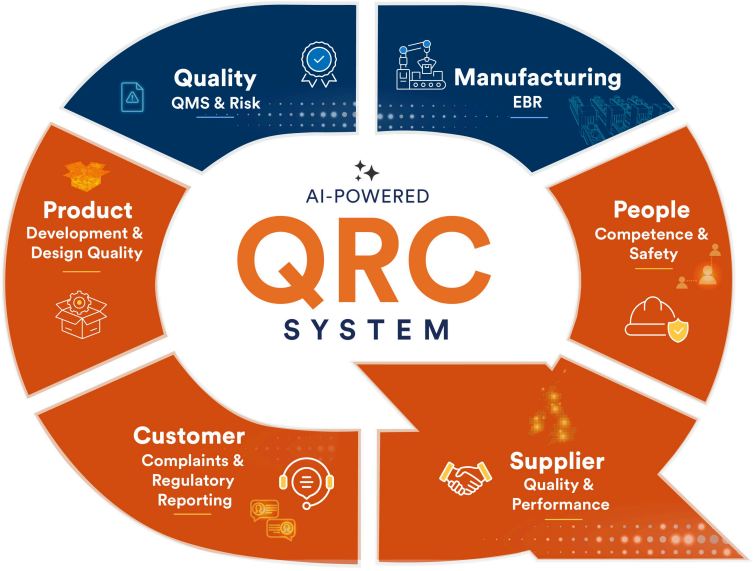
COMPLIANCEQUEST

Connected

Quality, Risk, and Compliance (QRC) for Medical Device Organizations

Quality no longer operates in isolation. Product complexity, evolving regulations, global supply networks, and increasing reliance on external partners require medical device organizations to connect quality, risk, and compliance across the entire product lifecycle.

ComplianceQuest unifies quality, manufacturing, suppliers, workforce safety, customer feedback, and product information on a single AI-powered QRC system. The result is greater visibility, stronger risk management, faster decision-making, and more resilient operations.



From Product to Patient Safety:

#1 AI-Powered Connected Platform for Quality, Risk, and Compliance.

TRUSTED BY LEADING MEDICAL DEVICE ORGANIZATIONS

Canon · Lifescan · IDEXX · Meta · Dentsply Sirona · solventum · stryker

Meeting the Needs of Modern Digital Medical Device

"The future of medical device quality belongs to organizations that can connect knowledge, risk, and decision-making across the product lifecycle and transform that visibility into action."

01 Protecting Product and Process Quality

MEDTECH CHALLENGE

Medical device organizations must ensure that approved procedures are current, understood and consistently executed across every site, shift and role.

CQ RESPONSE

ComplianceQuest connects controlled documents, Digital SOPs, forms, and training, helping teams preserve critical knowledge and translate approved procedures into consistent execution across every site, shift, and role.

KEY CAPABILITIES

- Document Lifecycle Control
- Controlled Forms
- Knowledge Checks and Assessments
- Mobile Access
- Digital SOPs and Work Instructions
- Training and Competency Management
- Electronic Signatures
- Document, Training and Quality Traceability

02 Managing Supplier and Partner Quality

MEDTECH CHALLENGE

Medical device manufacturers depend on component suppliers, contract manufacturers, sterilization providers, testing laboratories, packaging partners, and service organizations whose performance can directly impact product quality, regulatory compliance, and supply continuity.

CQ RESPONSE

ComplianceQuest connects supplier qualification, quality, performance and collaboration, helping organizations identify supplier risk earlier and respond before issues affect manufacturing or product supply.

KEY CAPABILITIES

- Supplier Onboarding and Qualification
- Supplier Audits and Findings
- Supplier Corrective Actions
- Document and Certification Control
- Approved Supplier Management
- Supplier Deviations and Escalations
- Supplier Change Management
- Predictive Supplier Performance

03 Keeping a Pulse on Change

MEDTECH CHALLENGE

Changes to parts, suppliers, specifications, equipment, manufacturing processes, or procedures can affect product quality, design integrity, validation status, patient safety, and supply continuity.

