Term/Concept	Proposed Action	Details
"Act"	Retain with Revision	Act will be expanded to precisely state Food, Drug and Cosmetic Act (as FDA has authority to promulgate regulations under other Acts as well) ((820.3(a))
"Customer Property"	Clarification	FDA expects manufacturers to comply with this provision to the extent necessary to ensure safety and effectiveness. (7.5.10)
"Customer"	Addition	"Customer" (ISO) added to 820 to encompass many types of customers such as: component manufacturers, contract manufacturers and end users.
"Design and Development" 7.3	Clarification	Maintains def of 820.30(a) for design control of certain Class I and all Class II and Class III devices unless excluded by regulatory authority. Documentation of exclusion applies.
"Device" and "Labeling" Section 201 FD&C Act	Supersede ISO definitions	Terms may not conflict with FD&C Act as FDA does not intend to change their statutory definitions: "Device" 201(h) Supersedes "Medical Device"; "Labeling" 201(m) Supersedes "Labelling"
"Establish"	Withdrawn	ISO Section 0.2 "documented" also requires estblished, implemented and maintained
"Implantable Medical Devices" 7.5.9.2	Revise	Reference § 820.65; "devices that support or sustain life, the failure of which to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury" (ISO limited to "implantable")
"Management with Executive Responsibility"	Replace	Replace 820 term with ISO term, "Top Management" but retain definition as it currently reads. ((820.3(n))
"Organization"	Conceptual clarification	ISO 13485 "organization" - the entity who is creating a QMS. Clarify the term "organization" to also include the meaning of the term "manufacturer" as it is defined in PROPOSED § 820.3.
"Process Validation"	Retain with Clarification	"Process Validation" (820) = "Validation of Processes" (ISO) ((820.3(z)(1))
"Quality System Regulation" (QSR)	Replace	"Quality Management System Regulation" (QMSR)
"Rework"	Retain with Revision	Retain the definition but remove the term "Device Master Record (DMR)" within the definition of "Rework" as DMR is not used in ISO, rather ISO uses the term Medical Device File (4.2.3) ((820.3(j))
"Risk Management"	Clarification	Risk Management expectations of 820 are more broadly and clearly defined by ISO as expected to apply across the QMS throughout the total product lifecycle
"Safety and performance"	Conceptual clarification	The same as "safety and effectiveness" in section 520(f) of the FD&C Act.
"Validation of processes"	Conceptual clarification	"validation of processes" as used in ISO 13485 to refer to "process validation," as that term is defined in part 820. ISO 13485 does not define "validation of processes"
"Applicable regulatory requirements" multiple ISO clauses	Clarification	Proposing to identify certain instances of the phrase "applicable regulatory requirements". Regulated manufacturers are responsible for identifying and meeting all applicable requirements, even if such requirements are not specifically called out in the PROPOSED § 820.10
"Component"	Retain	Retained as necessary to implement 820 (§ 820.3(c))
"Design validation"	Retain	Retained as necessary to implement 820 (§ 820.3(z)(2))
"Finished device"	Retain	Retained as necessary to implement 820 (§ 820.3(l))
"Human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device"	Retain	Retained as necessary to implement 820 (§ 820.3(bb))
"Manufacturer"	Retain and Supersede ISO definitions	820 definition is more comprehensive (§ 820.3(o))
"Nonconformity"	Retain	Retained as necessary to implement 820
"Product"	Clarification	ISO clause 0.2, which specifies that "when the term 'product' is used, it can also mean 'service'," for the requirements of clause 7.4 Purchasing we expect that when ensuring purchased products conform to requirements, oversight for purchased services are also included. (PROPOSED § 820.7) 820.3(q)) (§ 820.3(r))
"Product"	Retain and Supersede ISO definitions	820 definition is more comprehensive (§ 820.3(r))
"Readily identifiable and retrievable"	Clarification	ISO 13485 Clause 4.2.5 is substantially similar to 820.180 "FDA expects that such records will be made available during the course of an inspection. If the foreign manufacturer maintains records at remote locations, such records would be expected to be produced by the next working day or 2, at the latest. FDA has clarified that records can be kept at other than the inspected establishment, provided that they are made 'readily available' for review and copying."
"Remanufacturer"	Retain	Retained as necessary to implement 820 (§ 820.3(w))
"Verification"	Retain	Retained as necessary to implement 820 (§820.3(aa))
QMS Establish and Maintain	Revise and Relocate	A quality management system that complies with ISO 13485, as modified by the PROPOSED part 820, must be documented (§ 820.5)
Complaint Handling	Clarification	Manufacturer must record the listed information, at a minimum, for complaints that must be reported to FDA under part 803, complaints that a manufacturer determines must be investigated, and complaints that the manufacturer investigated regardless of those requirements
Confidentiality of Records FDA receives	Supplementary Provision	FDA protects such records (§ 820.180) in accordance with 21 CFR part 20; Must meet ISO 13485 Clause 4.2.5 and PROPOSED § 820.35
Control of Records	Supplementary Provision	Signature and date requirements for records subject to Clause 4.2.5 of ISO 13485
Definitions in ISO 9000 apply to ISO 13485	Clarification and Supersede	Any conflict between ISO 9000 and the FD&C Act and its implementing regulations, the FD&C Act and its implementing regulations Supersede.
Information for reportability under MDR (Part 803)	Supplementary Provision	Information to be captured on certain records of complaints and servicing activities
Labeling and Packaging	Retain	PROPOSED § 820.45 to maintain expectations for inspection of labeling. Must conform to ISO 7.5.1 (e), 4.2.5 and PROPOSED § 820.45
MDSAP	No Change	FDA will maintain inspection authorities FDA will NOT issue certificates of conformance FDA is NOT developing a certification program
Part 4 Combination Products	Conform	Amend Part 4 to conform to ISO 13485
Part 4 Combination Products	Revise	Revise the definition of "Device"
Part 4 Combination Products	Revise	Remove the definition of "QS regulation", and add in its place a definition for "QMSR for devices".
Part 4 Combination Products	Revision and Addition	§ 4.4 If the combination product includes a device constituent part and a drug constituent part, and the current good manufacturing practice operating system has been shown to comply with the drug CGMPs, the following clauses of ISO 13485 within the QMSR requirements for devices must also be shown to have been satisfied; upon demonstration that these requirements have been satisfied, no additional showing of compliance with respect to the QMSR requirements for devices need be made: **(i) Management responsibility**. Clause 4.1, Clause 5 and its subclauses and Clause 6.1 of ISO 13485; **(ii) Design and development.** Clause 7.3 and its subclauses of ISO 13485; **(iii) Purchasing.** Clause 7.4 and its subclauses of ISO 13485; **(iv) Improvement.** Clause 8.4, Clause 8.5 and its subclauses of ISO 13485; **(v) Installation activities.** Clause 7.5.3 of ISO 13485; and **(vi) Servicing activities.** Clause 7.5.4 of ISO 13485 and § 820.35(b).
Quality System Inspection Technique (QSIT)	Replace	Replace with new inspection technique consistent with the Final Rule
Servicing Activities	Clarification	Clause 7.5.4 and PROPOSED § 820.35(b)
Unique Device Identifier	Supplementary Provision	PROPOSED § 820.35(c) Clauses 7.5.1, 7.5.8, and 7.5.9 Firms document the Unique Device Identification (UDI) for each medical device or batch of medical devices in accordance with