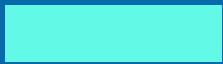


eCTD Global Implementation

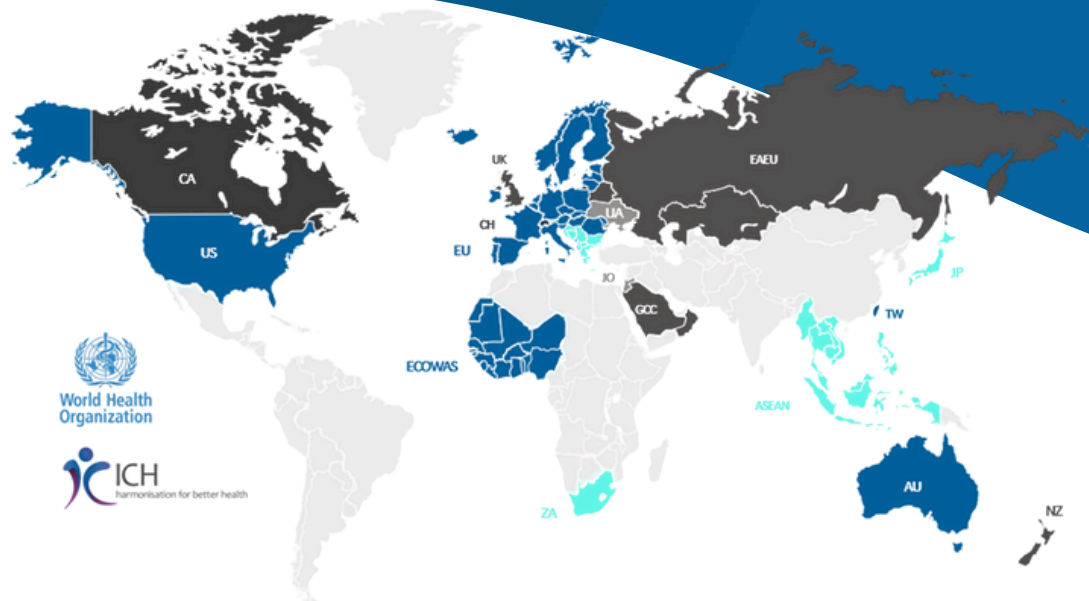


eCTD Global Implementation

At Asphalion, we have been at the forefront of electronic submission of regulatory information since the introduction of eCTD. Thanks to our flexible support and dedicated project management, we deliver high-quality submissions within critical timelines across all regions.

We are an international Scientific, Regulatory Affairs and Safety consultancy that offers strategic advice, expert consulting, operational support, and full outsourcing services for all types of products in every therapeutic area.

At Asphalion, we support you with eCTD services in all regions, as well as with paper-based and Nees submissions. The world map below highlights our most in-demand regions.



eCTD Implementation

Europe, Australia, Canada, China, EAEU, ECOWAS, GCC, Japan, Jordan, Singapore, South Africa, South Korea, Switzerland, Taiwan, Thailand, Ukraine, United Kingdom, USA, WHO

eCTD Deployment

Brazil, Egypt, Ukraine, Tunisia

Schedule a free meeting with the department Associate Director and EMA (European Medicines Agency) Subject Matter Expert for electronic standards.



Daniel Langa García
Regulatory Affairs Associate Director at Asphalion
EMA eCTD 4.0 SME

