

TITLE

CHALLENGES FOR PREPARATION OF MODULE 2 & 5 FOR BA/ BE FOR US & EMEA

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Common Technical Document for the Registration of Pharmaceuticals for Human Use (CTD) represents the agreed upon common format for the preparation of a well- structured harmonized application that will be submitted to regulatory authorities of US FDA, EMEA and Japan.

The Clinical data required in Module 2 & 5 is different for a New drug application and a Generic application. For a CTD of Generic application the Module 2 contain Clinical overview and clinical summary data of the Bioequivalence/ Bioavailability studies performed and in Module 5 the study report(s) of Bioequivalence/ Comparative Bioavailability under conditions of Fed/ Fast with their annexures. Individual Case Report forms are also a part of this module.

As the US, EU and Japan are not geographically similar; their documentary arrangements are also not the same. The differences major in US and EU CTD wrt to Module 2 and 5 are;

- US FDA requires a table for “**Reanalysis of Study samples**” where as this is not applicable to EMEA.
- The table “**Composition of Meal Used in Fed Bioequivalence Study**” is a requirement for US FDA where as the same is not required for EMEA.
- Literature References - Copies of referenced documents, including important published articles, official meeting minutes, or other regulatory guidance or advice should be provided for EMEA filing were as a the literature is readily available in the site of Office of Generic drugs. USFDA.

Similar type of differences is there which needs special attention and understanding before filing in US and EU in CTD format.