

Organizational Level

Corporate Quality and Strategic Objectives

Quality Management System (QMS)

Sourcing

- Fully Outsourced
- Hybrid
- Internalized

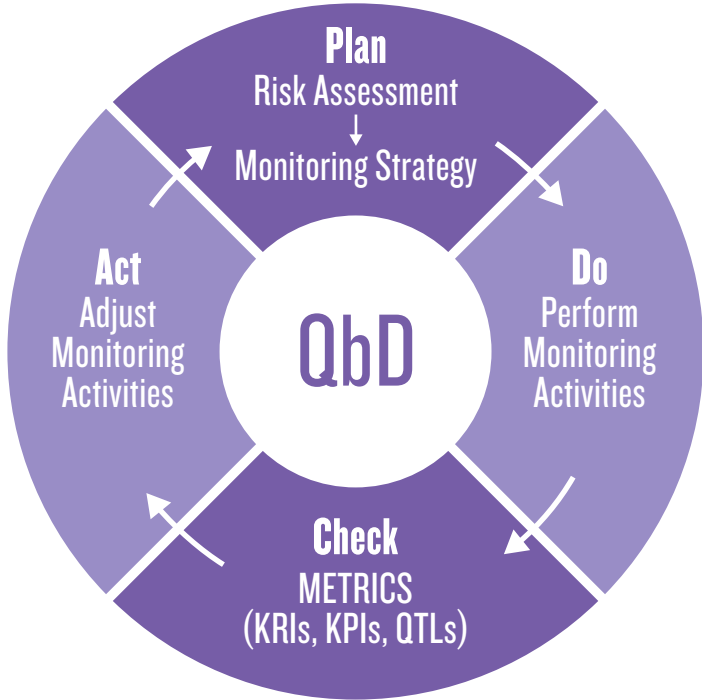
- Knowledge Management
- Issue Management
- Documentation
- Roles & Responsibilities
- Technology
- Quality Metrics
- Policies/Procedures
- Risk Management

Key Performance Indicators (KPIs)

Communication Pathways

Quality by Design (QbD)

Critical to Quality Data (CtQ)



Risk Control Mechanisms

Risk Based Monitoring (RBM)

- Onsite Monitoring
 - Reduced SDV/SDR
- Centralized Monitoring
 - Centralized Statistical Monitoring
 - Central Data Monitoring
 - Off-site/Remote Monitoring

Study/Trial Level (Sponsor/CRO)

Quality Tolerance Limits (QTLs)

Key Risk Indicators (KRIs)