ISO 13485 Purchasing Controls Readiness Checklist

Elexes

An initial self-assessment against clauses 7.4.1 to 7.4.3 of ISO 13485:2016, with links to 4.1.5, 8.3 and 8.5. FDA's QMSR also applies these clauses in the US from February 2, 2026. Tick an item only if you can show a controlled record for it.

Purchasing process and procedures — 7.4.1

- [ ] A documented purchasing procedure covers supplier evaluation, selection, approval, monitoring and re-evaluation.
- [ ] Orders are placed only with approved suppliers, and the approved supplier list shows each approval scope.
- [ ] Supplier controls are linked to risk management outputs for the device.
- [ ] Responsibilities of engineering, quality, purchasing and regulatory are defined.

Supplier evaluation and selection — 7.4.1

- [ ] Criteria cover ability to meet requirements, performance, effect on device quality and device risk.
- [ ] Suppliers are classified by risk, with an evaluation method defined for each class.
- [ ] On-site audits are used where risk justifies them, not by default for every supplier.
- [ ] Evaluation and approval decisions are recorded, including any conditions or limits.

Monitoring and re-evaluation — 7.4.1

- [ ] Monitoring and re-evaluation are planned, with frequency based on risk and performance.
- [ ] Performance data such as lot acceptance, delivery and corrective action closure is collected.
- [ ] Monitoring results are used as inputs to re-evaluation decisions.
- [ ] Unmet purchasing requirements are addressed with the supplier in proportion to risk, and recorded.

Purchasing information — 7.4.2

- [ ] Purchasing documents state specifications and product acceptance requirements.
- [ ] Process, equipment, personnel qualification and QMS requirements are included where appropriate.
- [ ] Purchasing documents are reviewed for adequacy before release to the supplier.
- [ ] Purchasing documents and records are kept to the extent traceability requires.

Quality agreements and supplier changes — 4.1.5 · 7.4.2

- [ ] Written quality agreements are in place for outsourced processes.
- [ ] Suppliers agree to notify you before changes that affect requirements, where applicable.
- [ ] Supplier changes are assessed for effects on product realization and the device.
- [ ] Change assessments consider risk, verification needs and regulatory submissions.

Verification of purchased product — 7.4.3

- [ ] Incoming inspection or other verification is defined for each purchased item.
- [ ] The extent of verification reflects supplier evaluation results and product risk.
- [ ] Verification and release methods are stated in purchasing information when checks happen at the supplier.
- [ ] Verification records are kept, and rejected material is handled as nonconforming product.

Supplier files and QMS links — 8.3 · 8.5

- [ ] Each approved supplier has a current file: evaluation, approval scope, agreements, certificates and performance.
- [ ] Repeat or significant supplier problems are raised as corrective actions.
- [ ] Supplier performance trends are reviewed at planned intervals.
- [ ] Critical suppliers are prepared for regulator or notified body audits, including unannounced visits where applicable.

Found gaps?

Elexes can design, remediate or review your supplier controls for FDA, EU MDR, UK, Health Canada and TGA expectations.

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Disclaimer: This checklist is an initial readiness tool and does not replace regulatory assessment, certification, legal advice, or authority review.
References: ISO 13485:2016, clauses 4.1.5 and 7.4; 21 CFR Part 820 (QMSR), effective February 2, 2026; Regulation (EU) 2017/745.