Elexes

Regulatory Partner Selection Checklist

- Confirm experience with multiple regulatory agencies (FDA, CDSCO, EMA, Notified Bodies)
- Check proven track record with 510(k), PMA, CE marking, MDSAP, and ISO 13485 certifications
- Ensure expertise across medical devices, IVDs, and SaMD, including AI/ML-based products
- Review client references, testimonials, and detailed case studies.
- Assess ability to handle end-to-end support (strategy, submissions, audits, post-market compliance)
- Verify knowledge of country-specific requirements in India, US, and EU.
- Evaluate team qualifications, technical expertise, and regulatory credentials
- Ensure they can provide ongoing QMS support, training, and remediation.
- Look for flexible engagement models, clear pricing, and transparent timelines
- Check responsiveness, communication style, and commitment to deadlines
- Confirm availability of local presence in India with global outreach in the US/EU
- Assess ability to adapt solutions to company size (startups vs. enterprises)