Medical Device Testing Requirements Checklist (FDA + CE)

Pre-Testing Preparation

- Device classification confirmed (Class I, II, III)
- Intended use and target market identified (US, EU, global)
- Applicable standards mapped (ISO 10993, IEC 60601, etc.)
- Schematics and BOM should be freezed
- Test reports of components (if applicable)

Testing Scope Checklist (where applicable)

- Biological evaluation plan developed (per ISO 10993)
- EMC and electrical safety plan created (IEC 60601 series)
- Usability testing strategy (IEC 62366)
- Software verification and validation plan
- Performance testing protocols
- Risk management file
- Instructions for use and technical description
- Device packaging labels
- Separate power suppliers

Documentation & Submission

- Complete test reports including protocols)
- Raw data reviewed and verified
- Reports formatted for FDA or CE
- Cross-references made in Technical File or FDA submission

Risk & Timeline Management

- Buffer time built in for re-testing or failures
- Risk management file updated with test results
- Final checklist reviewed before submission