ISO 13485:2016 Compliance

QT9™ Quality Management Software is a one stop ISO 13485 solution. QT9™ QMS is completely 21 CFR Part 11 compliant for electronic signatures and is validated (IQ, OQ, PQ) after every release. Let QT9™ QMS handle the burden of your ISO 13485 requirements and automate your management system making your organization more efficient and productive. Look below to see how QT9™ stacks up against the ISO 13485 standard.

Requirement	Description	QT9™ Module/Solution
Element 4.2.4	Control of Documents	QT9™ Document Control
Element 5.6	Management Review Requirements	QT9™ Management Review
Element 6.2.2	Employee Training	QT9™ Training
Element 6.3	Infrastructure	QT9™ Preventive Maintenance
Element 7.1	Risk Management	QT9™ FMEA Module QT9™ Risk Assessments
Element 7.3	Design & Development	QT9™ ECR/ECN
Element 7.4.1	Purchasing/Evaluation of Suppliers	QT9™ Supplier Evaluation QT9™ Supplier Surveys QT9™ Corrective Actions
Element 7.5.1	Control of Production and Service Provision	QT9™ Inspections
Element 7.6	Control of Monitoring and Measuring	QT9™ Calibration
Element 8.2.1	Customer Feedback System	QT9™ Customer Feedback (Customer Complaints)
Element 8.2.4	Internal Audit	QT9™ Audit Management
Element 8.3	Control of Nonconforming Product	QT9™ Nonconforming Products QT9™ Corrective Actions
Element 8.5.2	Corrective Action	QT9™ Corrective Actions
Element 8.5.3	Preventive Action	QT9™ Preventive Actions