Life sciences sector

Industry insight and global experience: the intelligent connection

Forensic & Integrity Services
Reactive response and proactive risk management

Life sciences companies are constantly under scrutiny, but it is most intense when shareholders, business partners or regulators suspect wrongdoing. Regulators and enforcement agencies are more joined up than ever before as they cooperate across borders in the fight against fraud, bribery and corruption. This demands increasingly higher levels of integrity, honesty and transparency in the way life sciences companies operate and makes it more critical than ever to respond rapidly, appropriately and robustly to any aberrational conduct.

Rapidly changing and increasingly complex regulatory requirements pose a critical risk to the life sciences sector. The avoidance of breaches of laws and regulations requires a robust approach to compliance and a multijurisdictional response. Executives who react appropriately to these challenges, and respond promptly to major incidents, can safeguard the financial and reputational value of their organization.

By making the intelligent connection between your business operations, markets and third-party relationships, EY can help you get to the root cause of problems resulting from impropriety. EY ability to make these connections helps you to uphold integrity in business behavior and drive corporate success. This approach is integral to all we do for you.

The EY compliance professionals, forensic accountants and data analytics technologists across the globe combine with life sciences industry knowledge, regulatory insight and innovative methodologies to provide transformative corporate solutions. Together, we can work closely with you to help manage the complex financial, regulatory, contractual and reputational risks that your business faces.

Leading insight: fraud and corruption risk in life sciences

16% of respondents stated that it is common practice to use bribery to win contracts in their sector*

34% of respondents could justify unethical conduct to help business survive an economic downturn*

43% of life sciences respondents believe bribery/corrupt practices occur widely in business in their country*

*EY 15th Global Fraud Survey: Integrity in the spotlight – the future of compliance
EY EMEIA life sciences teams are part of the global EY practices, an organization with the knowledge and scale to work closely with your business to help find solutions for you.

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<th>You need to...</th>
<th>EY can help you by...</th>
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<tr>
<td>Respond rapidly to allegations of fraud, bribery, off-label and other regulatory breaches</td>
<td>• Using our investigative experience, advanced forensic data analytics and e-discovery tools to indentify the facts, including what happened, how and why</td>
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<td>Investigate across multiple geographies and legal jurisdictions in a consistent manner</td>
<td>• Mobilizing EY professionals at short notice, leveraging the global operating model and common forensic technologies</td>
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<td>Make stakeholders and auditors confident that issues have been dealt with effectively to reduce financial losses and regulatory risks</td>
<td>• Strengthening your internal compliance controls and advising on the establishment of robust policies to mitigate the risk of future occurrences</td>
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<td>Understand and assess potential bribery and corruption risks in target acquisitions pre- or post-close</td>
<td>• Identifying the potential for exposure including specific business conduct, financial transactions and ownership or relationship links that could give rise to concern</td>
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<td>Capture data and evidence from electronic devices when fraud or impropriety is suspected or discovered</td>
<td>• Handling relevant electronically stored information (ESI) in a consistent, defensible and cost-effective way</td>
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<td>Comply with the data requests from regulators and other authorities</td>
<td>• Mobilizing people and technology resources to capture, process and prepare for review vast quantities of electronic data in a forensically robust manner</td>
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<td>Develop your Information Governance Strategy with a view to reducing risk and cost while demonstrating return on investment</td>
<td>• Using our experience of disputes, investigations and regulatory reviews to help you govern and manage your information in an active and strategic fashion</td>
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<tr>
<td>Proactively prevent and detect fraudulent or corrupt activities within the business and conduct ongoing monitoring</td>
<td>• Identifying patterns and indicators of potential fraud or corrupt activity, as well as designing and help implementing a proactive monitoring program through the use of advanced data analytics including social network analysis, and predictive modelling</td>
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<td>Respond quickly and effectively to cyber crime incidents</td>
<td>• Undertaking a detailed investigation to assess who was involved, how the attack was carried out, what damage was done and how your cyber breach response program can be strengthened</td>
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<td>Develop an effective and prudent approach to third-party risk management</td>
<td>• Using proprietary technology to collect, review, and protect data for your third-party vendors, and to provide detailed insights into risks associated with business collaborators, including joint ventures, suppliers and agents</td>
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Intelligent thinking applied

