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