



Quality Risk Management Associates, LLC

Business Portfolio

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Quality Risk Management Associates, LLC
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5 Derbyshire Lane Somerset, New Jersey 08873
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About Quality Risk Management Associates, LLC

Quality Risk Management Associates provides expert quality risk management, quality assurance and regulatory compliance support to the pharmaceutical and biotechnology industries around the world. With broad expertise in all phases of pharmaceutical development- from R&D through distribution and associated regulations focused on GxP, Quality Risk Management Associates ensures regulatory compliance and minimizes risk across the clinical development process.

Quality Risk Management Associates have demonstrated the ability to strengthen an organization by proactively accelerating risk identification and detection and resolving issues before they manifest as real problems. This has been accomplished by successfully transforming traditional auditing methods by spearheading innovative quality risk management and compliance systems and driving new governance and control standards that help business partners *proactively* identify, manage, and mitigate risk. Collaborating closely with Clinical Research, Medical Affairs and Safety personnel and working with business partners and regulators, we have created an environment that promotes risk awareness and elevates risk mitigation while focusing on customer needs aimed to improve overall compliance while ensuring confidence of data leading to safe and efficient delivery of medicines to patients.

Achievement highlights include development of quality risk management and mitigation models, tools and information management systems utilizing Six Sigma techniques, process optimization (Operational Excellence & LEAN techniques), elevated quality management efficiency and process auditing approaches through sound risk-based strategies.

Quality Risk Management Associates provides over 10 years of leadership and management experience including training, developing, mentoring in quality assurance/regulatory compliance in a GxP environment and inspiring highly effective quality management staff and teams by harboring superior work ethics and a commitment to excellence that optimizes measurable outcomes and leadership potential. Our innovative senior consultants have over two decades of quality assurance and quality management experience working in the pharmaceutical/biotechnology industries all with excellent analytical, problem-solving and conflict resolution skills.

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Our Services

Quality by Design
Quality Risk Management
Quality Assurance & Compliance
Pharmaceutical Clinical R&D
ICH GCP, ICH Q9 & Q10
FDA Regulations
EU Clinical Trial Directives
European Medicines Agency
Health Authority Regulations
Health Authority Inspections
QA Audits & Inspections
Audit Plan Development

Risk Based Monitoring
Due Diligence
Pharmacovigilance (Safety)
Systems Validation
Vendor Management
Personnel Management
Leadership Development
Diversity Management
Proactive Management
Team Leadership
Team Building
Organizational Development

QA / QC Conceptualization
Customer Service
Client Needs Assessments
LEAN/6 Sigma
Process Improvement
Procedure Development
Strategic Innovation
Strategic Planning
Research & Analysis
Compliance Direction
Creative Problem-Solving
Conflict Resolution

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Highlights/Core Objectives

A solid track record of transforming traditional quality assurance and quality control methods into prospective concepts using a risk-based approach to quality management. Foster a culture of proactive risk management, transparency, and continuous process improvements within the firm. Accomplished through creation of new governance and control standards, development of risk management tools, policies, procedures, and thorough understanding of pharmaceutical R&D regulations, along with exceptional communication and business support.

- Elevate risk awareness inherent in clinical research development by communicating and instilling a quality management philosophy that proactively—rather than reactively—analyzes, identifies, and minimizes risks across the board.
- Transform traditional quality assurance philosophy by applying operational excellence and LEAN 6 Sigma techniques, resulting in a risk-based approach to quality management.
- Champion innovative Quality Risk Management (QRM) systems, analytical tools, and QC/QA governance model that have become the driving force to detect, prioritize, manage, and resolve risks in high-risk areas.
- Spearhead internal process optimization initiatives by identifying best practices and methods to support a process audit approach within Quality Assurance.
- Assess and diagnose all risk and compliance issues early on thus ensuring timely implementation of corrective and preventive actions.
- Work with a wide range of clientele handling difficult customer problems in a courteous, positive, knowledgeable, and professional manner.
- Coach, motivate, and develop a winning quality management staff and other quality area teams through effective team building and communication resulting in a superior work ethic and a commitment to excellence.