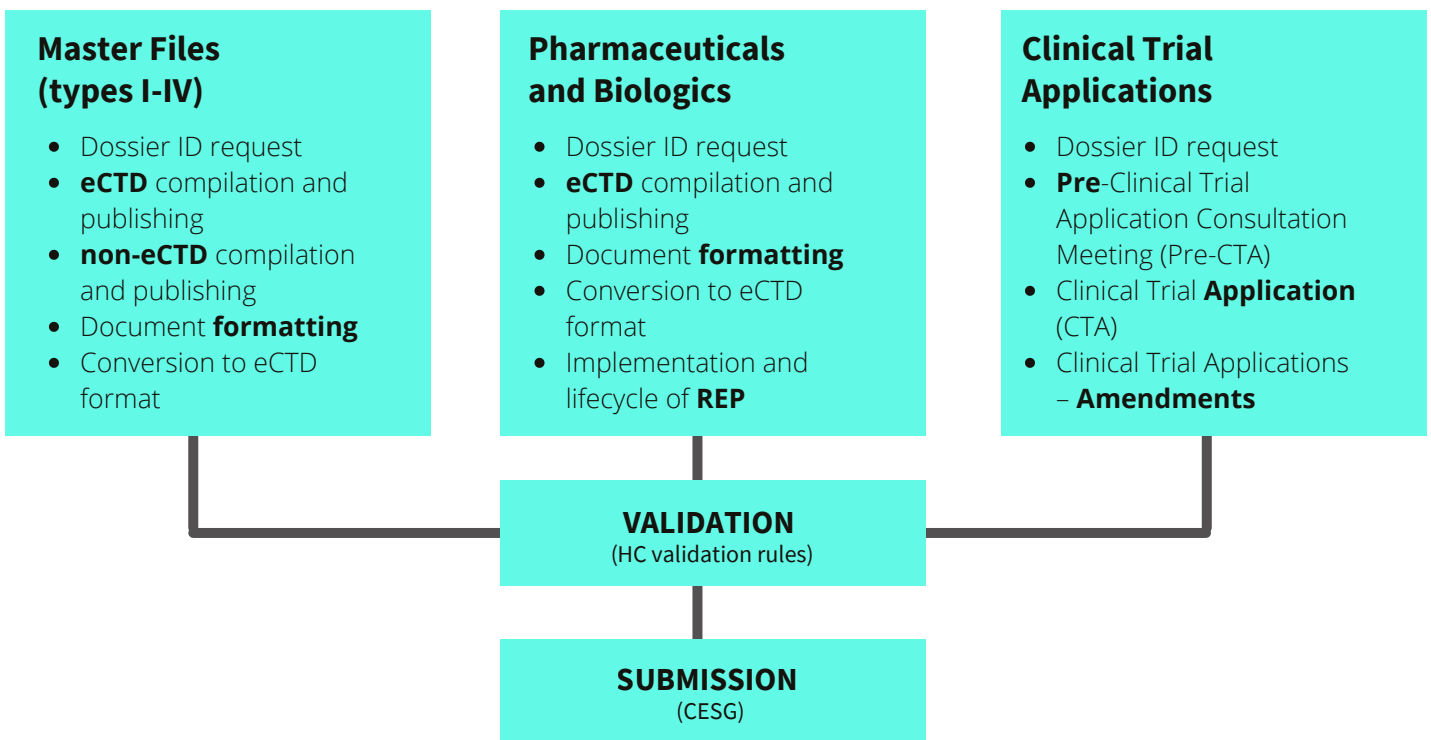


What you need to know about Health Canada

Updates

Since October 1st, 2020, the use of the Regulatory Enrolment Process (REP) is mandatory for pharmaceutical, biologic and radiopharmaceutical drugs for human use. We are happy to support with any question regarding REP and with all the REP templates (RT, PI and CO) to be filed for each submission.

Flowchart



Regulatory Services for Health Canada

- eCTD compilation and publishing for all Health Canada submissions (Master Files, Pharmaceuticals/Biologics and Clinical Trial Applications).
- Transition from non-eCTD to the mandatory eCTD format.
- Submission package fulfills all the strict requirements of the agency and validation according to the latest version of Health Canada validation rules.
- Submit to Health Canada on your behalf via the Common Electronic Submissions Gateway (CESG).

Regulatory Solutions for Health Canada

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



eSubmission Services in FDA



Our eSubmission department can support you across a full range of activities for the **U.S. Food and Drug Administration (FDA)**.

- **Consultancy** support for Regulatory Operations activities.
- Dossier document **templates** creation.
- Documents **formatting** to agreed ICH and FDA standards.
- Administrative **Module 1** issuance.
- **eCTD** Publishing.
- Portals **Submission**.
- Creation of **Structure-Data Files (SDF)**.
- Creation and maintenance of **Structured Product Labeling (SPL)**.
- Creation of **Datasets (DS)**.
- **FDA Adverse Events Reporting** through eCTD and ICH E2B(R3).
- **US Agents** Support through our network of resident agents.
- **DMF Representatives**.

Don't miss the chance to download our **FDA brochures** and connect with our regulatory operations expert.

What you need to know for Submissions in Switzerland

Updates

Switzerland's regulatory authority **Swissmedic** started with submissions for pharmaceuticals in **eCTD format in 2009**. Since 2020 Swissmedic is using eCTD M1 version 1.5. Additionally, Swissmedic is also accepting **eDok format and paper submissions**.

A Swiss specialty in eCTD is the "galenic form", an old term for the pharmaceutical form of the pharmaceutical product. In Switzerland, there needs to be a M1 folder for each "galenic form". Product life cycles with more than one galenic form contain a common folder in Module 1.

An **overview of the documents that need to be submitted** for different regulatory activities is **available**.