CQ RESPONSE

ComplianceQuest connects change assessment, approval, implementation and verification, providing visibility into affected records, risks, products, parts, tasks and quality controls throughout the change lifecycle.

KEY CAPABILITIES

- Change Requests and Change Orders
- Cross-Functional Impact Assessments
- Historical Change Retrieval
- Implementation Task Management
- Connections to Documents, Training, Equipment and CAPA
- Engineering Change Management (ECN/ECO/ECR)
- AI-Assisted Change Authoring
- Risk-Based Review and Approval
- Verification and Effectiveness Review

04 Maintaining Manufacturing reliability

MEDTECH CHALLENGE

Nonconformances, equipment failures, inspection findings, manufacturing exceptions, and production record discrepancies can disrupt operations, delay product release, and increase compliance risk when managed as disconnected records.

CQ RESPONSE

ComplianceQuest connects manufacturing quality, equipment, inspections, nonconformances, CAPAs, and electronic production records in a unified platform to accelerate resolution, improve visibility, and ensure inspection-ready compliance.

KEY CAPABILITIES

- Nonconformance Management
- CAPA and Effectiveness Reviews
- Equipment, Calibration, and Maintenance
- Manufacturing Exception Management
- Production Genealogy and Lot Traceability
- Investigation and Root Cause Analysis
- Product and Process Impact Assessment
- Incoming, In-Process, and Final Inspections
- Electronic Device History Records (eDHR) with BatchQuest
- Recurrence Monitoring and Audit-Ready Traceability

05 Turning Risk and Audit into Proactive Assurance

MEDTECH CHALLENGE

When risks and audit findings are managed in separate assessments, reports and spreadsheets, medical device leaders lack a complete view of product, process, supplier and operational exposure.

CQ RESPONSE

ComplianceQuest connects risk assessment, audit, findings, investigations and treatment actions, helping organizations move from periodic review to continuous, risk-based assurance.

KEY CAPABILITIES

- Enterprise and Operational Risk Management
- Configurable Risk Matrices and Scoring
- Risk Treatment Plans and Actions
- Audit Findings and Investigations
- Product, Process and Supplier Risk
- Inherent and Residual Risk Assessment
- Risk-Based Audit Planning
- Risk Heat Maps, Dashboards and Trends

06 Accelerating Design Control and Product Development

MEDTECH CHALLENGE

Managing requirements, design controls, risks, product specifications, and regulatory documentation across disconnected systems can slow product development, increase compliance risk, and make traceability difficult to maintain.

CQ RESPONSE

ComplianceQuest connects requirements, design controls, risk management, product structures, and quality processes in a unified platform, enabling faster innovation while maintaining compliance and end-to-end traceability.

KEY CAPABILITIES

- Requirements and Specifications Management
- Design History File (DHF) and Device Master File (DMF) Management
- Risk Management and Design/Process FMEA
- Requirements Traceability
- Digital Thread Across Product and Quality Processes
- Design Controls and Design Reviews
- Product Structure and BOM Management
- Verification and Validation Management
- Connections to CAPA, Complaints, and Quality Events
- Audit-Ready Design Documentation

07 Protecting People, Property and the Product Journey

MEDTECH CHALLENGE

Worker incidents, facility hazards, chemical exposures and operational disruptions can affect manufacturing continuity, equipment availability and product quality.

CQ RESPONSE

SafetyQuest connects safety, environmental risk and corrective action with the broader QRC environment, helping protect the people, facilities and operations behind medical device supply.

KEY CAPABILITIES

- Safety Event and Incident Management
- Safety Inspections
- Corrective Actions and Follow-Up
- Employee and Contractor Safety
- Mobile and frontline reporting
- Near-Miss and Observation Reporting
- Hazard and Operational Risk Assessments
- Chemical and Environmental Management
- Predictive Safety Intelligence

08 Transforming Data into Quality Intelligence

MEDTECH CHALLENGE

Traditional quality metrics show what has already happened. Medical device leaders need to know where performance is changing, what is driving it and where intervention is required.

