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Common technical document-Widely accepted reviewer friendly common dossier format for submission to health authorities for approval of pharmaceuticals

Manu Babbar
Canton Pharma Consultants, India

The common technical document is organized into five modules. Module 1 is region specific and Modules 2, 3, 4 and 5 are intended to be common for all regions. Module 1 consists of application form and other administrative documents such as manufacturing license and cGMP statements. Module 2 is the summarized version of subsequent modules and consists of section-wise summary for drug substance, drug product, non-clinical summary/overview and clinical summary/overview as applicable. Module 3 is collation of drug substance details and the drug product details. It is further explicitly divided into sections to classify the information which is easier to navigate. Module 4, if applicable consists of literature references and details of animal studies whereas, Module 5, consists of literature references as well as other clinical studies or the bio-equivalence studies. However, the CTD is only a format and not the description of information to be submitted in the dossier, thus each Agency across the globe still has minor differences in the extent and type of information to be submitted in each section of the CTD. Still the CTD remains the choice of format and gets accentuated with the electronic versions being followed now.

Biography

Manu Babbar has completed Masters of Pharmacy from Jamia Hamdard, New Delhi and has been associated with R&Ds of repute since 2005, in formulation and Regulatory functions. He is the founder of Canton Pharma Consultants, an upcoming regulatory consultancy offering regulatory and training services.

manu0101@yahoo.com