



## Synteract Offers Comprehensive eCTD Services to Support Electronic Submission to Regulatory Authorities

As electronic common technical document submission (eCTD) becomes the standard submission format, many sponsors need the guidance of an experienced and knowledgeable team to support their regulatory requirements worldwide. Synteract offers a comprehensive service that includes all aspects of eCTD publishing and submission management, running the entire program in-house for our Sponsors.

eCTD submission offers several advantages over paper submissions:

- eCTD shortens the development timeline by simplifying drug life cycle management and quickens the move from the CTA/IND to MAA/NDA
- eCTD allows for company-wide sharing of regulatory information, which can improve regulatory information quality, management and visibility.

eCTD is already the preferred format for many Regulatory Authorities. It is widely used in Australia, Canada, China, Croatia, Japan, Saudi Arabia, Singapore, South Africa, Switzerland, US, and all EU/EEA Member States.

### THE FDA AND THE EMA ARE MOVING TO MAKING eCTD SUBMISSIONS MANDATORY FOR MAAs/NDAs AND INDs

- January 2009** eCTD became the required format for medicinal products submitted to the EMA in the centralized procedure
- January 2015** The EMA adopted Annex 2 to the HMA eSubmission Roadmap: Implementation of mandatory eCTD format for regulatory submissions
  - July 2015: New MAAs in decentralized procedure (DCP)
  - January 2017: New MAAs in Mutual Recognition Procedure (MRP)
  - Q1 2018 eCTD for all regulatory activities in the EU (DCP/MRP)
- May 2015** The FDA issued its final guidance. eCTD will be the required standard for NDAs in May 2017 and INDs in May 2018

## WHAT DOES SYNTERACT'S eCTD OFFERING COVER?

Synteract offers a comprehensive service that includes all aspects of electronic document preparation, document management, eCTD publishing, submission management and Regulatory Authority submission. We take into account both the "story" and the operational specifics that will help you to gain approval.

Sponsors also gain access to a full-service regulatory offering that includes:

- Strategic regulatory advice
- Content authoring
- Legal/authorized representation services
- Regulatory/scientific advice meeting request, preparation and support
- Technical gap analysis
- Regulatory submissions

## WHO IS THE APPROPRIATE CUSTOMER FOR eCTD?

Synteract's eCTD offering can be the solution for any customer, including:

- Companies with personnel or budget constraints
- Companies preparing to start investigational trials or marketing authorization submission
- Small to mid-sized research companies that don't have eCTD capability in-house
- Those who don't have the technology knowledge/expertise to ensure all documents meet the international standards and requirements established

## WHAT ARE THE ADVANTAGES OF SYNTERACT'S eCTD OFFERING?

Collaborative and experienced Synteract team members understand the technology and benefits of the platform – helping sponsors gain improved turnaround time and higher quality. Perhaps most important for our sponsors, we are committed to improving our Sponsors' knowledge base and we walk them through the process, explain requirements, and handle gap analysis as needed.

- Synteract has the global knowledge required for multiple-country submissions
- Synteract team members care about accuracy and quality
- Pricing is competitive – when eCTD is outsourced to Synteract it allows our Sponsor to gain the advantages of using the electronic method without having to make a significant investment in the software
- Going to eCTD makes it easier to share information both internally and externally, and ensures that the data always stays up-to-date
- Synteract helps companies with their own Regulatory Affairs Department to convert current paper submission docs to electronic; then we manage and house the eCTD
- Synteract completes submissions in a timely manner, meeting sponsors' timelines

For more information on Synteract's eCTD offering, please contact  
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