

Term	ISO 13485	QSR (21 CFR 820)
Nonconformity	Non-fulfilment of a requirement.	Means the nonfulfillment of a specified requirement
Product	Result of a process.	Means components, manufacturing materials, in-process devices, finished devices, and returned devices.
Quality	Degree to which a set of inherent characteristics fulfils requirements.	Means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.
Quality audit	Systematic, independent documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.	Means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.
Quality Policy	Overall intentions and direction of an organization related to quality as formally expressed bytop management.	Means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.
Quality system	-	Means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

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Rework	Action on a nonconforming product to make it conform to the requirements	Means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

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