

Quality, Risk, and Compliance (QRC) for Pharmaceutical Organizations

Quality no longer operates in isolation. Product complexity, evolving regulations, global supply networks, and increasing reliance on external partners require pharmaceutical 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 PHARMACEUTICAL ORGANIZATIONS

CURIUM[™]
LIFE FORWARD

Dr.Reddy's

CDC
CENTERS FOR DISEASE
CONTROL AND PREVENTION

SUTRO
BIOPHARMA

Valeris

BIOGARAN

evotec



Meeting the Needs of Modern Digital Pharma

“The future of pharmaceutical 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

PHARMA CHALLENGE

Pharmaceutical 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 | ✓ Digital SOPs and Work Instructions |
| ✓ Controlled Forms | ✓ Training and Competency Management |
| ✓ Knowledge Checks and Assessments | ✓ Electronic Signatures |
| ✓ Mobile Access | ✓ Document, Training and Quality Traceability |

02 Managing Supplier and Partner Quality

PHARMA CHALLENGE

Pharmaceutical companies rely on API suppliers, material providers, CDMOs, contract laboratories, packaging partners and service organizations whose performance can directly affect product quality 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 | ✓ Approved Supplier Management |
| ✓ Supplier Audits and Findings | ✓ Supplier Deviations and Escalations |
| ✓ Supplier Corrective Actions | ✓ Supplier Change Management |
| ✓ Document and Certification Control | ✓ Predictive Supplier Performance |

**03**

Keeping a Pulse on Change



PHARMA CHALLENGE

Changes to materials, processes, suppliers, specifications, equipment or procedures can affect product quality, validated state, training, regulatory commitments and supply reliability.

CQ RESPONSE

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

KEY CAPABILITIES

- ✓ Change Requests and Change Orders
- ✓ AI-Assisted Change Authoring
- ✓ Risk-Based Review and Approval
- ✓ Verification and Effectiveness Review
- ✓ Cross-Functional Impact Assessments
- ✓ Historical Change Retrieval
- ✓ Implementation Task Management
- ✓ Connections to Documents, Training, Equipment and CAPA

04

Maintaining Manufacturing reliability



PHARMA CHALLENGE

Deviations, equipment failures, inspection results and batch exceptions can delay release and increase regulatory exposure when managed as disconnected records.

CQ RESPONSE

Deviations, equipment failures, laboratory events, inspection results and batch exceptions can delay release and increase regulatory exposure when managed as disconnected records.

KEY CAPABILITIES

- ✓ Deviation and Nonconformance Management
- ✓ CAPA and Effectiveness Reviews
- ✓ Equipment, Calibration and Maintenance
- ✓ Electronic Batch Records with Pharma BatchQuest
- ✓ Investigation and Root Cause Analysis
- ✓ Product and Process Impact Assessment
- ✓ Incoming, In-Process and Final Inspections
- ✓ Recurrence Monitoring and Inspection-Ready Traceability



05

Turning Risk and Audit into Proactive Assurance



PHARMA CHALLENGE

When risks and audit findings are managed in separate assessments, reports and spreadsheets, pharmaceutical 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 Laboratory OOS & OOT Investigations



PHARMA CHALLENGE

OOS and OOT results require scientifically sound investigations that support batch disposition, regulatory compliance, and product quality.

CQ RESPONSE

ComplianceQuest connects laboratory investigations with quality events, CAPA, risk, change control, and equipment histories to accelerate investigations and strengthen inspection readiness.

KEY CAPABILITIES

- ✓ Laboratory event tracking
- ✓ Phase I & II Reviews
- ✓ Root Cause Analysis
- ✓ Laboratory & Manufacturing Collaboration
- ✓ Inspection-Ready Documentation
- ✓ OOS & OOT Investigations
- ✓ Guided Investigation Workflows
- ✓ Product Impact Assessments
- ✓ deviation & CAPA Escalation
- ✓ Complete Investigation Traceability

**07**

Protecting People, Property and the Product Journey



PHARMA 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 pharmaceutical 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



PHARMA CHALLENGE

Traditional quality metrics show what has already happened. Pharmaceutical 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 Pharmaceutical Quality

Why CQ.AI

Pharmaceutical 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 Pharmaceutical 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



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 Pharmaceutical 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



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**

