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# FCPA AND ANTI-CORRUPTION STRATEGIES FOR THE LIFE SCIENCES INDUSTRY

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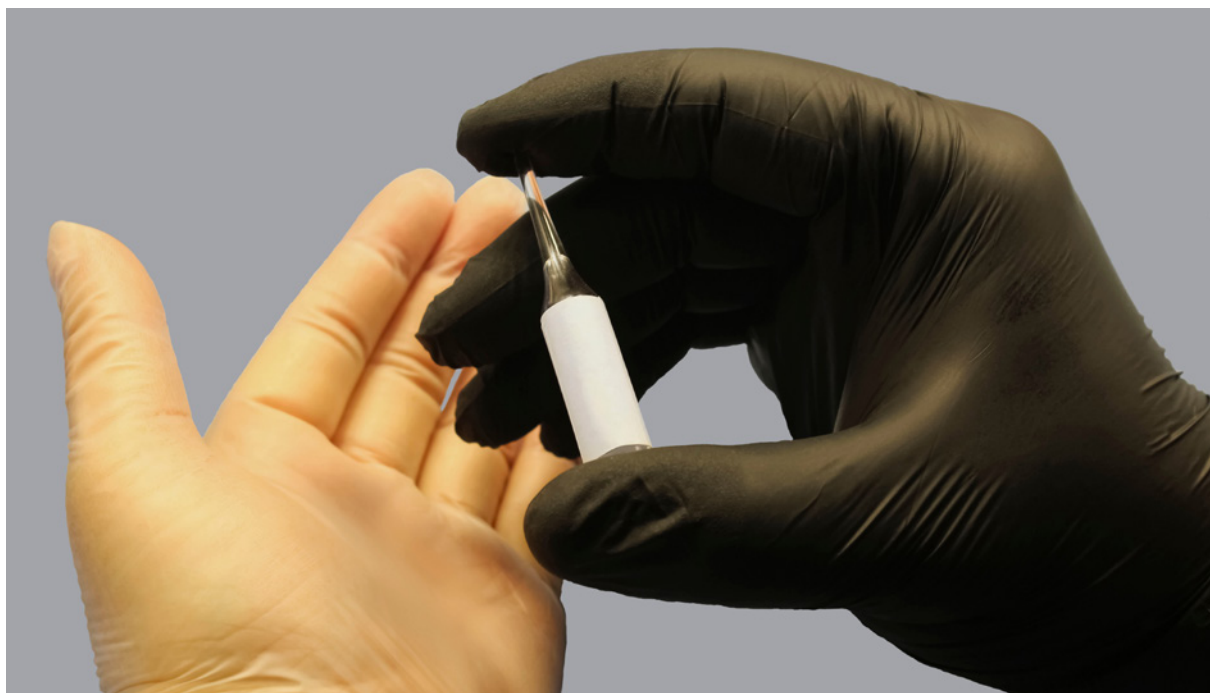
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MINI-ROUNDTABLE

# FCPA AND ANTI-CORRUPTION STRATEGIES FOR THE LIFE SCIENCES INDUSTRY



## PANEL EXPERTS

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**Rory M. Wilson**, a managing director in forensic services advisory at KPMG LLP, has over 18 years of experience advising companies and organisations to address and remediate a wide range of business threats, risks and complex issues. Clients benefit from his expertise in assisting with regulatory enforcement matters, conducting forensic investigations, combatting fraud and economic crime, and assessing, designing and enhancing technology-enabled compliance programmes.

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**Sammi Gu**, a director in forensic services advisory at KPMG LLP, helps multinational companies with their regulatory compliance needs. She leads a large portfolio of Foreign Corrupt Practices Act, anti-bribery and corruption compliance assessments, pre- and post-acquisition compliance due diligence, third party monitoring and audits, and cross-border forensic investigations for Global Fortune 500 companies, including their affiliates and business partners located worldwide.

