

RA/QA Outsourcing Readiness Checklist



Company Readiness:

- No internal VP of Regulatory or Quality role filled
- Current team lacks expertise in FDA, CE, or ISO submissions
- Have a time-sensitive regulatory pathway or market-entry goal
- Budget doesn't support a full-time leadership hire

Operational Fit:

- Need strategic direction + hands-on execution
- Team needs training or oversight in QMS
- Managing multiple submissions or country-specific compliance

Risk and Continuity:

- Facing gaps in audit or inspection preparation
- Approaching key milestones: 510(k), MDR, audit, or launch

Benefits & Next Steps:

- Want to reduce overhead without sacrificing expertise
- Need access to global regulatory knowledge
- Ready to delegate and streamline quality & compliance efforts