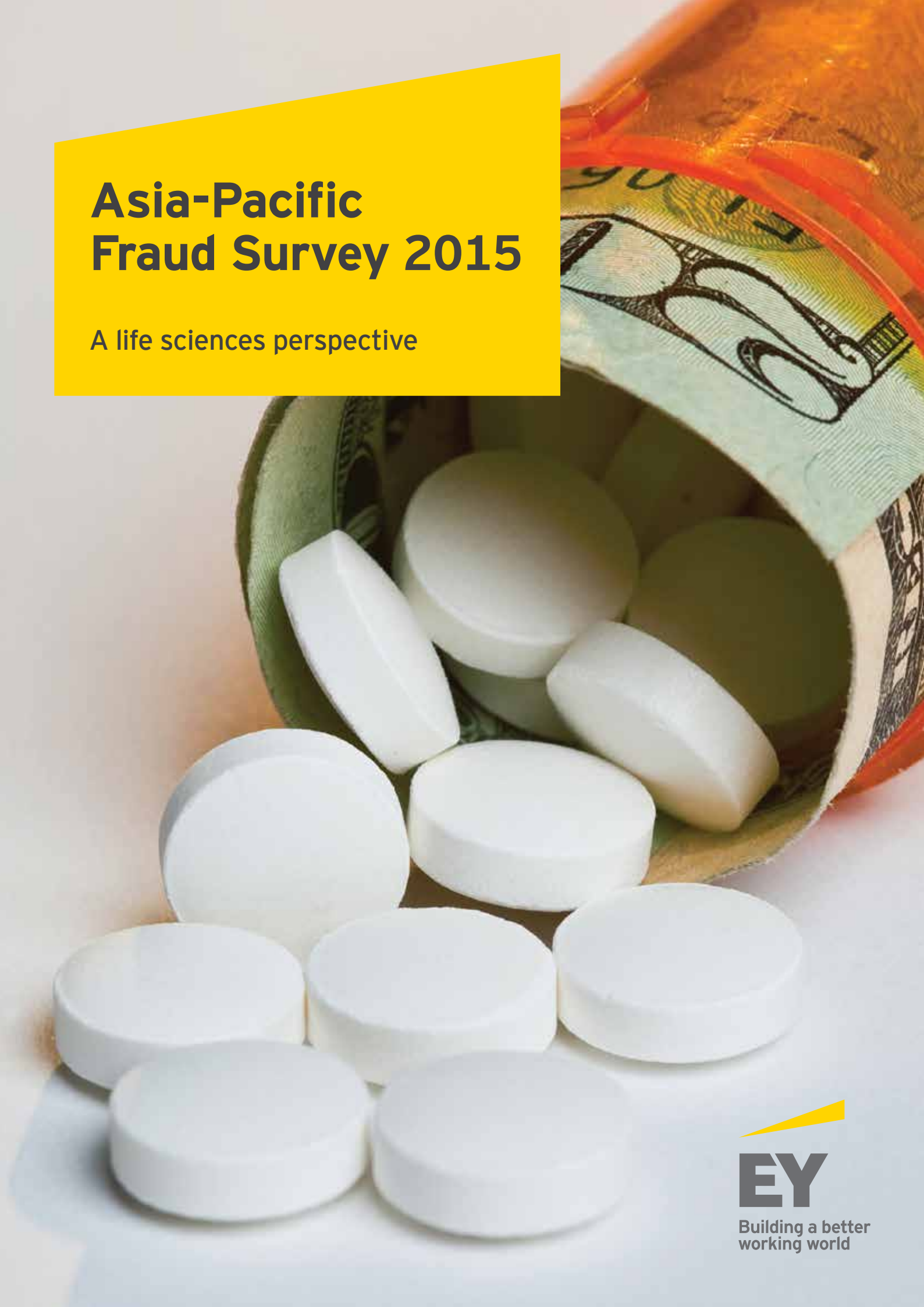
Asia-Pacific Fraud Survey 2015

A life sciences perspective



EY

Building a better working world

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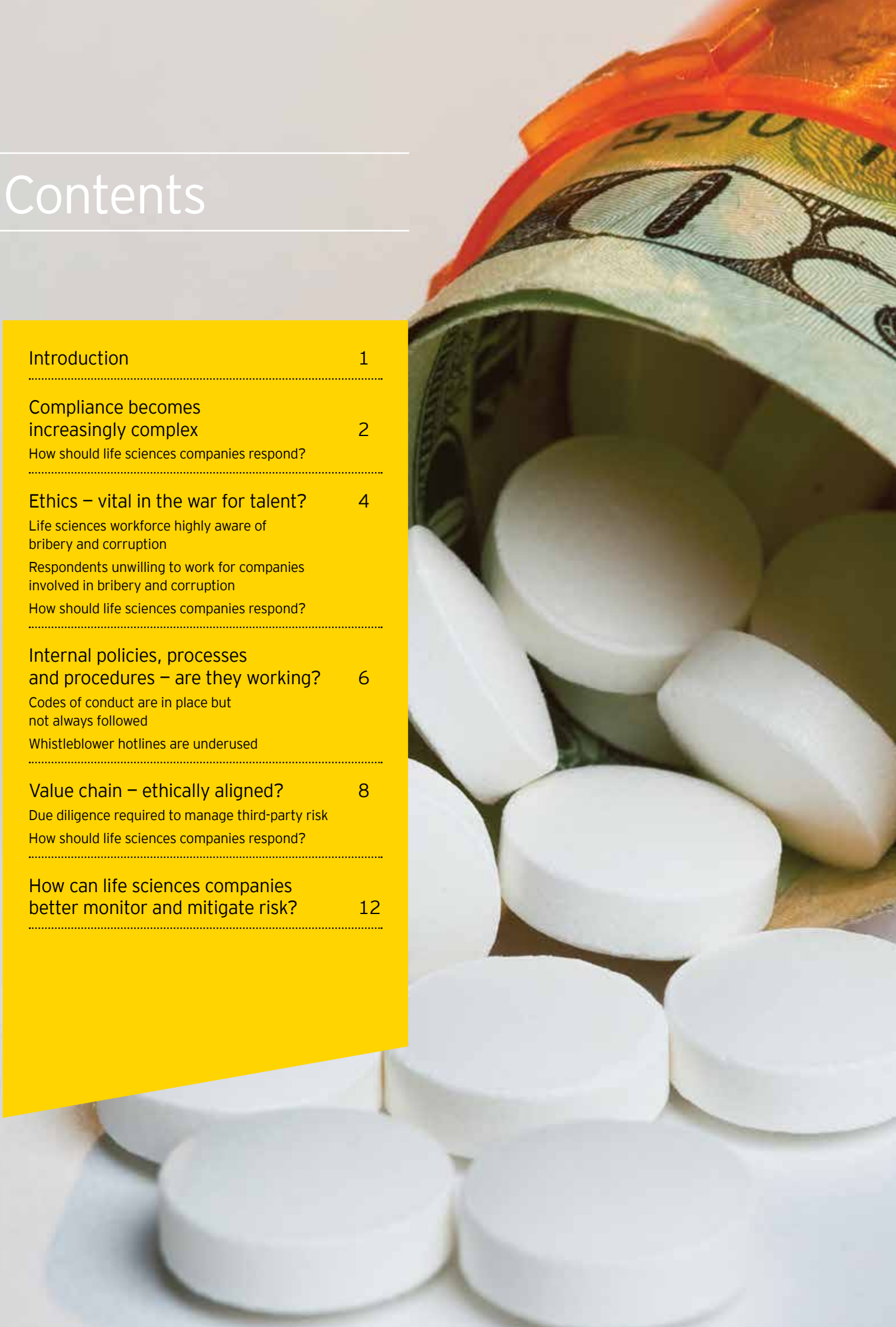


Introduction

Between 5 and 23 February 2015, researchers at the global market research agency, Ipsos, conducted an Asia-Pacific (APAC) Fraud Survey, which was released in June 2015. The survey comprised 1,508 interviews with employees of medium to large companies in 14 of the region's territories: Australia, China, Hong Kong, Indonesia, Japan, South Korea, Sri Lanka, Malaysia, New Zealand, Philippines, Singapore, Taiwan, Thailand and Vietnam. Respondents represented a cross-section of APAC's major industry sectors, including life sciences.

