Life Sciences Third-Party Compliance in the Asia Pacific

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The drive to grow top-line and improve bottom-line has seen Life Sciences companies in the Asia Pacific region turn to third parties for many aspects of their business operations – these range from research, manufacturing and supply chain to sales & marketing and various support functions. With this, comes significant new risks.

Expansion into geographic territories introduces new third-party vendors with unverified governance standards, thus giving rise to new and unforeseen risk for Life Sciences companies. An additional layer of complexity arises when the third parties themselves operate within a web of vendor networks.

Reliance on third-party interactions can spell significant risks in the areas of kickbacks, off-label promotions, policy adherence, cyber security, and unhealthy relationships with clinical research organizations and contract manufacturers. In fact, pressure to bribe officials or customers has been reported by numerous Life Sciences companies operating in the Asia Pacific region.

This article looks at the various challenges faced by Life Sciences companies in the Asia Pacific region when it comes to managing third-party vendors, as well as how KPMG can ensure more efficient and effective procedures to address such matters especially with advanced analytical techniques becoming available.

Regulations are more stringent, but still complex

In July 2018, the U.S. Department of Justice announced that its Healthcare Fraud unit and Foreign Corrupt Practices Act would partner to probe companies that "might be bribing foreign governments". Subsequently, the Asia Pacific region saw a slew of anti-corruption and transparency regulations enacted, in addition to more stringent codes of conduct. South Korea is the latest country in the region to roll out its own transparency regulations, joining Australia, Indonesia, Japan, and the Philippines.

As governments tighten anti-bribery and anti-corruption efforts, third-party vendor management poses perhaps the greatest challenge for companies. KPMG's research has highlighted concerns on the capacity and capability of Life Sciences companies to audit their third parties and to conduct proper due diligence. Among the respondents from the Asia Pacific region, only 40 percent had a formal process for identifying high-risk third parties. Moreover, more than half of the respondents with right-to-audit clauses over third parties have never exercised these rights.

Failure to address such vulnerabilities can lead to financial loss, cost overruns, and legal and reputational risks due to poor governance exhibited by third parties. For example, one pharmaceutical company paid more than US$25 million to resolve charges that its subsidiaries made corrupt payments to win business in the Asia Pacific region. In another case, a medical device company paid over US$6 million to settle charges that its subsidiary had used high discounts and improper payments to induce doctors under government employment.

Managing third parties comes with a wheel of risks

Closing the gap with advanced analytical techniques

While many in the industry have stepped up their assessments of third parties, gaps between the accountable company's management guidelines and those of the third party still exist. According to KPMG's research, 75% of Life Sciences companies have insider threat programs covering employees, contractors and third parties, but two-thirds of these programs are in the developmental stage. The process is typically a manual effort which starts with internal audits for a small sample size coupled with periodic review meetings; this approach is slow and generates false positives as well as misidentification.

In KPMG's opinion, the screening of third parties can be simplified through the use of artificial intelligence (AI) and machine learning (ML) tooling. AI/ML is designed to conduct natural language processing and sentiment analysis replicating the way human analysts carry out research, but faster and more consistently. In the same way, due diligence searches using AI/ML therefore reduce the time needed to review each third party file. Scaling up the volume of searches is also effortless, as there are no constraints on the amount of data, correlations, or number of sources to be analyzed.

Besides outsourcing the screening process, AI/ML solutions are cloud-based and can be integrated into existing company workflows. These solutions reduce the overall cost of compliance and free up staff to focus on more important strategic programs. As a result, compliance teams are now able to undertake training to up-skill and to focus on new emerging regulatory risks.

Benefits of using AI/ML to screen third parties

Save money

Increase accuracy

Save time

- Dynamically assess third-party information
- Conduct rules-based due diligence
- Apply a consistent approach to risk across your organization
- Ensure effectiveness and defensibility of your programme

Let's use the financial services industry as an example: anti-money laundering and anti-counterfeiting efforts have seen a revolution in the use of data and analytics. Bespoke mathematic models can take into consideration the unique characteristics of each financial institution in order to process first-level reviews of customers and transactions with greater accuracy and efficiency.

These models also look at an infinite number of money laundering scenarios which are beyond the human imagination, thus overcoming the rigidity of rules-based monitoring in a world of fast-changing typologies.

In the Life Sciences industry, KPMG's experience in the Asia Pacific has begun to traverse a number of enablers such as case management, data visualization, robotic process automation, and fraud risk scoring. Our use cases have included procurement, vendors with the same director, non-apparent conflicts of interest, suppliers providing several unrelated services, and even Benford manipulations. Much of this would be very difficult to achieve without advanced analytics and computing power.

For instance, one Life Sciences organization sought to find instances of misconduct in the procure-to-pay process. KPMG was able to process five years of historical data across more than 100 analytical scenarios. This ongoing data visualization technique allowed management to focus on the anomalies, reducing processing time by 40 percent (or an equivalent time reduction from 30 hours to one hour). These tools can also auto retrieve from source systems, run 24/7 tests, and provide real-time insights.

Activating your gameplan

Manual processes and adding headcount will never be enough. As such, Life Sciences companies must start to trust AI/ML to support their third-party risk management. This requires buy-in from the top. Leadership is critical to set the correct compliance culture within an organization and to instill accountability to do business the right way. While governments are starting to utilize analytics, they still rely on industry experts to spot the misconduct.

There are a few ways Life Sciences companies in the Asia Pacific region can get going:

1. Be a regional proof of concept (PoC) innovation for your company;
2. Run a data dump test through the analytical engines for exploration;
3. Identify areas of concern, and design new approaches to risk management accordingly.

KPMG

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