DESIGN HISTORY FILE UPDATED

GLOBAL DRUG DEVELOPMENT

Goals / Definition

To update the compilation of documentation that describes the design history of a finished medical device.

The DHF contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
• Design History File updated	a) Updated Design History File as data/information becomes available at the appropriate points in the development stage b) Changes made to product need to be captured within the Design History File	