



FDA QMSR (21 CFR 820) Transition Kit

Move from the old QSR to the QMSR (ISO 13485 by reference) with a gap assessment, plan and records matrix.

What's inside

File	What it is / how to use it
01_QMSR_Gap_Assessment_and_Records_Matrix.xlsx	22-row old-820 to 13485 mapping with status, actions and flags; readiness summary; records matrix with QMSR 820.35/820.45 items.
02_QMSR_Transition_Plan.docx	Key changes table, workstream plan, training and closure sign-off.

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Mapping notes are our plain-English reading of the public QMSR final rule; they are not FDA's official crosswalk.

About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

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QMSR Transition Plan

FDA QMSR (21 CFR 820) Transition Kit - Document 02 - Rev A (2026-10)

1. Purpose

Plan and document [Company]'s transition from the former Quality System Regulation (21 CFR 820, QSR) to the Quality Management System Regulation (QMSR), effective February 2, 2026, which incorporates ISO 13485:2016 by reference.

2. Key changes to address (summary)

Change	What we do
ISO 13485:2016 now the core requirement (incorporated by reference, 21 CFR 820.7)	Re-map procedures to 13485 clauses using the gap assessment
FDA definitions supersede conflicting 13485 definitions (820.3)	Update glossary in quality manual
Records content additions (820.35): complaints, servicing, UDI	Update complaint and service forms
Labeling and packaging controls retained (820.45)	Keep labeling inspection/release step
Management review, internal audit and supplier audit reports are no longer exempt from FDA inspection	Write reports expecting an FDA investigator to read them
Risk management expected throughout the QMS	Link risk file to design, purchasing, production, CAPA
FDA inspection approach updated (QSIT retired in favor of a new approach)	Train staff on QMSR-based inspections

3. Transition plan

#	Workstream	Owner	Start	Finish	Status

4. Training

Train all QMS document owners on the QMSR changes; record effectiveness.