eCTD – Benefits of adopting it early

The Road to **eCTD Readiness** beyond 2017

The Road

cunesoft
compliance delivered

The Solution

1. What is changing?

Where	By when	What
Canada	1st January 2018	eCTD mandatory for any NEW submission
United States	5th May 2018	DMF and IND mandatory in eCTD format
Austria	1st January 2018	New National applications must be submitted in eCTD format
Europe	In 2018	NeeS submissions will not be accepted anymore

2. What do these changes mean for me?

Checklist	Description
Getting "Submission Ready"	Streamline your submission process: • Following CTD granularity • Utilizing authoring styles/templates for automatic bookmark creation • Knowing when a document requires a TOC, hyperlinks, etc.
Old submissions	You don´t need to change already submitted files to the eCTD format.
Lifecycle management	Your eCTD submission sequences build upon your cumulative submission history and one sequence may relate to another sequence.
Working with enhanced document metadata	The importance of understanding and leveraging document metadata because it's crucial in the proper creation of the eCTD backbone, study tagging files, etc.
Implementing the right tools	Utilize tools to perform technical validation prior to submission to help avoid technical rejections, is key in submitting successfully.
Using an electronic gateway	The process of obtaining access to and submitting via an electronic gateway. Understanding what each acknowledgement means.
Change of working speed	eCTD speeds up the dispatch, receipt, and review of submissions by the agency. It minimizes (eliminates) the costs associated with paper. A higher granularity enables more efficient reuse of documents.

3. When is a good time to start with eCTD?

! NOW

4. Which tool do I need?

Function	Description
eCTD viewer	Software application for (re-)viewing and understanding the granularity and the lifecycle of electronic submissions.
Managing Hyperlinks & Bookmarks	Blue-colored font is used to indicate where a hyperlink is to allow the reviewer to easily access the cross-referenced data.
Managing Metadata	Meta-data are information about data which are contained in a xml file. Each submission document contains mandatory meta-data e.g.: • Title • Name of the file • Sequence • Operation attribute Each dossier contains mandatory meta-data, as well e.g.: • Type of submission • Location of the documents • Navigation aids
Creating submission-ready PDF's from Word documents	All pdf versions from 1.4 - 1.7, PDF/A-1 and PDF/A-2 are acceptable for documents. Submitted files should be: • Readable by Adobe Acrobat X, • Text searchable And should not: • Require additional software or plugins to be read and navigated More information can be found on the FDA page (s. link in the references)

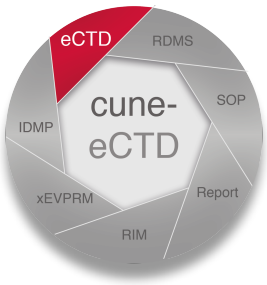
You need the right
People

- Extensive Regulatory Expertise
- Real Life Experience
- Outstanding Support

You need the right
Process

- Speedy implementation
- Live training
- Compliance Guarantee for the first submission

You need the right
Product



- Globally proven eCTD solution with built-in document management
- Built for eCTD
- All-in-one solution accessible via browser - no other software needed

Request a Demo

info@cunesoft.com

Reference:
https://www.fda.gov/downloads/Drugs/UCM163565.pdf
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf