

ISO 13485 Certification Readiness Checklist

- Conduct a gap analysis against ISO 13485 requirements
- Develop and document your Quality Management System (QMS)
- Define roles, responsibilities, and training for staff
- Establish and maintain risk management per ISO 14971
- Implement document control and record-keeping processes
- Plan and perform internal audits to check compliance
- Conduct and document management review meetings
- Establish a CAPA process to address nonconformities, determine root causes, and verify the effectiveness of actions taken
- Select an accredited Notified body or certification body
- Prepare for and undergo the certification audit