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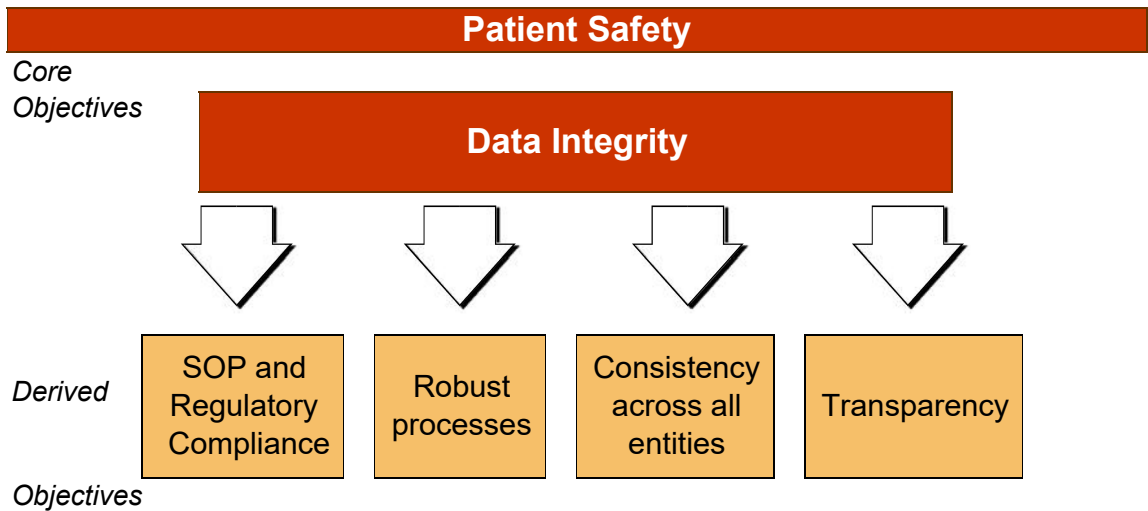
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The objective of quality risk management is to ensure safety of patients and integrity of data

Objectives of Quality Risk Management in GCP & Pharmacovigilance



Capabilities/Scope

Quality Risk Management Associates provides expert consulting support in the following areas. Risks in each area are assessed proactively and on a continuous basis.

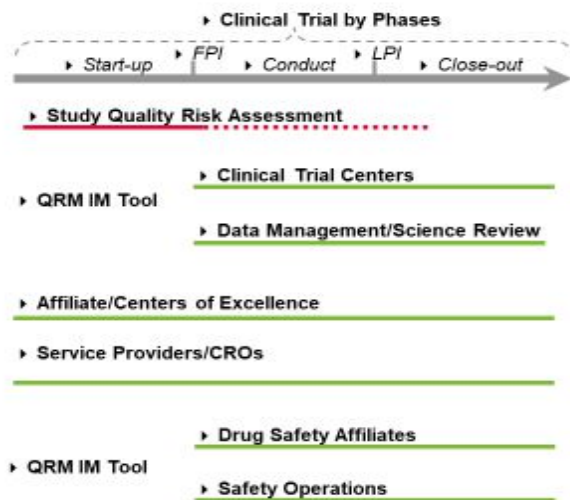
RISK ENTITIES (PROACTIVE RISK ASSESSMENTS)

- **Study/Protocol:** Assesses risk at study design and set-up, prior to protocol approval and site initiation. Monitors for ongoing risks during study execution as well.
- **Trial Sites:** Assesses key risk indicators and critical quality metrics, including data at investigational sites.
- **Data Management:** Assesses good clinical practice data quality on a study level.
- **Science Review:** Assesses risk on a scientific and medical level with focus on study data quality and completeness, including efficacy and safety results.
- **Affiliate/Centers of Excellence:** Assesses study management risks at the operational levels within a global organization.
- **Service Providers/CROs:** Assesses risk at service providers and CROs in support of all operational areas, including systems and processes involved in study development, study management and safety reporting.
- **Pharmacovigilance (Drug Safety) including Safety Operating Centers:** Assesses pharmacovigilance (including post marketing surveillance) and clinical trial safety reporting through established key risk indicators required by regulation.

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Analytical QRM tools which cover risks across the different entities and phases of clinical trials and safety reporting

Scope of Quality Risk Management (QRM)



QRM Risk Area	Entity	Focus
Study Quality Risk Assessment	Study / protocol	Study set-up
Clinical Trial Centers	Study center /investigator site	Good Clinical Practice
Data Management/Science Review	Study / protocol	Good Clinical Practice Data quality
Affiliate/Centers of Excellence	Affiliate	Study Management
Service Provider/CRO Assessment	Service Provider/CRO	All operational areas (systems, processes)
Drug Safety in Affiliates	Affiliate	Pharmacovigilance Clinical safety
Safety Operating Centers	Processing center Med. Eval. Group	Pharmacovigilance Clinical safety

