Q·hub

ISO 13485 Audit-Readiness Checklist

See where you stand against ISO 13485 and get audit-ready. Tick what you can already evidence today.

QUICK SELF-CHECK

- [ ] Do you have design and development controls with a device file?
- [ ] Is risk management (ISO 14971) applied across product realisation?
- [ ] Do you handle complaints and adverse-event vigilance with records?
- [ ] Are process and sterilisation validations documented?
- [ ] Do you have UDI and full traceability?
- [ ] Is your CAPA process robust with effectiveness checks?

ISO 13485 CLAUSES

- [ ] **Clause 4 — Quality management system & documentation**
  Establish a documented QMS with a quality manual, controlled documented information, defined processes and a medical device file for each device type, applying a risk-based approach throughout.
  Q-Hub: Document Hub controls the quality manual, procedures and each device's medical device file as version-controlled records with approval workflows, controlled distribution and enforced retention.

- [ ] **Clause 5 — Management responsibility**
  Demonstrate top-management commitment, set a quality policy and measurable objectives, define responsibilities and authorities, and hold management reviews with defined inputs and outputs.
  Q-Hub: Document Hub distributes the quality policy with read-and-understood sign-off and holds management review minutes; Company KPIs track quality objectives live for review inputs.

- [ ] **Clause 6 — Resource management**
  Provide competent personnel, suitable infrastructure and work environment, and control contamination and cleanliness where product quality can be affected.
  Q-Hub: Training Hub maintains competency matrices with certification-expiry alerts; Asset Hub schedules calibration and maintenance of equipment and infrastructure, with logs to evidence controlled conditions.

- [ ] **Clause 7 — Product realization: design controls, purchasing & production**
  Plan and control design and development with a design history file, verification and validation, control purchasing and suppliers, and validate production and service provision including sterile and process validation.
  Q-Hub: Document Hub controls design inputs, outputs and the design history file with change history; Register Hub manages approved suppliers and purchasing controls; Smart Forms capture production, sterilisation and process validation evidence with photos.

- [ ] **Risk management (ISO 14971)**
  Apply risk management across the product lifecycle to ISO 14971, maintaining a risk management file that identifies hazards, evaluates and controls risk, and monitors production and post-production information.
  Q-Hub: Register Hub manages the risk register and risk management file with hazard analysis, risk controls and assigned owners; dashboards keep residual risk visible and link to post-market feedback.

- [ ] **Clause 8 — Measurement, analysis & improvement**
  Gather feedback, handle complaints, report to regulatory authorities through vigilance and advisory notices, run internal audits, control nonconforming product and drive corrective and preventive action.
  Q-Hub: Smart Forms and CAPA capture complaints and nonconformances, drive root-cause analysis, effectiveness checks and vigilance reporting; Audit Hub schedules internal audits with medical device checklists and findings.

- [ ] **Traceability & unique device identification (UDI)**
  Maintain identification and traceability of product throughout realization, including records that link devices to components, batches and, where required, unique device identification.
  Q-Hub: Document Hub and Register Hub link device records, batch and component data and UDI references, giving a traceable thread from design record through production to distributed device.