

Goals/ Definition

Initiate the development of the Design and Development Plan.

Establish and maintain plans that: (1) Describe or reference design and development activities. (2) Define responsibility for implementation. (3) Identify or describe interfaces with different groups or activities. (4) Review, document, update and approve plans as design and development evolves.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> ▪ Design and Development Plan initiated 	<ul style="list-style-type: none"> a) Drug-device product Critical Quality Attributes (CQAs) ** and Critical Material Attributes (CMAs), as per the TPP b) Initiation of design control activities including associated documentations c) Initial quality plan d) Technical feasibility assessment e) Alignment on roles and responsibilities for different parties involved (i.e. specification developer, conduct of investigations, IP, publication policy etc.) 	