



Risk mitigation, Value maximization in M&A

KPMG Quality and Compliance services



KPMG supports life sciences organizations through every step of the M&A transaction.

Quality serves as the cornerstone of the life sciences sector, ensuring the production of high-quality products that meet regulatory standards, safeguard patient safety, and mitigate risks associated with product deficiencies and recalls.

Across the stages of M&A, we advocate for an increased focus on the “quality” function within the life sciences sector. Recognizing its significant interdependence with manufacturing, supply chain, regulatory, and financial operations underscores the necessity of early risk and opportunity identification for streamlined integration and divestiture planning.



Target examination

Discover acquisition targets based on strategic criteria.



Day 1 integration

Plan, execute, and manage business functions and processes on the day the deal closes.



Target information review

Evaluate details of the target company to determine whether to pursue acquisition.



Postmerger integration

Align the acquiring company's operations, systems, and processes with the target.



Due diligence

Appraise the potential strengths and weaknesses of the object of the transaction.

We advocate for an increased focus on the “quality” function within the life sciences sector

Potential benefits of quality due diligence

- Early identification of target company's quality policy, quality manual, and quality management systems
- Insights into quality assurance and quality control processes
- Insights into quality contract risks, supply chain integrity, and quality compliance status
- Insights into company's quality culture, quality's organizational structure, workforce turnover, workforce skill set, and training programs
- Insights into post market surveillance process and product recall procedures

Risks of not conducting quality due diligence

- Failure to uncover past and existing quality deficiencies and noncompliance with regulatory health agencies regulations that can have a systemic impact to the acquiring company's reputation and standings
- Increased liability exposure due to quality related issues
- Regulatory noncompliance leading to financial penalties, market withdrawals, and stoppages to new market approvals



Potential benefits of quality integration and divestiture strategy

- Thorough QMS integration, ensuring compliance and preventing supply disruptions
- Remediation efforts prioritized and executed commensurate of risk
- A right-sized organizational structure and operating model that captures the value drivers of the deal
- Receptive suppliers adjusting to new quality requirements

Risks of neglecting quality in integration/divestitures

- Quality control gaps leading to product disruptions and supply delays
- Contradictory and ambiguous priorities within the Quality Management System
- Overlooked indicators of product quality and noncompliance resulting in escalating scrutiny from the health agencies

Early identification of target company's quality policy, quality manual, and quality management systems are potential quality due diligence benefits

How we have helped our clients

A global pharmaceutical manufacturer sought help with their quality operations and compliance due diligence to acquire a target company's manufacturing site:

- Conducted an extensive analysis of risk considerations for all subsystems of the Quality Management System before integration planning and execution
- Strategized to integrate a target's manufacturing site into their operations under a specific deal type
- Provided findings to help the acquiring company develop tailored and thorough provisions in the Transition Service Agreement (TSA) and an integration strategy method and project roadmap

A global pharmaceutical manufacturer sought help for quality operations and compliance due diligence to acquire a Phase 2 pharmaceutical company:

- Conducted an extensive analysis of risk considerations for all subsystems of the Quality Management System for the client to consider before integration planning and execution
- Highlighted key considerations and risks while evaluating their effort and impact associated with integrating a target company into the primary elements of acquirer's Quality organization
- Assessed the cost implications and budgetary considerations associated with integrating the target company's Quality Management System

Why KPMG?

We are an experienced Quality M&A team that can enhance buyer's efficiency in integrations.

Our seasoned members help ensure quality and compliance across regulatory agencies.

We provide excellence in remediation through meticulous analysis and a risk-based approach.

We can help companies maintain high quality standards during integration.

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