Elexes

MDSAP Compliance Preparation Checklist

Company Structure & Quality Oversight

- Clear documentation of legal manufacturer and subsidiaries
- Quality policy aligned with MDSAP principles and management commitment
- Current org chart showing QMS ownership and escalation path

Quality System & Documentation Control

- ISO 13485:2016-compliant QMS procedures maintained
- Controlled SOPs, forms, and records management system implemented
- Change control procedures applied consistently across all functions

Product Lifecycle Controls

- Design and development documentation traceable (inputs to outputs)
- Device Master Record (DMR) and Device History Record (DHR) ready
- Evidence of product release controls and labeling verification

Supplier & Outsourcing Oversight

- Evaluation and monitoring procedures for critical suppliers
- Quality agreements signed with outsourced partners
- Supplier nonconformance logs and follow-up records available

Field Performance & Feedback Systems

- Complaint handling process integrated with vigilance/reporting
- Procedures for FSCA, recalls, and adverse event reporting established
- Trending of post-market surveillance and feedback conducted

Audit Strategy & Readiness

- Internal audit schedule with MDSAP alignment
- Pre-audit gap assessment and remediation actions documented
- Staff trained on MDSAP audit protocols and interview roles