ALYMPIX

MEDICAL DEVICE MANUFACTURERS
21 CFR PART 820 · ISO 13485:2016
QMSR IN EFFECT SINCE FEB 2, 2026

QMSR supplier controls self-assessment checklist

FDA's Quality Management System Regulation now brings purchasing controls in through ISO 13485 rather than the old 21 CFR 820.50. The practical change is that **supplier monitoring is expected to be ongoing and documented** — a qualification file from years ago no longer shows a supplier is in control today. Work through each item with your supplier files open, and note where the evidence lives.

How to mark each item

- ☐ **Y** — in place, with records to show it
- ☐ **P** — partly: exists on paper, or not for every supplier
- ☐ **N** — not in place

Items marked QMSR are where the new rule changed what an investigator will look for.

01 Supplier evaluation and selection

ISO 13485 7.4.1

	Requirement	Evidence to look for	Y · P · N
1.1	A documented procedure defines how suppliers are evaluated and selected.	Approved, current procedure	☐ ☐ ☐
1.2	Selection criteria weigh the supplier's ability to meet requirements, its performance, and the effect of what it supplies on device quality.	Criteria written into the procedure or a scoring form	☐ ☐ ☐
1.3	The level of control is proportionate to risk: critical suppliers get more scrutiny than commodity ones.	Risk tier assigned to every supplier	☐ ☐ ☐
1.4	Every supplier on the approved supplier list has an evaluation record behind it.	ASL cross-checked against evaluation files	☐ ☐ ☐

02 Ongoing monitoring and re-evaluation QMSR

ISO 13485 7.4.1

2.1	Each supplier has defined performance measures — for example defect rate (DPPM), on-time delivery, and open corrective actions.	Scorecards or a monitoring plan by supplier	☐ ☐ ☐
2.2	Re-evaluation frequency is set by risk tier — and the last cycle actually happened.	Dated re-evaluation records for the current period	☐ ☐ ☐
2.3	When a supplier misses requirements, the response is proportionate to risk and documented.	Escalation path; records of actions taken	☐ ☐ ☐
2.4	Records of evaluation, selection, monitoring and re-evaluation are retained.	Retrievable within minutes, not days	☐ ☐ ☐
2.5	Supplier performance data feeds management review.	Supplier metrics in management review minutes	☐ ☐ ☐

03 Outsourced processes and quality agreements

ISO 13485 4.1.5

3.1	Outsourced processes that affect product conformity are identified — contract manufacturing, PCBA, sterilization, testing, and the like.	List of outsourced processes with owners	☐ ☐ ☐
3.2	Controls over each are proportionate to risk and to the supplier's ability to meet requirements.	Control level documented per process	☐ ☐ ☐
3.3	A written quality agreement covers each outsourced process: responsibilities, change notification, records, and the right to audit.	Signed, current quality agreements	☐ ☐ ☐
3.4	Responsibility for conformity stays with you — the agreement allocates work, it does not transfer accountability.	Wording in agreements and procedures	☐ ☐ ☐

04 Purchasing information

ISO 13485 7.4.2

4.1	Purchase orders reference current specifications and drawings at the correct revision.	Sample POs checked against released revisions	☐ ☐ ☐
4.2	Acceptance requirements, and where relevant personnel qualification and QMS requirements, are stated.	PO terms, specs, or supplier quality manual	☐ ☐ ☐
4.3	Suppliers are required, in writing, to notify you of changes to purchased product **before** they implement them.	Change-notification clause; past notices on file	☐ ☐ ☐
4.4	Purchasing information is reviewed for adequacy before it is released to the supplier.	Approval step in the purchasing workflow	☐ ☐ ☐

05 Verification of purchased product

ISO 13485 7.4.3

5.1	Incoming inspection or other verification is defined for each purchased product.	Inspection plans or verification instructions	☐ ☐ ☐
5.2	The extent of verification follows the supplier's evaluation results and the product's risk.	Sampling tied to supplier tier	☐ ☐ ☐
5.3	Changes to purchased product are assessed for their effect on production and on the device.	Change assessments linked to supplier notices	☐ ☐ ☐
5.4	Verification records are kept; verification done at the supplier's site is specified in purchasing information.	Receiving records; source-inspection terms	☐ ☐ ☐

06 Supplier nonconformities and corrective action

ISO 13485 8.3 · 8.5.2

6.1	Nonconforming purchased product is identified, segregated, and dispositioned.	Hold area; MRB or disposition records	☐ ☐ ☐
6.2	Supplier corrective actions require containment and root cause, and effectiveness is verified with data before closure.	Closed corrective actions with effectiveness evidence	☐ ☐ ☐
6.3	Repeat supplier problems escalate — re-evaluation, restricted awards, or disqualification.	Escalation criteria and examples	☐ ☐ ☐

07 Risk management link

ISO 13485 7.1 · ISO 14971

7.1	Supplier risk tiers trace back to the device risk analysis, not to spend or convenience.	Traceability from risk file to supplier tier	☐ ☐ ☐
7.2	Failure modes of purchased components appear in the risk file or PFMEA.	Component-level entries with controls	☐ ☐ ☐

08 Inspection readiness under QMSR QMSR

21 CFR 820.10 · 820.35

8.1	Supplier audit reports are complete and fit to be read by an investigator. The old QSR exemption that kept supplier audit reports, internal audits and management review out of FDA's view did not carry into the QMSR.	Audit reports reviewed as if FDA will read them	☐ ☐ ☐
8.2	Procedures cite ISO 13485 clauses and the new Part 820, not retired QSR sections such as 820.50.	Document references updated	☐ ☐ ☐
8.3	Records also meet FDA's own record requirements in 21 CFR 820.35, which go beyond ISO 13485.	Gap check of record types against 820.35	☐ ☐ ☐
8.4	Your team knows FDA now inspects under Compliance Program 7382.850, which replaced the QSIT approach.	Inspection-readiness plan updated	☐ ☐ ☐

Reading your results

Every **N** is a likely inspection finding, and every **P** is one an investigator can turn into a finding by asking for a second supplier's file. If you have more than a handful, start with sections 02 and 08 — that is where the QMSR changed the most.

Y	P	N

ALYMPIX · SUPPLIER QUALITY

Want a second set of eyes on your supplier files?

Talk to an engineer: hello@alympix.com

This checklist paraphrases requirements of ISO 13485:2016 as incorporated by reference into 21 CFR Part 820 (the Quality Management System Regulation, effective February 2, 2026), together with FDA's supplemental provisions. It is a self-assessment aid, not legal or regulatory advice; confirm requirements against the current regulation and the standard itself. © Alympix.