eCTD

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The electronic Common Technical Document (eCTD) format was developed by the International Conference on Harmonisation (ICH) as a method of transferring regulatory information from the pharmaceutical industry to the agencies.

An eCTD consists of the 5 modules of the Common Technical Document (CTD) and is based on an XML backbone serving as navigation tool and providing additional meta data.

Over the years, the ERA team has gained substantial experience in compiling and submitting eCTD sequences to various agencies (e.g. FDA, EMA, Australian TGA and other national agencies).

ERA's dedicated eCTD group is pleased to support you in the following eCTD-related activities:

- Marketing Authorisation Application
- (Veterinary) Non-eCTD electronic Submission
- Investigational New Drug Application
- Biologic License Application/New Drug Application
- Active Substance Master File/Drug Master File
- Skeletal Dossier
- Training

Please contact us (ectd@eraconsulting.com) for detailed information on our capabilities and on how we can support you in making your eCTD application a success.

For further information on other consulting services please see: www.eraconsulting.com

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