



Counterpoint AI

**THE CONTROL SYSTEM
FOR REGULATED
OPERATIONS
THAT PROPAGATES
CHANGE
AUTOMATICALLY
CONTINUOUSLY
MAINTAINING
YOUR COMPLIANT STATE**

**CROs · CDMOs · Sponsors
Clinical · Quality · Regulatory**

The operational and regulatory burden on life sciences organizations is growing

- Protocol amendment frequency alone has increased 60% since 2015
- From 2013–2019, the number of countries and investigative sites engaged per protocol increased 44% and 63%, respectively
- ICH E6(R3) increases sponsor accountability for delegated activities and service providers
- QMSR requires documented evidence of personnel qualification, not just training completion

Yet organizations still depend on manual coordination across disconnected systems, documents, and people

Business Impacts

Cost	Scarce resources spent on manual coordination and administrative overhead
Compliance	Increased risk of inspection findings, sponsor escalations, reputational damage
Capacity	Inability to safely increase studies, sites, programs, and sponsor relationships
Deferred revenue	Delayed sponsor revenue realization and reduced asset value

And deploying ungoverned AI only deepens the problem

- AI content generation is subject to drift, and human content review is subject to automation bias
- AI generates artifacts too fast for quality teams to control them under manual governance processes

The Control System for Regulated Operations



A SYSTEM OF ACTION that maintains the organization's operational state automatically by:

Building a governed operational model from approved policies, regulations, and qualification requirements

Generating training, assessments, qualification evidence, and documentation automatically when change occurs

Synchronizing with systems of record to continuously maintain inspection readiness

QMS, CTMS, and RIM are SYSTEMS OF RECORD

- Essential infrastructure
- Store operational history and compliance evidence
- **Cannot reason about that information or do the work required to maintain operational readiness**

Counterpoint and Systems of Record form a complete operational system

- ✓ Systems of Record retain what happened
- ✓ Counterpoint determines what must happen next — and does it

The New Regulated Operations Infrastructure



QMS

CTMS

RIM

Automating the Operational Response to Change

Counterpoint replaces manual coordination and reduces compliance risk across common life sciences change events such as

- ✓

Protocol Amendments
- ✓

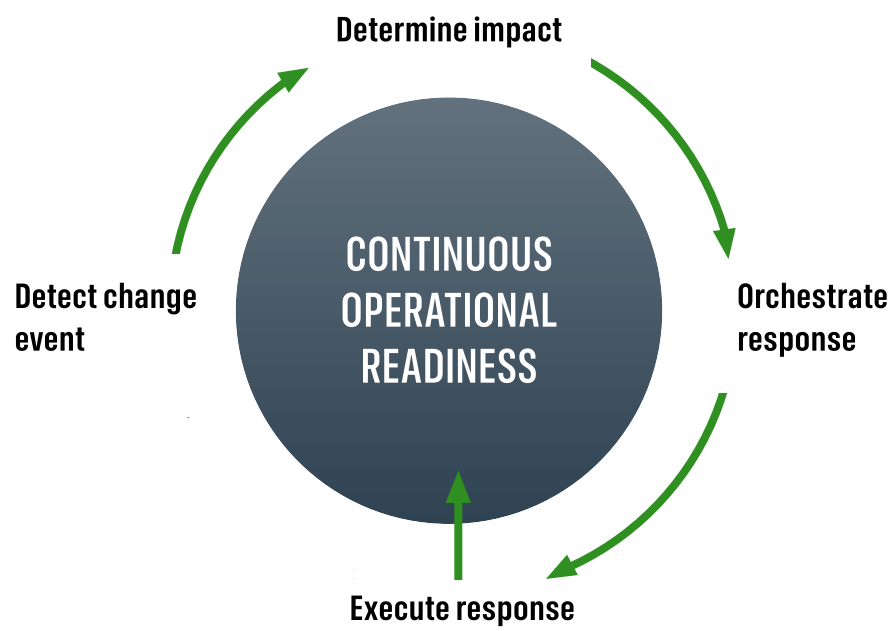
SOP Revisions
- ✓

Regulatory Updates
- ✓

New Site Activations
- ✓

CAPAs & Quality Events
- ✓

Vendor & System Changes



Protocol Amendment Example

1	Detects change	Evaluates a new study requirement and proposes that a protocol amendment is required
2	Determines impact	Identifies affected sites, roles, competencies & required actions for each to close new compliance gap
3	Generates & qualifies	Produces documentation, training materials, assessments, qualification thresholds, scoring
4	Governs & speeds expert review	Presents system proposals alongside scoping & decision rationale traced back to sources
5	Maintains governed state	Keeps decisions and qualifications connected to operational model and inspection-ready at all times

Governance by Design

Counterpoint automates governed operational readiness from end to end across documents, people, and systems — with full traceability and human oversight precisely where expert judgment is needed

Governance-First

Counterpoint determines the operational consequences of change before generating documents, training, or assessments

Human Judgment Where It Matters

Your experts review system proposals with evidence, rationale, and governing rules surfaced in context

Closed-Loop Traceability

Every change is connected to objective evidence, role-based approvals, and competency qualification, creating a continuous audit-ready record

Continuous Compliance

Counterpoint is actively working all the time to maintain your compliance in the face of change



Counterpoint AI

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