Elexes

DHF Remediation Readiness Checklist

Initial Assessment

- Existing DHF reviewed against FDA, ISO 13485, and MDR requirements
- Key gaps and deficiencies identified and documented

Legacy Documentation Audit

- Historical documents verified for completeness and accuracy
- Missing records and signatures flagged for remediation

Design Traceability Review

- Inputs and outputs reviewed for alignment and traceability
- Verification and validation activities linked to specific inputs

Risk Management Evaluation

- Existing risk files reviewed for compliance with ISO 14971
- Risk control measures assessed for implementation and verification

Change Control Validation

- Change history reviewed for justification and regulatory impact
- Records aligned with current configuration and documentation

Software and Cybersecurity Documentation

- Software lifecycle and validation records reviewed (IEC 62304)
- Cybersecurity risks and mitigations (FDA pre/post-market) included if applicable

Usability Engineering Gaps

- Usability and human factors documentation assessed (IEC 62366)
- User interface validations reviewed for completeness

Labeling and Instructions for Use (IFU)

- Current labeling and IFUs verified for alignment with outputs
- All revisions documented and version-controlled

DHF Structure and Format Review

- File organization checked for clarity and consistency
- Indexing and version history assessed for audit-readiness

Remediation Action Plan

- Remediation tasks assigned with timelines and ownership
- Final review process established with quality sign-off checkpoints