



21 CFR Part 820 in eStarHelper

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21CFRPart820eStarHelperDataSheet All Items ...

✓ Subpart A - General Provisions	QUALITY SYSTEM REGULATION	Sec. 820	Subpart A - General Provisions2	ID	+
Subpart E - Purchasing Controls ✱ ...	Purchasing controls	Sec. 820.50 (a)	Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:	92	
Subpart E - Purchasing Controls ✱ ...	Purchasing controls	Sec. 820.50 (a)(1)	Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.	93	
Subpart E - Purchasing Controls ✱ ...	Purchasing controls	Sec. 820.50 (b)	Purchasing data. Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with 820.40.	96	
Subpart M - Records ✱ ...	General requirements.	Sec. 820.180 (c)	Exceptions. This section does not apply to the reports required by 820.20(c) Management review, 820.22 Quality audits, and supplier audit reports used to meet the requirements of 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.	191	

Some items might be hidden. [Include](#) these in your search