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REGULATION CHECKLIST

FDA QMSR: requirements checklist

Reviewed by Abdul Azam, Founder & CEO, 25 years in regulated life-sciences quality. Last reviewed September 26, 2026.

> QMSdesk is designed to support these requirements. It covers key QMSR requirements, not every clause. Compliance is established in your environment, for your intended use; the last column is yours to complete. This checklist is general information, not legal or regulatory advice.

The clause-to-control map

Requirement (clause, paraphrased)	How QMSdesk supports it	Evidence the system produces	What you still own	Your evidence
§820.10(a). Document a QMS that complies with the applicable requirements of ISO 13485 and of this part.	The medical device profile carries ISO 13485 and the FDA QMSR. Procedures run through a signed document lifecycle.	Signed, effective procedures. Your profile record.	Your quality manual, procedures and medical device files.	
§820.35(a), ISO §8.2.2. Handle complaints, and keep the records §820.35(a) requires, including why any investigation was not done.	Complaint workflow: acknowledgment tracked against a 3-business-day target, investigation and root cause, a signed reportability review, a signed CAPA decision, and the reply.	The complaint record, its signatures and a closure-record PDF.	Deciding which complaints you investigate, and capturing every §820.35(a) element, including UDI, under your procedure.	
§820.10(b)(3), ISO §8.2.3. Report complaints that meet Part 803.	The reportability review is a signed decision with its justification. A reportable complaint records the authority and the reporting deadline.	The signed decision, the authority and the deadline.	Setting the deadline (30 calendar days from awareness under §803.50, or 5 work days under §803.53) and filing the report with FDA.	
§820.10(b)(1), (2), (4); §820.35(c). UDI, tracking, corrections and removals.	Nonconformances carry UDI and serial number under the medical device profile.	Nonconformance records with device identification.	Your UDI system and production records, tracking, and Part 806 reports. Outside QMSdesk's scope.	
§820.10(c), ISO §7.3. Design and development for class II, class III and listed class I devices.	Outside QMSdesk's scope. Under the medical device profile, each CAPA records whether it affects the design.	The CAPA's design-impact field.	Your design and development records.	

Requirement (clause, paraphrased)	How QMSdesk supports it	Evidence the system produces	What you still own	Your evidence
§820.10(d), ISO §7.5.9.2. Traceability for devices that support or sustain life.	Outside QMSdesk's scope.	—	Your traceability records.	
ISO §7.1. Risk management throughout product realization.	A risk register on a 5×5 matrix, with FMEA scoring available. Assessments and residual-risk acceptance are signed, and risk controls are verified separately from their implementation.	Signed risk records and their linked CAPAs.	Your risk management process and file, and your risk acceptability criteria.	
ISO §8.5.2, §8.5.3. Corrective and preventive action.	CAPA as its own record: signed action-plan review, verification, and an effectiveness check that can't be skipped. A failed check raises a new linked CAPA.	Signed CAPA records, action evidence and effectiveness results.	Investigation methods, and actions proportionate to the effects of the nonconformity.	
ISO §8.3. Control of nonconforming product.	Nonconformance workflow with a signed disposition (reject, rework, use as is or return). Use as is needs a technical rationale.	Signed nonconformance records.	Your disposition criteria, rework instructions and any concessions.	
ISO §7.4. Supplier evaluation, monitoring and re-evaluation.	Risk tiers set qualification gates and 6, 12 or 24-month reviews. Signed status decisions. SCARs answered through a single-use link.	The Approved Supplier List, signed decisions and SCAR records.	Supplier audits, purchasing data and incoming acceptance.	
ISO §5.6. Management review, now open to FDA inspection.	A frozen, signed snapshot of the quality system as of the period end. Minutes and decisions signed at closure.	The snapshot, signed minutes and tracked follow-up actions.	Running the review and making its decisions.	
ISO §8.2.4. Internal audit, now open to FDA inspection.	Audit program and calendar. Auditors can't audit their own department. Critical findings raise a nonconformance and a risk.	Signed audit reports and a register of every finding.	Your audit program and the audits themselves.	
ISO §4.2.4. Document control.	Author, reviewer and approver are different people. Training is assigned on approval. External standards are controlled as reference documents.	Signed versions, controlled copies with logged downloads, periodic review tasks.	Document content.	
ISO §6.2. Competence and training.	Training assigned on approval, change and CAPA. Quizzes, practical assessments and competency assessments.	Completion records (signed acknowledgments and practical assessments, auto-graded quiz results) and training transcripts.	Competence criteria and training content.	

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§820.35, ISO §4.2.5. Control of records, including retention.	A SHA-256 hash-chained, insert-only audit trail, verified daily. Records raised in error are cancelled with a signed reason, never hard-deleted. Under the medical device profile, records are kept for at least 15 years after they reach a final state, and you can set a longer period.	The audit trail, verification results and retention clock.	Defining device lifetime and any longer retention it needs (ISO §4.2.5), and marking confidential records for FDA (§820.35(d)).	
§820.35(b). Servicing records.	Outside QMSdesk's scope.	—	Your servicing records.	
§820.45. Labeling and packaging controls.	Your labeling procedure can run as a controlled document.	The approved procedure.	Label inspection and release records on your line.	
ISO §4.1.6. Validate software used in the QMS before first use and after changes, in proportion to risk, and keep records.	QMSdesk's core platform is validated under a QA-approved Validation Summary Report.	We'll walk you through the full record under a mutual NDA.	Validating QMSdesk for your intended use, and revalidating after changes.	
21 CFR Part 11. Electronic records and signatures.	Re-authentication at every signature, a recorded meaning, and the signature committed with its change.	The signature manifest on closure records and controlled copies.	Your Part 11 procedures (including §11.10(i), (j) and (k), and §11.300) and the §11.100(c) letter to FDA.	