This report looks at the survey findings through a life sciences lens, one of the sectors identified as facing some of the region's greatest compliance and prevention challenges. It is augmented by the results of a later, separate focus group of senior compliance officers for life sciences companies in the region, who validated the observations of the original survey and provided their insights in October 2015.

This report reveals:

- Growing risks surrounding fraud, bribery and corruption that could put the talent-based growth strategies of life sciences companies in danger
- Policies, processes and procedures to tackle fraud, bribery and corruption may not be as effective as designed
- A worrying lack of employee awareness of the risks related to third parties

The report also suggests strategies to take control and proactively mitigate these risks.

We hope life sciences companies find the report's conclusions useful as they develop their anti-bribery and anti-corruption policies and programs. We also thank the focus group participants for generously contributing their time and insights.

Emmanuel Vignal

Asia-Pacific Fraud Investigation & Dispute Services Life Sciences Leader

Life sciences defined:
A sector comprising pharmaceutical companies, biotechnology companies, medical technology companies and supporting entities such as outsource manufacturers and distributors.

Compliance becomes increasingly complex

The life sciences sector is facing increased regulation and stronger enforcement. With intense competition for compliance talent, companies must find new ways to meet their regulatory obligations.

Every one of the compliance officers in our life sciences focus group reports that their companies are implementing significant changes in response to the new regulatory pressure impacting the sector. All of them have revisited their compliance programs and policies in the last two years. More than half are using technological solutions, such as forensic data analytics, to detect fraud earlier and help make compliance programs more sustainable.

Across the APAC region, a number of countries have passed new anti-corruption legislation or taken steps to strengthen their existing anti-corruption frameworks. For example, new amendments to China's Criminal Law, which were effective from 1 November 2015, add a new crime of offering bribes to close relatives of current and former state functionaries. China has also recently set out comprehensive requirements on key aspects of sponsorships and donations in the health care sector.

Other countries have introduced new regulations prohibiting all gifts to public sector employees. In Singapore, public officers are not permitted to receive any present in money or in kind.

> "In the last two years, we've regularly updated and enhanced our anti-bribery and anti-corruption policies and procedures, and deployed forensic monitoring programs locally."
>
> **Compliance Director**
> Asia-Pacific

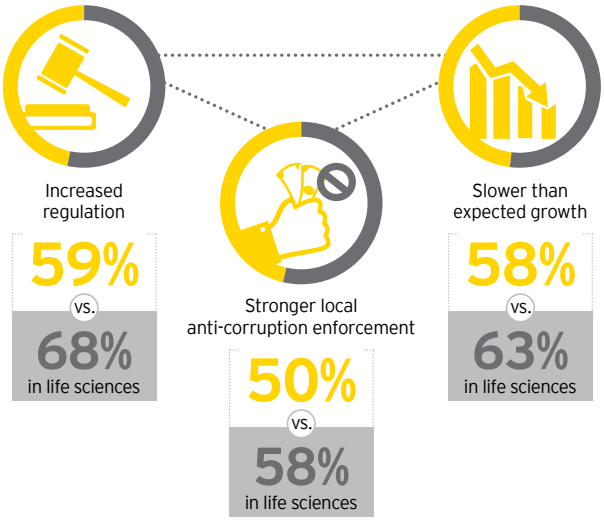
> "With mounting regulations in most jurisdictions, compliance has a major role to play in helping to maintain our license to operate, identify and mitigate risk."
>
> **Compliance Director**
> Asia-Pacific

In addition to the expanded scope of prohibited conduct and increasing regulation, we are also seeing increasingly sophisticated measures being taken in local anti-corruption enforcement. Thailand's National Anti-Corruption Commission is demonstrating its teeth, indicting hundreds of former lawmakers. In China, the Government's commitment to tackle official corruption has resulted in several dramatic prosecutions at senior levels – ensnaring both local Chinese and multinational companies.

