

Goal / Definition

Conduct a Design Input Review for the initial requirements that describe the medical devices to be produced.

Design review is a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

In general, formal design reviews are intended to:

- Provide a systematic assessment of design results, including the device design and the associated designs for manufacturing (DFM) and support processes.
- Assess project progress; and/or
- Provide confirmation that the project is ready to move on the next stage of development

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> • Design Input Review conducted 	<ul style="list-style-type: none"> a) Conclusions and recommendations from the Design Input Review b) Control plans updated based on risk assessment and Design Input Review 	<ul style="list-style-type: none"> ▪ Summary report containing key data / information or information to substantiate conclusions ▪ Illustrative data tables or figures may be reported in an appendix