

Medical Device Internal Audit

Readiness Checklist



Prepare your audit scope, evidence and follow-up arrangements. Tick each item when it is confirmed; record gaps, owners and due dates in your preparation tracker.

Scope and audit criteria

Prepare

- ☐ Devices, activities, sites and outsourced processes in scope are identified.
- ☐ Applicable standards, regulations and internal procedures are listed as audit criteria.
- ☐ Market-specific requirements reflect device class and organizational responsibilities.
- ☐ Audit objectives, boundaries and any exclusions are agreed.

Jurisdiction-specific evidence

Select applicable markets

- ☐ US: applicable FDA QMSR and related regulatory obligations are included.
- ☐ EU/UK: applicable MDR, IVDR or GB obligations and PMS interfaces are identified.
- ☐ Canada/Japan: applicable MDSAP and MO169 criteria are identified.
- ☐ Australia: applicable TGA and MDSAP country requirements are identified.

Programme and auditor objectivity

Plan

- ☐ Audit timing reflects process importance, changes and previous audit results.
- ☐ The audit plan identifies processes, owners, timing and evidence needs.
- ☐ Auditors have relevant competence and do not audit their own work.
- ☐ Remote or onsite arrangements support access to the evidence needed.

Findings and corrective action

Record and act

- ☐ Each finding states the criterion, objective evidence and identified gap.
- ☐ Finding classification follows the agreed audit method.
- ☐ Owners, corrections and corrective action needs are assigned.
- ☐ Follow-up addresses implementation and effectiveness where appropriate.

Documents and sampled records

Gather

- ☐ Current QMS procedures and document indexes are available.
- ☐ Process owners can retrieve representative completed records.
- ☐ Previous findings, complaints, CAPA and quality trends are available.
- ☐ Changes to products, suppliers, processes and sites are identified.

Management oversight and follow-up

Review

- ☐ Results are communicated to relevant process owners and management.
- ☐ Open actions and recurring issues are tracked to appropriate closure.
- ☐ Audit results feed into management review and improvement activities.
- ☐ Remediation support and follow-up review responsibilities are agreed.

Process implementation

Examine

- ☐ Design, purchasing and supplier controls can be followed through sampled records.
- ☐ Production, validation, release and traceability evidence is accessible where applicable.
- ☐ Training and competence records support assigned responsibilities.
- ☐ Feedback, complaint handling and reporting decisions can be traced.

Found gaps?

Plan an internal audit that connects requirements, process evidence and clear follow-up actions.

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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.

Basis: ISO 13485:2016 clause 8.2.4; applicable market requirements must be selected for the audit scope.

This preparation tool does not replace an audit, certification assessment or regulatory inspection.