



Medical Device QMS Readiness Checklist

A practical one-page check of whether core quality controls are implemented and evidenced.

01

QMS Scope, Governance & Resources



- ☐ QMS scope reflects the organization role, devices, sites, markets and outsourced activities.
- ☐ Quality responsibilities, authorities, objectives and escalation routes are defined.
- ☐ Applicable regulatory and standards requirements are identified and kept current.
- ☐ Personnel competence, training, infrastructure and essential resources are maintained.

02

Documentation, Design & Risk Controls



- ☐ Controlled procedures and records show that the QMS is implemented in practice.
- ☐ Applicable design and development controls are planned and supported by objective evidence.
- ☐ Risk management is connected to design, production, complaints and post-market information.
- ☐ Document approval, revision, access, retention and record integrity are controlled.

03

Supplier, Production & Change Controls



- ☐ Suppliers are selected, qualified and monitored according to product and process risk.
- ☐ Production, acceptance, release, traceability and preservation controls are implemented as applicable.
- ☐ Processes requiring validation are identified, validated and maintained where applicable.
- ☐ Product, process, supplier and QMS changes are assessed before implementation.

04

Quality Events, CAPA & Oversight



- ☐ Complaints and nonconformities are evaluated, investigated and documented consistently.
- ☐ CAPA decisions are risk-based, with root-cause work and effectiveness checks where needed.
- ☐ Internal audits evaluate applicable processes, requirements and previous problem areas.
- ☐ Management review uses quality data and tracks decisions and actions to closure.

05

Monitoring, Maintenance & Improvement



- ☐ Meaningful QMS and product-quality indicators are monitored, analyzed and escalated.
- ☐ Complaint, CAPA, supplier, audit and post-market trends are reviewed together when useful.
- ☐ Periodic QMS activities have clear owners, frequencies and documented completion evidence.
- ☐ The QMS is updated as devices, processes, markets, risks and responsibilities change.