Internal Audit Plan & Checklist – ISO 13485 & FDA QSR Compliance

Audit Preparation

- Annual internal audit schedule prepared
- Audit Scope, criteria and objectives documented as per ISO 19011.
- Qualified internal auditor(s) assigned- (or external auditor selected)
- Audit plan reviewed and approved by QA or management

Documents & Records to Audit

- SOPs and Work Instructions
- Training Records
- Corrective and Preventive Action(CAPA)records and Nonconformance(NCR) Logs
- Internal Audit Reports and Follow-up Records
- Management Review Records
- Risk Management Files
- Design History Documentation
- Complaint records and Post-Market Surveillance(PMS) Feedback Log

Execution & Reporting

- Opening and closing meetings held
- Objective evidence gathered and recorded
- Nonconformities classified based on severity (minor/major)
- Audit report completed and reviewed by management

Follow-up & Closure

- Corrective actions (linked to root causes) linked for all audit findings and documented in CAPA log.
- Verification of effectiveness for corrective actions documented
- Final closure of audit and management review done