

Goal / Definition

To initiate 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
<ul style="list-style-type: none">Design History File initiated	<ul style="list-style-type: none">a) Design History File to document history of the device design and the design controls elementsb) Design Input Requirements	