CQ RESPONSE

CQ Intelligent Analytics and the Quality Maturity Index transform connected quality data into forward-looking intelligence for executives, sites and process owners.

KEY CAPABILITIES

- Quality Maturity Index
- Quality, Compliance and Productivity Metrics
- Impact Analysis for Score Changes
- Cross-Site Performance Comparisons
- Site, Process and Enterprise Scores
- Predictive Quality-Maturity Modeling
- Management Review Control Towers
- Cycle-Time, Trend and Recurrence Analytics

CQ.AI
Purpose-Built Intelligence for Medical Device Quality

Why CQ.AI

Medical device AI must operate with the right context, within governed processes and with accountable experts in control.

CQ.AI is embedded within connected QRC workflows, turning trusted quality data into recommendations, predictions and actions while preserving review, approval and traceability.

39 applied AI use cases in quality

Detect **Generate** **Retrieve & Relate** **Predict** **Recommend**

AI Medical Device Organizations Can Trust

Some of CQ.AI Capabilities

- Conversational Issue and Deviation Reporting
- Investigation Intelligence
- Root Cause and Action Recommendations
- Similarity Search and Recurrence Detection
- AI-Powered Risk Assessments
- Investigation Summaries
- AI-Assisted Change Impact Assessments
- Predictive Quality and Supplier Intelligence
- Next Best Action Recommendations
- Training Assessment and Knowledge Generation

Grounded in connected CQ data and protected by the Salesforce trust architecture, CQ.AI respects role-based access, preserves human review and approval, logs AI assistance and maintains traceability to source records. Customer data is not used to train external AI models.

Humans remain in control.
Review. Decide. Approve.

Business Outcomes Broader than just Compliance

1 FINANCIAL VALUE

$9M+

ROI from EQMS implementation

Global Manufacturing

$400K

Scrap-related cost savings

Medical Device

Lower cost of quality, scrap, labor and system ownership

2 OPERATIONAL PERFORMANCE

90%

Reduction in Deviation Closed

Global Pharma

8% → 1%

Defect-rate improvement

Medical Device

Faster cycle times, fewer defects and stronger right-first-time performance

3 COMPLIANCE & RISK

Zero

Critical Audit Findings

Medical Device

100%

Training completion

Medical Device

Audit readiness, training compliance and standardized controls

4 WORKFORCE PRODUCTIVITY

50%

Faster investigations

Mid-Market Specialty chemicals/ingredients

80%

Fewer Clicks

Global Pharma

Simpler work, fewer clicks, faster approvals and better visibility

Trusted by Industry Leaders

Gartner

Magic Quadrant™ for Quality Management Systems 2026

LEADER
Highest in Ability to Execute

FROST & SULLIVAN

Best Practices Recognition

"Real applied AI that drives hyper-automation and intelligent analytics."

verdantix

Green Quadrant Quality Management Systems 2025

"Strong AI performance Embedded in quality workflows ."

Empowering Medical Device Organizations

One Platform. One Quality Story.

- Connect Product, Process, People, and Suppliers
- Detect Risks Earlier
- Accelerate Quality Decisions
- Maintain Inspection Readiness
- Improve Operational Resilience
- Deliver Safe, Effective Products

Connected QRC Powered by CQ.AI

COMPLIANCEQUEST | salesforce partner

About ComplianceQuest

ComplianceQuest is the **#1 AI-powered Quality, Risk, and Compliance (QRC) system** that connects product, manufacturing, people, and partner quality in a single system. Built on Salesforce, the platform delivers end-to-end visibility, AI-driven intelligence, and enterprise-scale execution, enabling organizations to **prevent risk, ensure compliance by design, and turn quality into a driver of growth.**

By replacing fragmented systems with a single, intelligent platform, ComplianceQuest empowers enterprises with AI-driven automation, real-time insights, and predictive analytics, helping leaders embed compliance, enhance collaboration, and make smarter, faster decisions.

For more information, or to request a demo with a ComplianceQuest expert, contact us today:

- Visit **www.compliancequest.com**
- Email us at **marketing@compliancequest.com**
- Call us at **408-458-8343**