Is Your Medical Device QMS Audit-Ready?

A 10-Minute Self-Assessment for Medical Device Companies

Section 1: Quality System Foundation

- Have you defined the scope of your QMS?
- Are quality objectives documented and reviewed regularly?
- Are management responsibilities clearly assigned?
- Has top management conducted a documented management review within the last 12 months?
- Are quality policies communicated across the organization?

Section 2: Document & Record Control

- Is there a documented process for creating, approving, and revising procedures?
- Can employees easily access the latest approved documents?
- Are obsolete documents removed from use?
- Are quality records retained according to defined requirements?
- Is document change history maintained?

Section 3: Training & Competency

- Are employee training requirements defined?
- Are training records complete and up to date?
- Is competency assessed for quality-critical roles?
- Have new employees received QMS training?

Section 4: Design & Development Controls

- Are design activities documented and controlled?
- Is design verification and validation evidence available?
- Are design changes formally reviewed and approved?
- Is design history documentation maintained?

Section 5: Risk Management

- Is risk management integrated into product lifecycle activities?
- Are risk assessments reviewed when significant changes occur?
- Are risk control measures documented and verified?

Section 6: CAPA & Continuous Improvement

- Is there a documented CAPA process?
- Are corrective actions tracked to closure?
- Is effectiveness of corrective actions verified?
- Are recurring quality issues analyzed for trends?

Section 7: Audit Readiness

- Have internal audits been completed as planned?
- Are previous audit findings fully closed?
- Could your team provide objective evidence if an auditor requested it tomorrow?

Score Your Readiness

22–25 Yes

- **Strong QMS Foundation**
- Your system appears mature, but an independent assessment may uncover hidden risks.

16–21 Yes

- **Moderate Risk**
- Several areas may require attention before audits or inspections.

10–15 Yes

- **Significant Gaps Likely**
- Your QMS may contain compliance weaknesses that could lead to findings.

Below 10 Yes

- **High Compliance Risk**
- A comprehensive QMS Gap Assessment is strongly recommended.