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A brief analysis of regulatory structure and approval process of pharmaceuticals in GCC

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The pharmaceutical manufacturer needs to incorporate the technical requirements and all other documents of new pharmaceuticals to market their products in other countries. Any product should reach the criteria of the individual country guidelines. This study mainly discusses a brief analysis of regulatory structure and approval process of pharmaceuticals in GCC. By following the guidance and regulations of GCC, ICH and WHO, filing process of pharmaceuticals in GCC countries will become very easy and accurate. Compilation in eCTD module will be helpful in reviewing of dossier in a very short time. In GCC, countries will follow the centralized procedure and decentralized procedure to produce approval for the compilation of dossier especially for generics.

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