Elexes

Design History File (DHF) Compliance Checklist

Design Planning & Control
- Design and Development Plan documented and approved ✓
- Roles and responsibilities clearly defined ✓

Design Inputs
- User needs captured and documented ✓
- Regulatory, functional, and performance requirements identified ✓

Design Outputs
- Engineering drawings and specifications created ✓
- Manufacturing procedures and software outputs included ✓
- Outputs reviewed for compliance with inputs ✓

Design Reviews
- Formal design review meetings conducted at each phase ✓
- Issues identified and resolved with documented outcomes ✓

Design Verification & Validation
- Verification protocols and test reports complete ✓
- Validation activities performed under actual use conditions ✓
- V&V results traceable to design inputs ✓

Design Changes
- Change control process implemented and documented ✓
- Rationale and impact assessment included ✓

Risk Management Integration
- Risk analysis in accordance with ISO 14971 ✓
- Risk controls documented and verified ✓

Traceability Matrix
- Inputs, outputs, verification, and validation clearly mapped ✓

Usability & Human Factors
- Usability engineering documentation (if applicable) included ✓
- Human factors testing results integrated ✓

Final DHF Compilation
- All documents indexed, approved, and version-controlled ✓
- File organized for audit-readiness and future updates ✓