



Design History File for Medical Devices

Get your [Design History File](#) planned and approval for your medical devices in Vietnam, Malaysia, Hong Kong and Thailand. Get complete assistance in creating DHF as per the requirements of ISO 13485:2016, EU MDR 2017/745 and EU IVDR 2017/746. A Design History File is a complex document, as it is a collection of records which demonstrates the design of the device through its development cycle. The Design History File (DHF) provides evidence that the device has been developed in accordance with the user requirements and the design plan.

