21 CFR Part 820 Compliance

QT9™ Quality Management Software is a one stop FDA quality system compliance 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 FDA quality system requirements and automate your management system making your organization paperless and productive. Look below to see how QT9™ stacks up against the 21 CFR Part 820 standard.

Part 820 Requirement	Description	QT9™ Module/Solution
Subpart B 820.20	Management Responsibility	QT9™ Management Review
Subpart B 820.22	Quality Audit	QT9™ Audit Management
Subpart B 820.25	Personnel	QT9™ Training
Subpart C 820.30	Design Controls	QT9™ Engineering Change Requests/Notifications (ECR/ECN)
Subpart D 820.40	Documented Controls	QT9™ Document Control
Subpart E 820.50	Purchasing Controls	QT9™ Supplier Evaluation QT9™ Supplier Surveys QT9™ Corrective Actions
Subpart G 820.70	Production & Process Controls	QT9™ Product Management QT9™ Inspections
Subpart G 820.72	Inspection, measuring, and test equipment	QT9™ Calibration QT9™ Inspection Modules
Subpart I 820.90	Nonconforming Product	QT9™ Nonconforming Products QT9™ Corrective Actions
Subpart J 820.100	Corrective & Preventive Actions	QT9™ Corrective Actions QT9™ Preventive Actions
Subpart M 820.198	Customer Complaint Files	QT9™ Customer feedback Customer Complaints