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Clients We Serve

Quality Risk Management Associates serves a diverse, cross-cultural base of global clients that include pharmaceutical, biotechnology and biopharma companies as well as service providers and contract research organizations. Clients range in size from start-ups to multinational corporations. Quality Risk Management Associates consistently provides high-quality management expertise and risk-based approaches for clients of virtually any size, geography or specialty including:

- The world's largest pharmaceutical companies
- Biotechnology companies
- Biopharma companies
- Emerging pharmaceutical/biotechnology companies
- Service providers
- Contract Research Organizations
- Government Health Funded Organizations
- Collaborative/Cooperative Groups

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Innovative Solutions

Quality Risk Management Associates helps organizations to proactively identify, manage and mitigate risks to prevent and resolve compliance problems and to develop efficient and effective strategies. The benefits of our services include early detection of risks, providing a broader reach than traditional quality assurance and quality control methods can obtain and performing deeper insights with regards to quality risks and compliance within an organization.

- **Early detection:** allows the ability to correct issues in a more timely fashion, avoids large costs by addressing risks and compliance concerns proactively-rather than reactively- which minimizes risk across the board ensuring business continuity.
- **Broader Reach:** a more comprehensive risk landscape, issue detection and effective risk mitigation system in a continuous fashion, risks that are quantifiable through established risk-based methodologies (Six Sigma) and focused allocation of resources to the areas of highest risk and immediate need.
- **Deeper Insights:** leads to a more defined approach and detection of systematic issues, providing continuous and meaningful trend and pattern analysis reports, and prioritization of risks. Foster an environment of continuous process improvement and knowledge sharing in the firm leading to risk-based approaches to pharmaceutical development and clinical trial management.

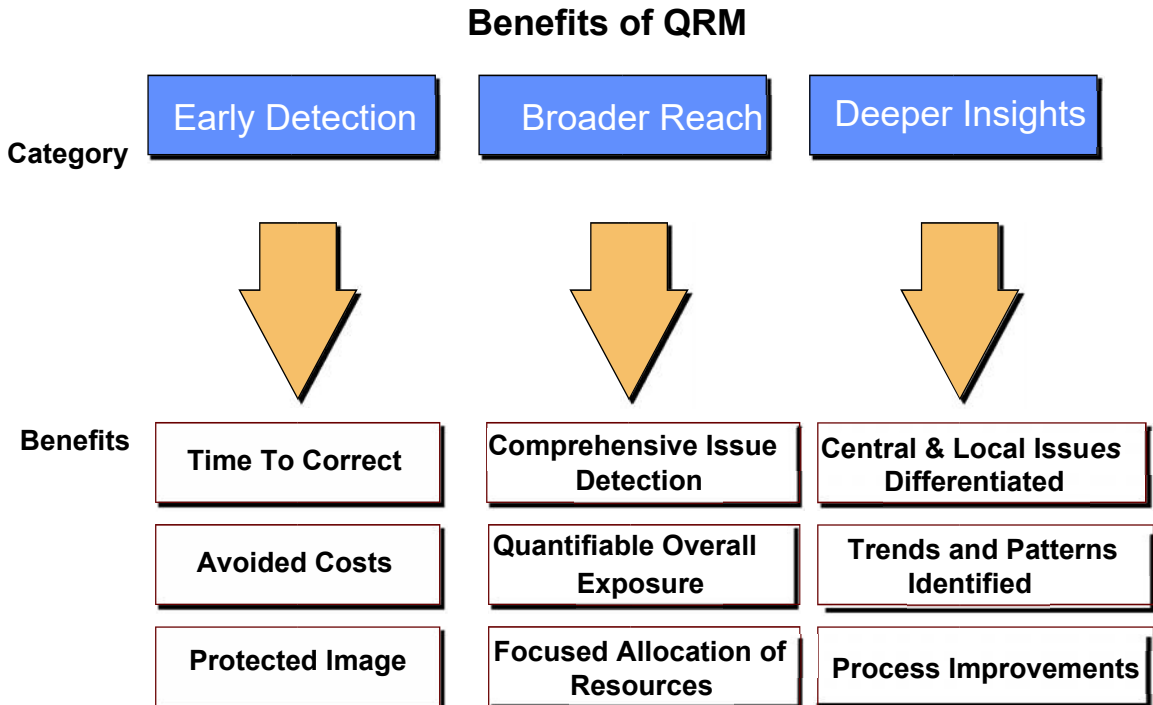
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The benefits of the QRM system include early detection, broader reach and deeper insights with regards to quality risks



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