

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none"> Instructions for Use updated 	<ul style="list-style-type: none"> a) Updated Instructions for Use as data/information becomes available at the appropriate points in the development stage 	<ul style="list-style-type: none"> Summary report containing key data / information to substantiate conclusions Illustrative data tables or figures may be reported in an appendix
<ul style="list-style-type: none"> Process risk assessment completed 	<ul style="list-style-type: none"> a) Critical molding and assembly process parameters b) Identification of CMOs and assessment of impact on manufacturing costs and COGS c) Creation of manufacturing flow diagram and assess product demand to verify COGS based on projected demand forecast 	
<ul style="list-style-type: none"> Review TPP 	<ul style="list-style-type: none"> a) Review TPP developed and determine if modifications are necessary 	