

# VECTOR QUALITY SCIENCES

Risk-Based Quality Management Consulting

## Our RBQM Implementation Process

A proven 7-step methodology refined through dozens of Phase I-IV clinical trial implementations. Each phase builds on the previous to create a comprehensive quality ecosystem.

### 01 Risk Assessment & RACT Facilitation

2-4 weeks

Structured risk identification and categorization aligned with ICH E6(R2)/E8(R1). Deliverables include comprehensive risk register and stakeholder-aligned quality tolerance limits.

### 02 KRI Design & Threshold Configuration

2-3 weeks

Custom Key Risk Indicator specifications with statistically justified thresholds. Includes alert escalation matrix and response protocols.

### 03 Platform Setup & Configuration

3-6 weeks

Full configuration of your RBQM platform (Medidata Detect, CluePoints, Veeva, or custom). Includes data integration and validation documentation (IQ/OQ).

### 04 Quality Signal Detection & Monitoring

Ongoing

Real-time dashboards, automated alerts, and weekly/monthly trend reports. Signal triage workflows ensure proactive issue identification.

### 05 Investigation & Mitigation

As needed

Structured root cause analysis and CAPA planning. Site-specific interventions with documented resolution tracking.

### 06 Documentation & Reporting

Ongoing

Audit-ready RBQM summary reports for regulatory submissions. Complete audit trail and quality metrics documentation.

### 07 Continuous Improvement

Quarterly

Regular performance reviews, KRI effectiveness assessments, and threshold optimization. Evolving process improvement roadmap.

## Ready to Start Your RBQM Journey?

Schedule a consultation: [vectorqualitysciences.com/schedule](https://vectorqualitysciences.com/schedule)