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Vendor Selection Checklist for Regulatory Outsourcing

Strategic Fit & Experience

- Vendor has prior experience in your specific product category (e.g., SaMD, IVD, implants)
- Experience with target regulatory bodies (FDA, EU MDR, TGA, Health Canada, etc.)
- Familiarity with applicable standards (ISO 13485, MDSAP, ISO 14971, IVDR)
- Client portfolio or case studies available in similar project types
- Alignment with your company's risk tolerance and growth goals

Team Qualifications & Resources

- Senior consultants with ≥5 years of hands-on regulatory experience
- Cross-functional expertise (QA, RA, clinical, labeling, software)
- Dedicated project manager assigned to your account
- Ability to scale team based on project complexity and urgency
- Multilingual or region-specific support if entering global markets

Operational Clarity & Deliverables

- Defined scope of work and responsibilities shared before kickoff
- Transparent timelines and work breakdown structure (WBS)
- Templates and tools offered for submissions, SOPs, audits, etc.
- Clear ownership of documentation, review cycles, and submissions
- Agile response system for addressing changes or emergency filings

Data Handling & Security

- Signed NDA and confidentiality agreement before data access
- Secure file-sharing portals (encrypted, GDPR/HIPAA compliant)
- Clearly documented access levels for sensitive data
- Backup and version control systems in place
- Cybersecurity certifications or third-party audits completed

Value & Performance

- Pricing model aligns with your project type (hourly, milestone, retainer)
- Clear KPIs or success metrics (e.g., submission success, audit readiness)
- Review schedule (monthly/quarterly) to evaluate collaboration
- Escalation protocol in case of scope creep or delivery issues
- Client references or testimonials provided during selection phase