

Managing the Risks of Third Party Intermediaries





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Corruption risks shift and expand alongside market opportunities and business models. For the Life Science industry, reliance on product suppliers, contract CROs and CMOs, and sales agents has been a fact of life for many years. This emerging "fact of life" expands the use of outsourcing substantially to include business functions more commonly associated with corporate operations. The result is a rapidly growing reliance on Third Party Intermediaries (TPIs) who can range from lawyers and accountants to customs facilitators, procurement agents, consultants, distribution companies and government advisors. In short, a TPI is any individual or organization that performs a service on behalf of a company.

How Much Risk?

More than ever before, Life Science companies would be hamstrung without TPIs to negotiate contracts, obtain permits, provide legal and tax advice, manage facilities and perform other business functions. Yet, despite the value TPIs bring to global companies, they also have played starring roles in some of the most highly publicized global corruption investigations. Perhaps the most high-profile evidence of TPI risk is the breakdown of GSK's China operation because of the actions of a local travel agency providing third-party services to GSK. But don't think TPI risk is reserved for GSK or China.





90% of FCPA investigations brought by the US Department of Justice involve third-party intermediaries.



More than 2/3 of the cases brought by the US Securities and Exchange Commission were related to third parties with TPIs and travel/entertainment, the two biggest issues of the unit's FCPA enforcement work.



According to the 2013/2014 Kroll Global Fraud Report, the percentage of companies describing themselves as highly vulnerable to vendor, supplier or procurement fraud jumped from 5% in 2012 to 18% in 2013.



30% of those surveyed for the AlixPartners Annual Global Anti-Corruption Survey admitted that they had stopped doing business with certain parties because of concerns related to corruption.



52% of respondents in a survey by Control Risks ("International Business Attitudes to Corruption") stated that their risks of corruption and fraud were associated with their third-party relationships.



Managing TPI Risk

According to the Control Report, 58% of respondents cited "operational" bribes as a main cause of concern and only 29% pointed to the more familiar risk associated with gaining or keeping business. Further, 52% said "Risks associated with the company's relationship came from third parties (e.g., commercial agents, consultants)." Those routine, often-small "running the business" TPI arrangements are particularly risky when a company is entering a new market with which it is unfamiliar and lacks an established network of trusted third parties.

While the US remains the most aggressive enforcer of anti-corruption and anti-bribery laws including the FCPA, other countries are sprinting forward in enacting and enforcing their own laws, some of them more restrictive than the FCPA. The UK Bribery Act expressly forbids



"facilitation payments" allowed by the FCPA. New laws in fast-growing countries including Brazil and China are combining high risks with harsh enforcement penalties, confronting many global companies with significant challenges as they struggle to operate in unfamiliar territory.

The question isn't whether a company will need to use TPIs for business services but how to manage the compliance risks of those relationships.

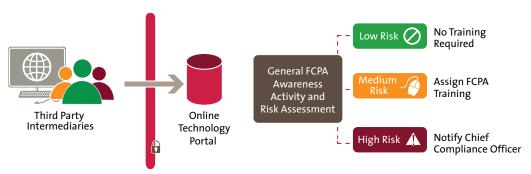
Assessing TPI Risk

Risk will be determined by multiple factors that fall under the general categories of "where" and "what" is being outsourced.

Where is the company's operation? Is the new location at high risk for corruption as measured by surveys and reports including those from Transparency International? How familiar is the company with the local customs, language, legal structure and tolerance for actions that could qualify as bribery or corruption under laws applicable to the company? Are there unique issues in the new location affecting Life Science companies, such as government-owned healthcare facilities? Are there national anti-corruption laws that go beyond the FCPA and UK Bribery Act? Does the company have an established network of TPIs in the region and/or a well-developed due diligence program for selecting TPIs?

Just as important as understanding the landscape is knowing the risks posed by the business functions performed by TPIs. Assess each outsourced function based on its "inherent risk" and its relationship to your company. Some functions are obvious: procurement and acquisitions, supply chain management, sales and marketing, financial and legal services. Others may not be as recognizable, including human resources, real estate management, translators, customs and license consultants, community advisors and even travel agencies. How much exposure does each function have for potential corruption?

Finally, examine each specific TPI. Does the company have a strong compliance program? Does it have full-time employees or does it rely on subcontractors? Does the company have systems in place to prevent unqualified, unvetted individuals from performing jobs "on behalf of the global company?" Is the TPI willing to open its records to the contracting company? Has it been audited and found lacking, either by government agencies or other companies? Is its anti-corruption training current and adequate to support compliance behavior?



