Elexes

Medical Device Training Compliance Checklist: FDA, ISO 13485 & MDR

Required Training Records

- Employee training matrix aligned with job functions
- Records of training on SOPs, CAPAs, and WI
- Training dates, trainer details, and attendee sign-offs
- Documentationof training effectiveness evaluation.
- Regulatory-specific training included where applicable (FDA, ISO, MDR).

Program Setup & Maintenance

- Training SOP and quality manual reference
- Defined frequency for each training module
- Roles assigned for training administration and oversight
- Retention policy for training records per region, consistent with regulatory requirements.
- Periodic review and update of training materials.

Compliance Readiness

- System ready for FDA 21 CFR 820.25 inspection
- ISO 13485 clause 6.2 compliance verified
- Document personnel competence and training per MDR Art. 10(9)(d)
- Process in place to train temporary and contract staff
- Training records readily available and traceable for audits.

Common Audit Red Flags

- Missing records or lack of proof of retraining
- Outdated training materials still in use
- Untrained personnel performing regulated tasks
- No documented evaluation of training effectiveness.
- Inconsistent retention or missing regulatory-specific documentation.