Paper submissions are still possible, also Paper submission with eDok copy (Swissmedic's application submission format), paper version + electronic version (see Swissmedic website), but eCTD is encouraged. Other electronic submissions, **e. g. NeeS, will be rejected**.

Submissions can be uploaded via **Swissmedic's eGov portal** or **submitted on CD/DVD**.

Drug Master File

- The **eCTD DMF dossier is a stand-alone dossier** and is independent of the marketing authorization eCTD dossier. Therefore, the DMF (DMF Holder, substance name) and the Drug Product (Authorisation Holder, tradename) consists of two individual eCTD life cycles.
- It is possible to **submit the marketing authorization application as eCTD and the DMF/ASMF dossier** as a paper dossier and vice versa.
- The **DMF/ASMF can be a hybrid submission**, which means that the restricted part is submitted in paper, whereas the open part is submitted in eCTD format as part of Module 3.
- **M1 Galenic Form is "common"**.
- **Envelope Elements:**
 - Swissmedic DMF number (if known)
 - DMF Holder
 - Galenic form name is common
 - Marketing Authorisation Number is n/a
- **Submission description:** the corresponding version of the DMF should be described in the element, e.g.: AP & RP Version 3.00 / description.

Clinical Trial Application

- **Sponsor needs location/agency in Switzerland.**
- Submission on **CD/DVD and Paper**, including cover letter and application form.
- **eDoc Folder Structure on CD/DVD** since 01.01.2022 to reduce paper usage:
 - **Submit CD/DVD and form «Confirmation electronic submission»** to allow Swissmedic to review the submission from CD/DVD.
 - Form **«Confirmation electronic submission» needs to be submitted each time** with follow-up submissions on CD/DVD.



EXTEDO's Regulatory Solutions for Switzerland:

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



Asphalion can give you support in the following areas:

- eCTD compilation and publishing for Swiss 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 Swiss validation rules



Gulf Cooperation Council (GCC) Regulatory Services

Updates

Gulf Cooperation Council countries (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates) have implemented eCTD format for submissions as per the following schedule. The only GCC country that still remain on CTD standard is Yemen.

- Saudi Arabia (July 17th, 2016)
- United Arab Emirates (October 1st, 2017)
- Oman (January 1st, 2015)
- Bahrain (November 1st, 2016)
- Qatar (September 1st, 2019)
- Kuwait (March 02nd, 2025)

GCC countries follow the GCC eCTD specifications, common for the entire region. This includes a specific Module 1.

Asphalion ensures that eCTD submission will always follow the most updated Module 1 specifications and validation rules (current Module 1 version for GCC Countries is v1.5).

When needed or required, Asphalion can give you support on preparing physical media to be exchanged with the Regulatory Authorities (CD/DVD or paper copies).

Registration procedures

- National Procedure in one specific country
- Centralized Procedure in all GCC countries simultaneously through the Central Gulf Committee for Drug Registration

Submission Types

Most relevant are:

- ASMF
- MAA (Biological, Generic, New chemical Entity or Radiopharmaceuticals)
- Reformatting from any format to eCTD (Baseline)
- Renewal
- Variation (Type 1 or Type 2)



ASPHALION's Regulatory Solutions for GCC:

- eCTD/CTD Publishing
- Document Formatting
- Regulatory Consulting
- CMC & MW Dossier Writing
- Full Dossier Lifecycle Management



EXTEDO's Software Solutions for GCC:

- eCTDmanager: eCTD compilation and publishing for GCC 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 nonserious adverse events.



What you need to know for eCTD submissions in Australia

Updates

Electronic Common Technical Document (eCTD) and Non eCTD electronic Submission (NeeS) are the standard electronic formats for AU TGA (Therapeutic Goods Administration). Although other formats or structures may also be accepted.

eCTD can also be used for:

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

Asphalion ensures that eCTD submissions will always follow the most updated Module 1 specifications and validation rules (currently version 3.2, optional since April 01st, 2025 and mandatory from October 31st, 2025).

TGA is able to accept both physical and electronic submissions of sequences (email or through Govteams portal solution). From Asphalion we can help you with the publishing and submission by all means.



ASPHALION's Regulatory Solutions for Australia:

- eCTD/CTD Publishing
- Document Formatting
- Regulatory Consulting
- CMC & MW Dossier Writing
- Full Dossier Life-Cycle Management



EXTEDO's Software 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.

ASEAN Submissions

What do you need to know about ASEAN Submissions?

The Association of Southeast Asian Nations (ASEAN) was established on 8th August, 1967. The Member States are: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam.

