



7 PRODUCT REALIZATION

	REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	COMPLIANT Y/N? Estimated % Complete	ITEMS NEEDED
	Planning or Product Realization			
<p>This section may be addressed in a documented procedure or in the quality manual. Does your organization understand the processes needed to meet product requirements? The planning activity for the processes related to product realization must address the requirements in section 4.1.</p>				
	How is planning initiated?			
	a) Where are quality objectives and requirements of the product documented?			
	b) How does planning determine documentation needs for the process? Resources for the process?			
	c) Does planning address validation requirements? Where are the monitoring, inspection and test and criteria for the product documented?			
	d) Does planning identify what records are required for the process?			
	e) Are resources for support of			