













21 CFR Part 211 Compliance

QT9™ Quality Management Software is a one stop FDA quality system compliance solution. QT9™ QMS is 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 & automate your management system – making your organization paperless & productive. Look below to see how QT9™ stacks up against the 21 CFR Part 211 standard.

Part 211 Requirement	Description	QT9™ Module/Solution
 Subpart B 211.100	Management Responsibility	QT9™ Management Review
 Subpart B 211.22	Quality Audit	QT9™ Audit Management
 Subpart B 211.25	Personnel	QT9™ Training
 Subpart A 211.100	Design Controls	QT9™ Engineering Change Requests/Notifications (ECR/ECN)
 Subpart D 211.22	Documented Controls	QT9™ Document Control
 Subpart B 211.84	Purchasing Controls	QT9™ Supplier Evaluation QT9™ Supplier Surveys QT9™ Corrective Actions
 Subpart B 211.110	Production & Process Controls	QT9™ Product Management QT9™ Inspections
 Subpart B 820.72	Inspection, measuring, and test equipment	QT9™ Calibration QT9™ Inspection Modules
 Subpart B 211.192	Nonconforming Product	QT9™ Nonconforming Products QT9™ Corrective Actions
 Subpart A 211.22	Corrective & Preventive Actions	QT9™ Corrective Actions QT9™ Preventive Actions
 Subpart B 211.192	Customer Complaint Files	QT9™ Customer feedback Customer Complaints
 Subpart B 211.192	Risk	QT9™ Risk Assessments

