Software Documentation Quality Assurance Checklist

Planning & Scoping

- Documentation scope and software classification confirmed
- Regulatory deliverables mapped to development phases
- Stakeholders and reviewers identified for each document
- Documentation plan includes timelines and responsible parties

Specifications & Inputs

- Functional and performance requirements documented
- Inputs from clinical, regulatory, and marketing captured
- Intended use and user environment explicitly stated
- Compatibility and interoperability documented if applicable

Structure & Consistency

- Consistent use of terminology across all documents
- Version control and document ID system in place
- Document templates follow ISO 13485 or internal QMS formats
- Indexing and cross-referencing used for traceability

Review & Approval Process

- Peer and cross-functional reviews completed
- Review comments and resolutions tracked
- Final approvals from QA, RA, and software leads obtained
- Audit trail of changes and approvals maintained

Storage & Accessibility

- All documentation stored in controlled repositories
- Backups scheduled and access restricted based on role
- Obsolete documents clearly marked and archived
- Documentation available for inspection and audits