What you need to know for **eCTD submissions in China (NMPA)**

Updates

The final version of the specification v.1.0 was released at the end of September. Along with the release, it was announced that starting December 29, 2021, eCTD submissions for some submission types would be accepted.

eCTD Submission Types

- Initial NDA for Type 1 and Type 5.1 Chemical drugs.
- Initial BLA for Type 1 of Therapeutical and Preventive Biological drugs.
- At this time, no lifecycle or variations or other types of dossiers, such as INDs can be submitted in eCTD format.

eCTD Specifics in China

- A paper copy will need to be submitted as well within 5 working days of the eCTD submission acceptance.
- The paper cover letter should confirm that the paper and eCTD content is the same.
- M2 to M5 are defined according the ICH and M1 is unique for China.
- In M4 and M5, studies are expected to use study tagging files using the current ICH STF v2.2 DTD and valid values 5.0.
- The underscore is allowed to be used with file names.
- Bookmarks and hyperlinks are required for Chinese documents and are allowed for documents in English.
- Two documents are required for all submissions: cover letter and application form. Other files will be required as well depending on the application type.
- The validation criteria has both errors and warnings. If you send a submission with warnings, you will need to update your cover letter to explain why there are warnings and these have not been corrected.
- There is no gateway at this time and eCTD submissions will need to be submitted using labeled CDs/DVDs (single side only). Password protection is not allowed.
- Discs should be virus checked and an explanation letter will need to be provided with the details in a statement, together with the disc(s).

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Knowledge from experience

Asphalion can give you support in the following areas:

- Non-clinical and clinical development
- CMC
- Dossier writing
- Regulatory procedures
- Vigilance
- eSubmissions
- Data management

EXTEDO
eRegulatory Affairs

EXTEDO's Regulatory Solutions for China:

- eCTDmanager: eCTD compilation and publishing for Chinese submissions.
- eSUBmanager: Viewing and reviewing of archived and in-progress electronic submissions.
- eDOCSmanager: Manage all your regulatory documents in a secure document management system.

For further information, please contact: ectd@asphalion.com | info@extedo.com