Software Validation Readiness Checklist

Foundational Planning

- Validation objectives clearly defined for intended use
- Documented roles and responsibilities for validation activities
- Software categorized by intended medical use and operational risk
- Identification of regulatory frameworks (FDA QSR, EU MDR, IEC 62304, ISO 13485)

Requirement Development

- Functional and performance requirements documented
- Defined software operating environment and system dependencies
- Design input and output correlation documented
- Configuration management and software item identification

Design & Development Testing

- Comprehensive review of test strategy aligning with lifecycle model
- Review of design verification and validation
- Evidence of static/dynamic code analysis and peer reviews
- Documented issue tracking system for test failures and resolution

Hazard & Risk Documentation

- Comprehensive software hazard analysis
- Linkage of risks to control measures and testing evidence
- Documented cybersecurity threat model and mitigations
- Use of risk acceptability criteria and benefit-risk analysis

Validation Execution & Post-release

- Results of validation documented and reviewed by quality function
- Change management process in place for post-validation updates
- Post-release support documentation: service, updates, and monitoring
- Advise on Pre-determined Change Control Protocol (PCCP)