Global compliance monitoring program
EY advised on the design of a risk-based compliance monitoring program for a multinational pharmaceutical company. This included governance and reporting infrastructure to drive a consistent compliance monitoring approach across its global operations, increasing the transparency in findings and clarifying accountability for remediation. We used data analytics techniques to inform the testing program, allowing a focus on high-risk or unusual transactions to test for compliance monitoring.

Third-party compliance program
EY helped a global medical device company to develop a risk-based approach for third-party due diligence and then assisted in implementing dedicated programs for assessing third parties of a specific risk profile. For over 50 third parties classified as high-risk from more than 20 countries, we performed third-party audits which followed the same process and reporting structure.

Compliance program maturity assessment
A global medical device manufacturer requested assistance in assessing the maturity level of its compliance program worldwide. EY worked closely with the compliance department to identify emerging risks across the enterprise and design a compliance program with a structure and capability to adapt to the challenges posed by entering new lines of business and new markets.

Government investigation
A global pharmaceutical manufacturer sourced its investigation capabilities worldwide, requested support with the triage process, investigation strategy and execution process. EY worked in collaboration with the company’s in-house and external legal counsel, to investigate issues including off-label “promotions,” employee misconduct and anti-trust compliance activities to prevent bribery of government officials.

Third-party due diligence
EY helped a global pharmaceutical company with the design of an ABAC analytics work plan that encompassed customized, country-by-country analytics in support of its ABAC compliance program. Leveraging our library of anti-corruption tests and country-specific keyword terms around corrupt payment descriptions, EY professionals teamed with compliance and internal audit to analyse vendor and procurement-related data, as well as employee and agent expense-related submissions. We developed interactive dashboards and risk-scoring models to assist the client with the identification of high-risk vendors, employees and agents for further substantive testing in the field.

Anti-bribery and anti-corruption (ABAC) forensic data analytics

Transparency reporting
A global pharmaceutical company requested support to implement its Transparency Disclosure self-regulation initiative and subsequently assess compliance against local transparency disclosure legislation already in place. This work also included support to re-assess and update the Fair Market Value HCP approach.
Global experience, local knowledge, relevant skills

The EY Forensic and Integrity services brings you the people, tools and insights you need to protect your business from financial and reputational risk.

Multidisciplinary professionals

- 4,500 professionals worldwide
- Forensic accountants, technologists, former law enforcement and intelligence agency professionals
- Working in 70 countries
- Across 27 industries

Understanding how regulations, laws and compliance issues vary by country and region

Cross-sector life sciences professionals – including:

- Pharmaceuticals
- Medical Devices
- Generics
- Government & Public Sector

Market-leading breadth and depth of insight into complex, international business processes

Thought leadership

Managing bribery and corruption risks in the life sciences industry

Implementing effective third-party frameworks in the life sciences industry – leading practices and challenges

14th Global Fraud Survey, Corporate misconduct – individual consequences – life sciences summary

EY 15th Global Fraud Survey: Integrity in the spotlight – the future of compliance

Talk to us

Find out how EY can help you protect the financial and reputational value of your business. We can react quickly and efficiently to prevent, detect and resolve any threats you face, however complex.

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About EY Forensic & Integrity Services
Dealing with complex issues of fraud, regulatory compliance and business disputes can detract from efforts to succeed. Better management of fraud risk and compliance exposure is a critical business priority – no matter the size or industry sector. With approximately 4,500 forensic professionals around the world, we will assemble the right multidisciplinary and culturally aligned team to work with you and your legal advisors. We work to give you the benefit of our broad sector experience, our deep subject-matter knowledge and the latest insights from our work worldwide.

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ED None

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