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**Florencia Schuster**, a director in forensic services advisory at KPMG LLP, has over 18 years of accounting experience in KPMG Buenos Aires, New York and Miami. She has been with the forensic practice for the past 15 years, specialising in forensic investigations and remediations, including those related to the FCPA. She has also led multinational investigations and remediation projects for global clients, performed anti-bribery and corruption risk assessments, developed remediation recommendations, drafted policies and procedures, and assisted with compliance training and implementation.

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**Monica Young**, a director in forensic services advisory at KPMG LLP, assists multinational companies with updating their compliance programmes or performing investigations. She focuses on anti-bribery and corruption and other compliance matters, such as internal controls and modern slavery risks. She also leverages her international experience, experience with regulators and language skills, to manage complex projects outside of the US, including in Asia, Europe, South America, CIS and Africa.

**R&C: To what extent is the life sciences industry susceptible to bribery and corruption? Could you provide an overview of the risks companies in this sector typically face?**

**Young:** Life sciences companies have been one of the most regulated industries over the past 10 to 15 years, with a significant number of Foreign Corrupt Practices Act (FCPA) enforcements in total, which is on a par with aerospace and just behind industrial goods and the oil and gas sectors.

**McFerran:** We see a few factors potentially increasing the risk of bribery and corruption violations for multinational life sciences companies. Governments across the world increased their demands to purchase personal protective equipment (PPE), medical devices such as respirators and medicines, and in many cases have issued special regulation to bypass requirements to organise public tenders. With government agencies closed across the world due to the coronavirus (COVID-19) pandemic, companies experienced significant delays in obtaining required permits, licences and visas. Governments paid large grants to pharmaceutical companies for research and development, which are prone to corruption. Given the travel restrictions in place, companies reduced

or put on hold their in-country audits of distributors and other third parties.

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*Monica Young,  
KPMG LLP*

**R&C: How would you characterise recent enforcement action under the Foreign Corrupt Practices Act (FCPA)?**

**Wilson:** While the pace of FCPA enforcement continues to be slower than previous years, there are prevalent signals in both messaging and actions from regulators that indicate a potential significant increase in enforcement for the remainder of the year and beyond. Earlier this year, a senior Department of Justice (DOJ) official stated that the DOJ has “a very robust pipeline” and “expects to see some significant resolutions in the next year”. The deputy attorney general indicated that corruption and white-collar crime is a priority of the Biden

administration, noting the ramping up of additional resources to the criminal division's fraud section, which is tasked with investigating FCPA cases. Furthermore, the Biden administration announced its 'Strategy to Counter Corruption', making it clear that battling global corruption is also a national security priority. The strategy includes new beneficial ownership disclosure obligations, use of anti-money laundering (AML) laws against gatekeepers such as accountants and lawyers, a proposed amendment to the FCPA to punish bribe takers and increased anti-bribery and anti-corruption compliance expectations. That said, it appears that the stage is set for a surge in upcoming cases and enforcement.

### **R&C: What trends have you observed in the authorities' approach and intent?**

**Wilson:** We continue to see a rise in whistleblower-initiated cases and a decrease in companies self-reporting. Companies should consider assessing the efficacy of their whistleblower programmes along with their wider compliance programme – ensuring that their employees and business partners are aware of their ethics reporting mechanism and encouraged to raise compliance concerns and questions. There is a focus on compliance by US regulators. There has been an emphasis

on the importance of adequate resourcing in the compliance function – not just from a headcount perspective, but also the need for data analytics tools and capabilities to bolster the effectiveness of a company's compliance programme in a meaningful way. The DOJ also issued a new policy that requires chief compliance officers (CCOs) to certify that compliance programmes have been designed to prevent anti-corruption violations. This requirement has been prevalent in recent FCPA resolutions and has added an additional layer of potential liability for compliance officers.

