# **Solutions at Work**

## Reed Tech Electronic Common Technical Document

Reed Tech is now offering eCTD services to our Pharmaceutical customers.

The Electronic Common Technical Document, commonly referred to as eCTD, is a standard format for submitting regulatory applications, amendments, supplements and reports to Global Health Authorities.

eCTD is structured into five modules of information and data relating to a medicinal product and allows for electronic submission from applicant to regulator using an XML backbone as a navigation file and for effective version control.

#### eCTD and Consultation

- eCTD strategy
- eCTD project management & compilation
- Experienced validation troubleshooting
- 100% validated submission transmission to FDA, EMA, CESP, MRHA etc.
- Perform Lifecycle Management
- eCTD Web Viewing Tool

#### PDF & MS Word Publishing

- ICH & regional regulatory authority standards & best practices
- MS word formatting & PDF publishing
- Clinical Study Reports

#### Turnkey, Automated and Affordable Services Available!

### Why Reed Tech?

Reed Tech has decades of experience in structured formatting (XML, SPL) in the US and globally. Members of our Pharma Professional Services Team have served hundreds of pharma and biotech organizations to manage eCTD submissions, assisting in converting, validating and submitting necessary information to Global Health Authorities. We work to provide life sciences companies with long-term partner relationships and seamless, streamlined support through all stages of the drug lifecycle.

The Health Authorities supported (varying by service type) include FDA, EMA, MHRA, Health Canada, Gulf Central Committee for Drug Registration, TGA and more.

#### For more information, please reach out to our Pharma team at 215.557.3010 / pharma@reedtech.com.



"Superb services; ie, knowledge of the subject matter, accommodating the needs, timeliness, quality of work and reasonable pricing."



