What you need to know about **Taiwan (TFDA) submissions**

Updates

As of January 1st, 2020, the use of the eCTD format is mandatory for NDA submissions and voluntary for all other submission types for pharmaceutical, biologic and radiopharmaceutical drugs for human use. We can guide you with the transition to eCTD to be filed for each submission after that.

Drug Master File

Dossier ID at first submission from Receive Table Person

CTD compilation and publishing (Disk or Paper)

Local (TW) API plant submit DMF to TFDA (DMF Team)

Foreign API plant needs local API import Agent to submit

Pharmaceuticals, Biologicals

Dossier ID via ExPRESS portal

eCTD compilation and publishing
Document formatting

Conversion to eCTD format
- Validation TFDA Validation Rules
- Submission via ExPRESS portal

Clinical Trial Applications

CTA Application ID via ExPRESS portal

Pre-Meeting possible but not mandatory (to consult submission information compliance or not).

CTA submit on ExPRESS portal by un-eCTD format

Submission via ExPRESS, no paper version to provide

Submission via disk, a paper version is still to provide

After approval by TFDA – Finish clinical study.

Submit clinical close report

ASPHALION
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

Regulatory Solutions for Taiwan

- eCTDmanager: eCTD compilation and publishing for all Taiwanese submissions.
- eSUBmanager: Viewing and reviewing of archived and in-progress electronic submissions.
- eDOCSmanager: Manage all your regulatory documents in a secure document management system.
- SafetyEasy: Reporting and management of all serious and non-serious adverse events.

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