 ${\it Use of automated ``SmartForms" align compliance oversight with TPI \ risk.}$



Anti-Corruption Training

Effective training is a combination of relevant engaging content, tailored instructional design and targeted delivery and testing. Across-the-board, one-size-fits-all training doesn't work, especially when it is being applied to TPIs performing different job functions and exposed to different levels of corruption risk.

In fact, companies should consider two distinct training tracks when dealing with TPIs. The first applies to the TPI and involves the specific risks associated with the relevant culture and job function. In areas with government-supported health care, for example, outsourcing sales and marketing functions poses significant risk and should be addressed through very specific training related to interactions with government officials. In emerging economies with fast-growing imports and exports, a third-party customs facilitator would be associated with specific bribery risks related to that function. Just as important as the relevance of the content is the way in which training is presented to the target audience. Training that works at corporate headquarters is unlikely to have much impact in a newly-developing country with a vastly different history and culture of business. The training content must also be relevant to the knowledge level of the learner. Of most importance, knowledge of this critical material should be demonstrated through assessments and reinforced periodically based on risks related to the territory, TPI structure and regulatory climate.

A second training initiative should focus on corporate employees, arming them with the knowledge necessary to identify "red flags" among TPIs. As with TPI training, employees should receive content that is relevant to their roles within the company and their interactions with TPIs. Some common red flags: the TPI requests an unusual advance payment, offers to submit an inflated or inaccurate invoice, requests cash or payment in an area outside his or her home country, asks for a donation to a charity, or refuses to accurately document expenses. A company's employees represent a first-line defense against violations by TPIs; training employees should extend beyond their compliance responsibilities to include factors that might signal risky behaviors by TPIs.



Monitoring and Reinforcement

A key challenge for companies is the identification and ongoing monitoring of TPIs. Increasingly, sponsor companies are requiring TPIs to adhere to their anti-corruption policies. This process can be managed via a portal with self-registration and risk-based surveys to align policy sign-off and relevant training in an audit-ready and reportable manner

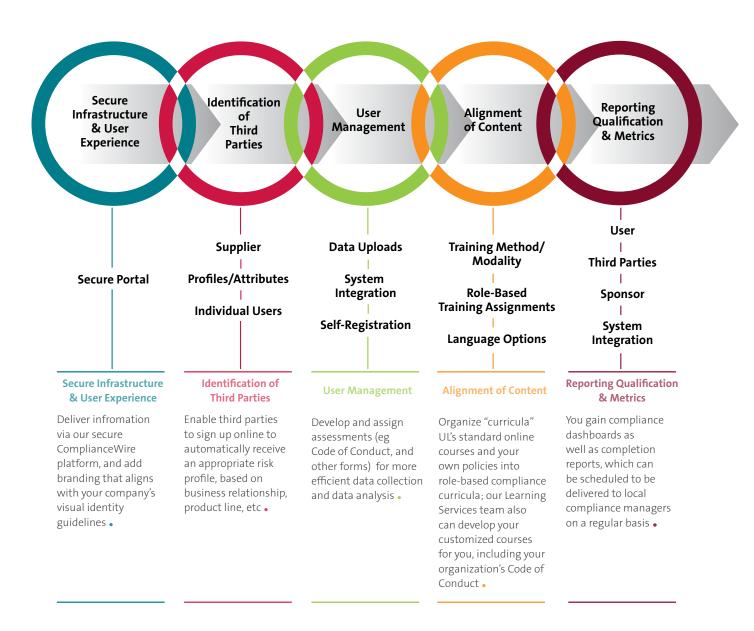
An effective compliance program cannot be static. It must be continually monitored for effectiveness and adjusted or updated as necessary. That is particularly true of ensuring that a company's employees and those of any third-party intermediary are well trained on the company's policies, anti-corruption requirements and compliant behaviors. The portal allows companies to easily and cost-effectively push out new policies and short communications to reinforce the criticality of compliant behavior.

The Cost of Noncompliance

No company can escape all risks posed by third parties, just as they cannot guarantee that every one of their thousands of employees will abide by the company's policies and requirements. Companies can, however, focus attention and resources on those areas of greatest risk for corruption based on job function, physical location and routine interaction with foreign government officials. Both the US DOJ and the UK Serious Fraud Office have been clear: "Credit will be given to those companies that have a strong compliance program."







Onboarding and ongoing monitoring of TPIs is simple, yet structured to meet company-specific TPI management program.

About UL EduNeering

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UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

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