Elexes

A MedTech Readiness Guide

Organizational Indicators:

- Internal team lacks regulatory or QA leadership
- Multiple submissions/audits are due within the next 6 months
- No recent experience with FDA or CE Mark compliance
- Resource constraints prevent hiring full-time senior staff

Compliance & Readiness Factors:

- Need help navigating ISO 13485, 510(k), or MDR
- Previous audit uncovered QMS or documentation gaps
- Launching new products in the U.S., EU, or UK

Financial & Strategic Considerations:

- Budget is limited but timelines are strict
- Want flexibility and expertise on-demand
- Team needs training or guidance from senior RA/QA experts

Engagement Fit:

- Project-based or interim needs exist (e.g., remediation, submission)
- Need part-time or fractional VP-level guidance
- Looking for a partner with global compliance knowledge