

Risk Mitigation, Value **Maximization in M&A**

KPMG Manufacturing, Quality, and Regulatory services



regulations.

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

Manufacturing, quality management, and regulatory affairs are intertwined functions that should be approached and viewed holistically rather than individually during the M&A transaction stages since product must be manufactured under

We advise our clients to prioritize these bedrock functions since they are fundamental to the core operations and success of companies.

strict quality standards and applicable laws and

During M&A stages, evaluating manufacturing for compatibility and efficiency is vital for thorough integration, maintaining production levels, and meeting customer demand. Simultaneously, assessing quality systems and harmonizing processes mitigates risks to product quality and noncompliance. Regulatory affairs play a crucial role in navigating the complex regulatory landscape, ensuring compliance, and securing necessary approvals for company products.

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Target examination

Discover acquisition targets based on strategic criteria.



Target information review

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



Due diligence

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



Day 1 integration

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



Postmerger integration

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

The potential benefits of prioritizing manufacturing, quality, and regulatory across the M&A stages include:

Potential benefits

- Early identification of the target company's manufacturing and supply chain processes, technologies, infrastructure, quality management systems, compliance to quality standards and regulations, operational performance, and talent
- Thorough operating model integration, enhancing operational efficiencies while ensuring compliance and supply continuity
- · Early identification of the target company's documentation, licenses, permits, and compliance status with applicable health agencies

Risks

- Neglecting or downplaying the assessment of operations can directly influence a company's revenue-generating activities, specifically centered around developing and selling high-quality products
 - Failure to uncover past and existing quality deficiencies and noncompliance with regulatory health agencies' regulations can have a systemic impact to the acquiring company's reputation and standings
 - Network supply chains and production attainment can be disrupted



How we have helped our clients

We helped a global pharmaceutical manufacturing and operations organization with functional due diligence to acquire a target company:

- On-site due diligence audit provided objective feedback on technical, operations, and compliance capabilities
- Enhanced understanding of target's operational landscape and key risks for deal negotiations
- Guided focus on critical areas for remediation and strengthening post-deal close

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

- Conducted extensive analysis of risk considerations for all elements of the quality management system
- Helped the company develop its strategic integration planning and execution for target's manufacturing site under a specific deal type

We led the separation of a leading diagnostics company:

- Developed the product registration, labeling change, and ISO certification strategy for the separation of a leading In-Vitro Diagnostic organization
- Organized and supported "Day 1" readiness assessment process

Why KPMG?

We have a dedicated M&A team with extensive due diligence, integration, and separation experience.

Our multidisciplinary team spans various operational disciplines.

We apply rapid mobilization of governance models for a successful transactional execution.

We implement leading practice methodologies for consistent and efficient problem-solving.

Contact us:



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