The ASEAN Common Technical Dossier (ACTD) is the agreed common format for the preparation of a well-structured Common Technical Dossier (CTD) applications that will be submitted to ASEAN regulatory authorities for the registration of pharmaceuticals for human use.

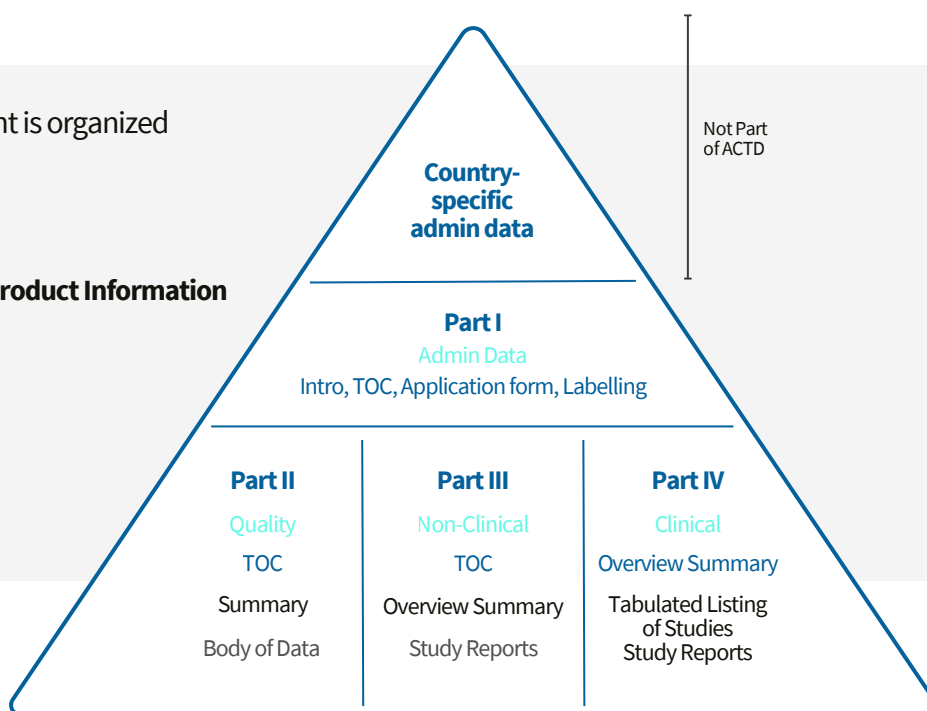
The Common Technical Document is organized into four parts, as follows:

Part I. Table of Contents, Administrative Data and Product Information

Part II. Quality Document

Part III. Nonclinical Document

Part IV. Clinical Document



Asphalion eSubmissions team can give you support in the following areas:

- ACTD Compilation and Publishing
- Document Formatting
- Conversion from CTD to the mandatory ACTD format



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 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.

What you need to know about South African (SAHPRA) submissions

Updates

- In 2013, the South African authority SAHPRA started accepting submissions in eCTD format for pharmaceuticals. They included an enhanced granularity in Modul 3.2.R which should be technically built with node extensions and subfolders.
- In 2019, SAHPRA introduced the additional “eSubmission” format, which will be accepted for a limited time. The acceptance of eSubmission ended on 31th March, 2022.
- In 2020, SAHPRA updated section 3.2.R with new titles, but no update of the specification and eCTD structure. The previous titles can still be used in eCTD submission. We can guide you with the transitions in South African eCTD submissions. In 2024, SAHPRA has enhanced the submission process via portal and updated the eCTD standard.

Master File (APIMF)

- APIMF number (Dossier ID) allocated after submission
- Open and closed part
- Request SAHPRA portal access for closed part
- Document formatting
- CTD compilation and publishing format
- Submission Form via e-mail. APIMF document via SAHPRA submission portal.

Pharmaceuticals and biologicals

- Application number request before submission to SAHPRA
- Document formatting
- eCTD compilation and publishing
- Conversion to eCTD format
 - Validation ZA Validation rules
- Submission (DVD/CD/USB)
 - Submission via SAHPRA eCTD portal

Clinical Trial Application

- Predetermined dates for submission and obtain proof of delivery
- Contact CTU (Clinical Trials Unit) to inform about submission
- Application form accompanied by the prescribed fee
- Document formatting in PDF
- Communication via e-mail
- CTC (Clinical Trials Committee) meeting to discuss reports



Asphalion can give you support in the following areas:

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



EXTEDO's Regulatory Solutions for South Africa:

- eCTDmanager: eCTD compilation and publishing for all South African 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.