



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 and 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 Application

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 can give you support in the following areas:

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

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.