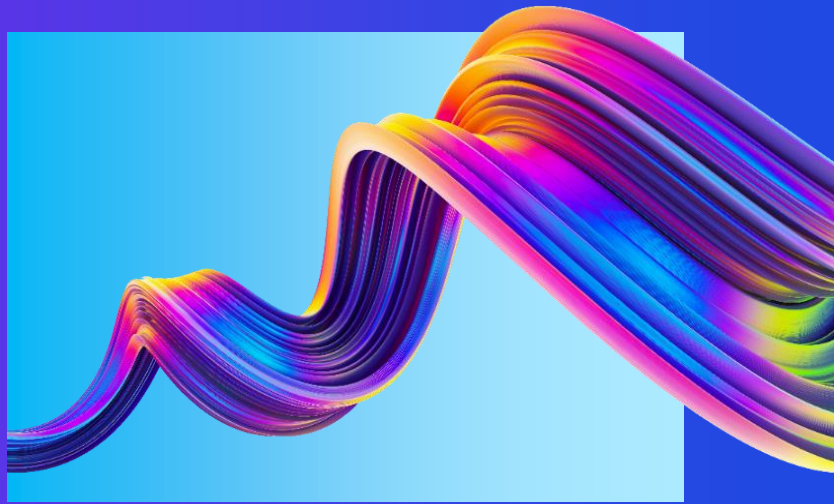




Third Party Risk Management in Life Science

Navigating a complex environment into the future



An Unprecedented Challenge

The global life sciences sector faces an unprecedented challenge in today's post-pandemic, geo-politically unstable environment to deliver a cost-effective risk management strategy in an increasingly complex environment. Risk management is critical at an operational level throughout the product lifecycle, where clear regulatory requirements dictate behaviours. Life Science companies must also ensure that all of their third-party relationships adhere to regulatory requirements globally.

Complex Ecosystems of Stakeholders

Life science companies typically have a complex ecosystem of stakeholders. Factors such as a lack of integration of legacy businesses and technology systems, R&D and business functions operating in silos and evolving internal risk landscapes compound this complexity.

A Focus on Risks That Matter Most

From discovery through to product launch and administration to patients, risks are embedded in the life science product lifecycle. Life science companies need to carefully manage critical stakeholder relationships whilst maintaining compliance with global regulation which is continuously evolving. A clear focus on risks that matter most to the organization and regulators is key.

Risk management levers

A combination of levers are required to manage risk effectively, including:

- Third party risk management with KPIs and SLAs
- Managed services
- AI and risk automation
- Risk management assurance
- Quality management systems
- Standard operating procedures
- Internal
- External audit

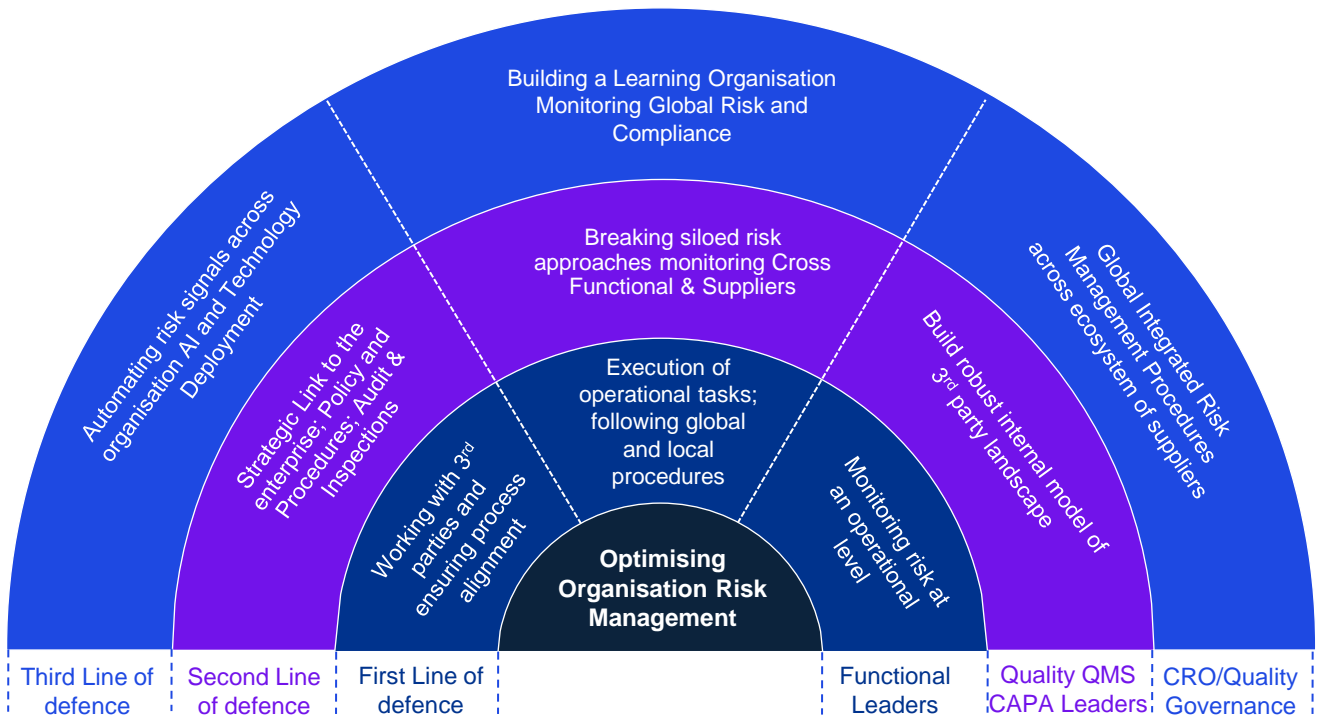
Data integrity and cyber security across the ecosystem of stakeholders are also critical to ensuring appropriate risk management.

- Non-compliance with regulatory commitments
- Government affairs, lack of awareness of geopolitical situations
- Loss of public trust
- Damage to brand value
- Safety issues unreported
- Manufacturing defects not acted upon
- Compromised data quality
- Not adhering to global regulatory compliance



- Restrictions on studies, legal, operational risk
- Delay in approval, unable to market product
- Product withdrawals or suspension
- Inappropriate promotion
- Missed safety signals
- Incorrect patient information materials
- Product defects

Traditional risk defence architecture in life science is often siloed and driven by manual quality reconciliation



Future Trends For Life Science Risk Management Solutions

Risk management in the life science sector is enshrined in global regulatory frameworks and a careful analysis of risk benefit at the product level is the foundation for the sector. Life science organisations have unique challenges with operational teams that must meet prescriptive regulatory requirements that have evolved into complex silos of risk domains within organisations and external third parties.

The future of effective life science risk management will incorporate a holistic approach to facilitate risk assessment at an organisational rather than a functional level. Life science organisations must also be able to monitor risks continuously and capture risk learnings during the lifecycle of their assets to ensure ongoing control improvements. Agile technology that can assimilate data across different data platforms should also be adopted to provide real time metrics and use AI to identify and monitor both single and systemic risks across the organisation to ensure that risk is managed as part of organisational strategy.



How we can help

KPMG works with Life Science companies in selecting appropriate partners and identifying impacted quality processes and procedures.

KPMG recently worked with a client to understand the scope and risks for services that were to be outsourced in future. KPMG articulated the overarching guiding principles, requirements and standards for a successful relationship with service providers whilst managing the complex third party risk impact.

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