OMICS International
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V Sreevalli et al., J Develop Drugs 2015, 4:4
http://dx.doi.org/10.4172/2329-6631.C1.012

4th International Summit on

GMP, GCP & Quality Control

October 26-28, 2015 Hyderabad, India

Comparison of regulatory requirements for the submission of dossier to South Africa (ZA-CTD) and ASEAN (ACTD)

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In this study, mainly the comparison between South Africa and ASEAN countries dossier submission were discussed. Dossier is a file document submitted based on requirement of drug approval process. It is a comprehensive scientific document used to obtain worldwide licensing approval of a drug by diverse health authorities. Its creations, processing, compilation & dispatch to the field by a regulatory affairs department, is dependent upon many interrelated activities. The filling process in the emerging markets will depend upon the region. In South Africa region, ZA-CTD filling procedure and in the ASEAN region ACTD filling procedure will be followed. After compilation, 1 copy of the dossier will be submitted to the regulatory authorities for the registration of the drug product. Main differences are numbering, granularity and naming of sections. The ZA-CTD has five modules with subsections that are numbered. In comparison, ACTD consists of Parts I to IV which have subsections A to F. Module 1 of the ZA-CTD is purely country specific whereas Part I of ACTD is administrative data. The summaries of the quality (Part II), non-clinical (Part III) and clinical (Part IV) are located at the beginning of each part of the ACTD. The ZA-CTD dedicates these summaries a separate Module 2. As the ACTD does not have such summary part, it consists only of four. From company to company Quality Assurance procedures may differ, but the goal is to be in compliance with Regulatory guidelines of every country and maintain the quality of the product.

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