ISO 13485 Readiness Checklist

Elexes

An initial self-assessment of your medical device QMS. Tick an item only when current documents and records support it. Mark non-applicable items with a documented rationale.

QMS scope and management

4.1 / 5

- [ ] QMS scope reflects current devices, sites, activities and outsourced processes.
- [ ] Applicable regulatory requirements and justified non-applicability decisions are documented.
- [ ] Quality objectives, responsibilities and management representative duties are defined.
- [ ] Management reviews record required inputs, decisions, actions and follow-up.

Production, validation and release

4.1.6 / 7.5 / 7.6

- [ ] Applicable production, installation and servicing instructions are controlled.
- [ ] Required process and software validation is completed before use and changes are assessed.
- [ ] Identification, traceability, preservation and release records meet applicable requirements.
- [ ] Measuring equipment, maintenance and sterile-device controls are addressed where applicable.

Documents, records and competence

4.2 / 6

- [ ] Current procedures and forms are approved, controlled and available where used.
- [ ] Completed records are legible, retrievable and retained for defined periods.
- [ ] Personnel competence and required training are supported by records.
- [ ] Infrastructure, work environment and contamination controls suit the product.

Feedback, complaints and CAPA

8.2 / 8.3 / 8.5

- [ ] Feedback and complaints are assessed, investigated and linked to relevant actions.
- [ ] Regulatory reporting decisions and applicable notifications are documented.
- [ ] Nonconforming product is controlled; disposition and rework are documented.
- [ ] Corrective and preventive actions have appropriate investigation and effectiveness evidence.

Design and development

7.3

- [ ] Applicable design stages, responsibilities and review arrangements are planned.
- [ ] Design inputs and outputs are defined, reviewed and connected.
- [ ] Verification and validation records support approved acceptance criteria.
- [ ] Design transfer and changes are reviewed, approved and documented.

Internal audit and quality data

8.2.4 / 8.4 / 8.5

- [ ] An audit programme covers applicable QMS processes and requirements.
- [ ] Auditors are objective; findings and follow-up are supported by records.
- [ ] Quality data and trends are analysed to identify needed action.
- [ ] Changes and recurring issues are evaluated for impact on QMS effectiveness.

Suppliers and purchasing

7.4

- [ ] Supplier selection and evaluation criteria reflect the supplied product and risk.
- [ ] Approval, monitoring and re-evaluation records support supplier status.
- [ ] Purchasing requirements and applicable supplier agreements are controlled.
- [ ] Purchased product verification and supplier-issue follow-up are recorded.

Found gaps?

Request an ISO 13485 readiness review to prioritize QMS gaps and implementation evidence.

elexes.com/iso-13485/

Use: Record gaps, evidence references, owners and due dates in your action tracker.
FDA scope: Assess applicable QMSR provisions separately; ISO certification alone does not establish FDA compliance.
References: ISO 13485:2016, clauses 4-8; FDA 21 CFR Part 820 (QMSR), effective February 2, 2026.
This initial readiness tool does not replace a full assessment, certification audit or regulatory review.