

Goals / Definitions

Conduct a Design Output Review which includes production specifications as well as descriptive materials which define and characterize the design.

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) production and support processes;
- provide feedback to designers on existing or emerging problems;
- assess project progress; and/or
- provide confirmation that the project is ready to move on to 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 Output Review conducted	<ul style="list-style-type: none">a) Conclusions and recommendations from the Design Output Reviewb) Control plans updated based on risk assessment and Design Output Review	