What you need to know for
eCTD submissions in Australia

Updates

The Therapeutic Goods Administration (TGA) recommends eCTD for prescription medicine applications.

eCTD can also be used for:

- Biologicals
- Over-the-counter medicines
- Registered complementary medicines
- Assessed listed medicines
- Ingredients for listed medicines master files

eCTD format is now the accepted format for all prescription medicine applications.

TGA highly recommends to use a baseline when converting to eCTD from another format. However, you can choose to not baseline and submit a new application without resubmitting any previous documents.

The submissions of the sequences are via email, post or via TBS portal.

ASPHALION
Knowledge from experience

Asphalion can give you support in the following areas:

- eCTD compilation and publishing for TGA submissions
- Document formatting
- Non-eCTD compilation and publishing
- Transition from non-eCTD to the mandatory eCTD format
- Submission to the agency according to the latest version of TGA validation rules

EXTEDO
eRegulatory Affairs

EXTEDO's Regulatory Solutions for Australia:

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