

eQMS Requirements Checklist for medical Device Companies

Company & Compliance Readiness

- Are you using a paper-based or partially digital QMS?
- Have you received any audit observations related to documentation or traceability?
- Do you operate in multiple locations or with remote teams?

Process Complexity

- Managing over 50 SOPs or work instructions?
- Frequent document revisions and approvals required?
- Struggling with version control or training documentation?
- Is your organization trained and aligned on quality compliance?
- Does leadership support compliance and continuous improvement?
- Do you have a defined process for change control, document updates, and approvals?

Risk & Regulatory Pressures

- Preparing for ISO 13485, FDA audit, or CE marking?
- Using manual logs for CAPA, NCR, or complaints?
- Facing issues with delayed QMS updates?
- Is your current document control fragmented across drives, email, or cloud folders?
- Are you scaling operations, which will require better visibility and compliance tracking?
- Have you listed your must-haves and nice-to-haves for an eQMS?

Operational Readiness

- Have internal champions for QA/RA or digital transformation?
- Budget allocation made for implementation or SaaS costs?
- Timeframe of 3–6 months available for migration & validation?
- Do you have internal IT support for system onboarding and access management?
- Have you defined your user roles and approval workflows?
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