

Company Name	Procedure Number:	Page 3 of 25
Title: 21-CFR 820 Quality Systems Regulations Gap Analysis Check-list	Implementation Date:	Version Number 1.0

Question	<i>Answer (Yes / No)</i>	<i>Doc. # or Reference</i>
Subpart B - Quality Systems Requirements		
Section 820.20 – Management Responsibility		
Does a quality policy exist?		
Are organizational charts in place?		
Are responsibilities, authority, and independence of functions documented?		
Are resources sufficient to maintain compliance?		
Has management representative been designated with responsibility for establishing, maintaining and reporting on performance of Q systems?		
Does management review effectiveness of quality systems at defined intervals?		
Is a procedure detailing this review in place? Does it include review of: Quality Audits		
Does it include review of: Customer complaints?		
Does it include review of: MDR's ?		
Does it include review of: CAPA's ?		
Does it include review of: Non-conformance reports?		
Does it include review of: Other quality indicators?		
Are dates and results of quality reviews documented (reports)?		
Does the site have a documented quality plan?		