cencora
PharmaLex

Are you prepared for eCTD 4.0?

We are committed to supporting you with the operational, implementation and integration steps toward eCTD 4.0 adoption.

Our team of experts has carefully monitored the eCTD 4.0 development to help you prepare for the transition

The switch to eCTD 4.0 will require an update to the eCTD tool but could also have an impact on Content Management Systems and will change how applications are reviewed and approved.

Companies need to familiarize themselves with the new features and capabilities of eCTD 4.0 and analyze its impact on:

- Document authoring: enable re-use of documents across applications, document granularity
- Submission compilation: changed handling of metadata and attributes, submission publishing, validation
- Submission review and approval: implement new process
- Software and systems: plan and perform software updates, new tools, implementation
- Training and education on all new processes: authors, compilers and other stakeholders

The timeline for the regions currently providing eCTD 4.0 implementation guides ranges from 2025 to 2029

Driving toward a smooth transition | **Meet the latest standards** | **Adhere to assigned timelines**

We have the expertise to help you navigate through the various complexities of eCTD publishing, submissions, and compliance requirements.

- A solid technical knowledge on eCTD 4.0 capabilities and limitations
- Proficiency in analyzing company specific needs and process changes for eCTD 4.0 implementation
- Expertise in supporting software update and implementation processes
- Proven track record of supporting clients all over the globe in the transition to eCTD
- Regulatory expertise in all regions: EU, US, Japan, Canada, Australia, Switzerland, China, and others
- Support clients to participate in agency pilots and to create eCTD 4.0 submissions on demand

Your trusted partner in regulatory submissions - from planning to embedded quality control

15+
years of experience with eCTD

>3,500
eCTD sequences per year

>10,000
HA submissions per year

80+
publishing experts worldwide

eCTD The electronic Common Technical Document
HA Health Authority

Have the right expertise by your side

www.pharmalex.com

Contact us