DESIGN HISTORY FILE CLOSED

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Complete 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 closed	a) Close Design History File when final data/information becomes available b) Changes made to product from CAPA need to be captured within the DHF	