

ASEAN Submissions

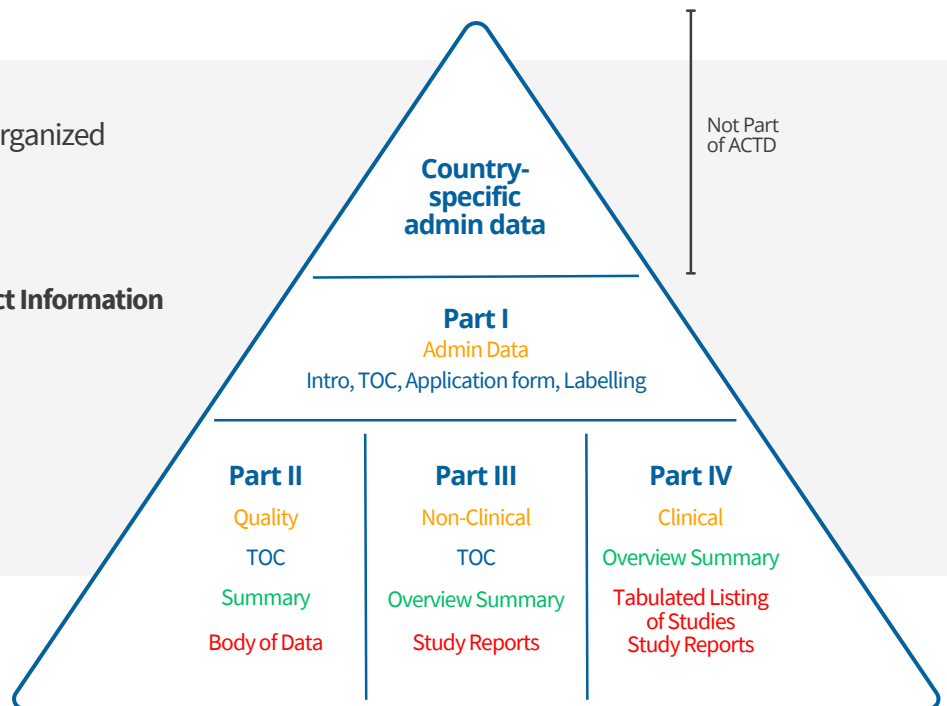
What do you need to know about ASEAN Submissions?

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