

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