eCTD Outsourcing Services

cunesoft
compliance delivered

Our regulatory team has profound experience in creating eCTD, ASMF, DMF, CTA, IND, MAA and other submission types. In particular we offer:

Execution and monitoring of regulatory procedures:

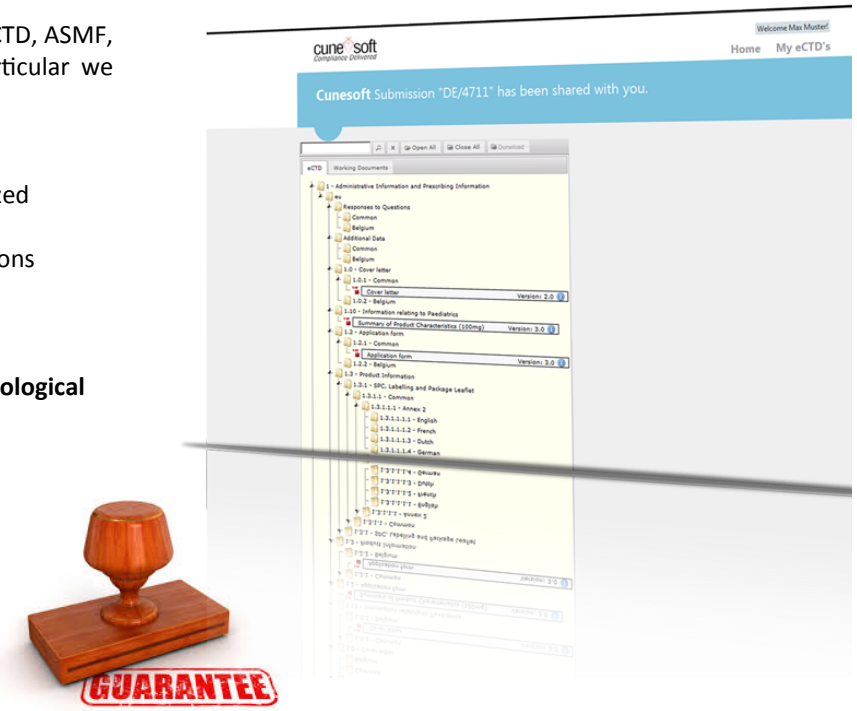
- National, decentralized, mutual recognition or centralized procedures (NP, DCP, MRP, CP)
- New registration requests / approval renewals / variations
- Support processing / notification of defects answer
- CE marking for medical devices

Elaboration and editing of chemical, pharmaceutical and biological submission documentation:

- Module 3 / Part II / CMC
- Quality Overall Summaries
- CEP Dossiers, DMF / ASMF
- Site Master File / VMF

Conformity assessments:

- Review and checking the quality of documents
- Evaluation and assessment of quality approvals



100% timeline compliance | 100% budget control

Cunesoft Advantages

100% eCTD compliance | 100% customer satisfaction

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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