

Transforming Regulatory Submissions in Singapore



Singapore's Health Sciences Authority (HSA) is adopting the **Electronic Common Technical Document (eCTD) format for regulatory submissions**. This advancement marks a significant shift towards more efficient and transparent application processes.

eCTD will be implemented in phases and the adoption by industry will be on a voluntary basis during the initial roll-out. HSA will provide advance notice to the industry on subsequent phases.

- **eCTD Specifications and Validation Criteria v1.0** released by September 25th, 2024.
- eCTD will be **accepted from Q2-2026**.
- Initially intended for **new drug and generic applications and drug master files**.
- **eCTD baselines required** also for products already registered.

Moreover, HSA released a **new eCTD submission portal**, which is entirely paperless and offers the advantage of system validation to ensure successful receipt of the package. However, the **PRISM** (Pharmaceutical Regulatory Information System) application must be submitted before the eCTD package. The eCTD package should be submitted within 10 working days of the PRISM Application date.

| | eCTD | Non-eCTD |
|---|-------------|------------------------------|
| Regulatory Application | PRISM | PRISM |
| Regulatory Outcome Communication | PRISM | PRISM |
| Dossier Submission | eCTD Portal | CD7DVD or PRISM or EasiShare |
| Format | ICH CTD | ICH CTD or ACTD (ASEAN CTD) |

ASPHALION's Regulatory Solutions for Singapore:

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