ISO 13485 Compliance Preparation Checklist

Strategic Planning

- Identify applicable regulatory jurisdictions (FDA, EU MDR, etc.)
- Establish quality objectives and metrics
- Define organizational chart and QMS responsibilities

Core Documentation

- Develop ISO 13485:2016-compliant Quality Policy
- Draft procedures for product realization and traceability
- Create Design History File (DHF) and Device File
- Maintain risk analysis and mitigation strategies per ISO 14971

System Implementation

- Conduct QMS gap assessment and closure actions
- Train staff on QMS procedures and roles
- Implement supplier qualification and monitoring system
- Establish complaint handling, CAPA, and change control systems

Audit & Certification

- Schedule and complete internal quality audits
- Select and coordinate with an accredited certification body
- Prepare audit response protocol for nonconformities
- Plan for ongoing surveillance and recertification audits