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*Florencia Schuster,  
KPMG LLP*

**R&C: What steps should life sciences companies consider when designing, implementing, monitoring and updating their anti-corruption framework?**

**Gu:** Companies may assess where compliance resources would be most needed to address the critical risk areas at the regional, entity or functional levels, and evaluate the skill gaps considering the adoption of advanced analytics and insights into the emerging risks. Continuously engaging stakeholders across various functions and regions to provide insights will significantly improve the effectiveness of an anti-bribery and corruption programme. The compliance department should establish trusted partnerships with key process owners and innovate ways to manage risks without disrupting business activities. Leveraging technology in data analytics enables companies to be more targeted and multidimensional in risk assessment, ongoing monitoring or audits and analysis of compliance priorities. It is critical to understand the systems generating the datasets, and to develop and refresh key risk indicators regularly considering geographic locations, business models and process maturity to account for regulatory and business changes.

**R&C: With the majority of reported FCPA cases involving third-party intermediaries, what specific considerations should life sciences companies make to mitigate this risk?**

**Gu:** Third-party relationships remain one of the highest risks for organisations. It is important to revisit the standard contract agreement template with third parties to ensure that key clauses

**“The compliance department should establish trusted partnerships with key process owners and innovate ways to manage risks without disrupting business activities.”**

*Sammi Gu,  
KPMG LLP*

related to service scope, compensation model, responsibilities and obligations, such as anti-bribery and corruption compliance, audit rights and documentation retention, are specified and enforced. Implementing additional third-party governance controls and a risk-focused monitoring programme will allow for better oversight and timely identification of potential issues. The monitoring results can be used in the risk assessment when selecting third parties for compliance assessments. Customising the training programme for third parties ensures they understand how risks will impact future business growth and best practices to manage such risks.

**R&C: How important is it to have boardroom buy-in when creating and rolling out anti-corruption strategies? Is tone from the top essential to building a culture of compliance?**

**Schuster:** Tone from the top is critical to building a culture of compliance in any organisation, no matter the industry. The board of directors sets the organisation's values and ethical climate, ensuring that ethical activities are built into the organisation's strategy. The board of directors has ultimate responsibility for overseeing the organisation's anti-bribery management system, delegating to senior management the day to day direction of the organisation. An organisation with a poor tone from the top results in an organisation that is more likely to show unethical behaviour and engage in fraudulent or corrupt activities. Without boardroom buy-in, senior management cannot effectively enforce organisational compliance.

**R&C: What essential advice would you offer to life sciences companies on ensuring they maintain ongoing compliance with applicable anti-corruption rules and regulations, including the FCPA?**

**Schuster:** Organisations should continuously evaluate and improve their compliance programme to ensure it addresses control gaps, risk assessment results and regulatory changes based on risk profile and tolerance. Organisations spend extensive time and resources designing compliance programmes to prevent and respond to corruption. However, based on our experience, they usually lack one key component in the detection area: monitoring and testing. Monitoring regulatory changes and periodic monitoring and testing of the effectiveness

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*Rory M. Wilson,  
KPMG LLP*

of controls around interactions with healthcare professionals, government officials and third-party relationships is key to maintaining ongoing compliance with anti-corruption laws and regulations, including the FCPA.

**R&C: What are your predictions for the bribery and corruption challenges life sciences companies will face in the coming months and years? To what extent will this area remain a key source of regulatory risk for the sector?**

**Wilson:** We anticipate an uptick in FCPA enforcement with a continued focus on certain compliance issues. One key compliance challenge, particularly in the life sciences sector, will be around the centralisation and application of data analytics. We continue to see an emphasis by the DOJ on the importance of companies using data in a centralised way to help inform decision making and compliance programme enhancements. Companies should assess what information is key and readily available to help identify key risks, red flags and trends – and use this information in a way that is actionable to

demonstrate an effective, evolving and adaptable compliance programme. For example, companies should consider data sources, targeted analytics,

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KPMG LLP*

and ongoing monitoring that applies to sector-specific risks, such as interactions with healthcare professionals and patient associations, travel, gifts and entertainment, particularly in the sponsorship of educational meetings and conferences, and the use of third-party distributors and sub-distributors. **R&C**