Elexes

12 Things to Check Before Your Medical Device Audit

- Define the audit scope and applicable standards (FDA, ISO 13485, MDSAP)
- Verify all QMS procedures are current and approved
- Review CAPA records for timely closure and effectiveness
- Check design history, risk management, and traceability records
- Confirm complaint handling and post-market surveillance documentation
- Ensure training records are complete and up to date
- Review supplier qualification and monitoring records
- Validate document control and revision history
- Conduct a mock audit with key process owners
- Verify objective evidence is available for critical processes
- Identify and prioritize high-risk compliance gaps
- Prepare an audit response plan and assign responsibilities