunesoft modules to ease project management (**cune-RIM**) and enable online sharing (**cune-Portal**).

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About Cunesoft: We offer a ready to use, pre-validated and highly secure cloud based regulatory compliance suite. Our software has been built to fulfill regulatory needs holistically and end to end. Our vision is to keep it as simple as possible while delivering compliance and fulfilling FDA 21CFR11, EU Annex 11, ICH, and GxP requirements.

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