In most territories in APAC, enforcement agencies are now experienced and more confident in conducting raids and investigations, in which they seek specific information right across the business and its value chain, including reviewing transactions at third parties. As a result, with fraud, bribery and corruption scandals increasingly in the media spotlight, life sciences companies are being forced to step up compliance activities and look at their business transactions and relationships in greater depth.

As a consequence, the vast majority of our focus group representatives are finding that competition for the already limited pool of qualified compliance professionals is growing, leading to increased attrition in the employee cohort within the life sciences sector. Part of the issue is that life sciences companies are not only fighting their competitors for compliance talent, other organizations in highly regulated sectors, such as financial institutions, are also targeting this skills base.

Top challenges to businesses in Asia-Pacific



"In response, we have strengthened our internal policies according to industry trends, enhanced risk assessments and introduced data solutions."

Compliance Director
China

How should life sciences companies respond?

Increased regulatory reforms and heightened enforcement activities mean life sciences companies should ask themselves if they are prepared for unannounced visits by the local authorities. Companies need to bolster their internal controls, internal audit, legal and compliance teams to better and more frequently monitor their:

- Business operations
- Third-party relationships
- Sales and marketing activities and expenses
- High-risk interactions with health care professionals (HCPs)

Organizations in the region will need to move away from the traditionally strong relationship building and gift-giving culture and come up with creative and ethical marketing campaigns that will promote awareness among HCPs.

"Life sciences companies operating in APAC need to be aware of the cultural norm of building strong personal relationships in the conduct of business, since if poorly monitored this culture can lead to risks of fraud, bribery and corruption."

Chris Fordham
Asia-Pacific Leader
Fraud Investigation & Dispute Services

Ethics – vital in the war for talent?

Life sciences employees say they will leave or refuse to join companies involved in bribery and corruption. This adds a new dimension to compliance. Not getting it right will put retention and recruitment of top talent and growth strategies at risk.

Life sciences workforce highly aware of bribery and corruption

Almost three-quarters of life sciences respondents agree that corruption happens widely in their sector, significantly higher than the APAC average. Almost half (48%) of life sciences respondents report they have seen people with questionable ethical standards being promoted in their organization, again, higher than the APAC average of 40% across all industries.

Two out of three respondents say their colleagues are aware of fraudulent activities within their own organizations. But 37% of life sciences employees say that, even though their colleagues are aware of fraudulent activities, they do not report them.

31% of life sciences respondents say that they would definitely leave for an equal opportunity at another organization

78% of life sciences respondents say if an organization was involved in bribery and corruption, it would affect their willingness to work for that company

> "We have an increased focus on ensuring the business understands the importance of ethical practices and ethical decision making – not just compliance with policies and procedures."
>
> **Regional Compliance Manager**
> China

Respondents unwilling to work for companies involved in bribery and corruption

The bigger issue for life sciences employers is that 31% of life sciences respondents would definitely leave for an equal opportunity at another organization if their own employer was involved in bribery and corruption. Millennials[1] are the employee subgroup most affected, with this group exhibiting a high awareness of social accountability driven by social media. An overwhelming 86% of total respondents aged below 25 years say they are unwilling to work for, or would leave, an organization involved in bribery or corruption.

One in five life sciences employees would be willing to work for such employers, but would "need reassurance" about the organization's actions to address the problem. And only 2%, as compared with the APAC average of 5% for all industries, say it would "make no difference to their willingness to work for them." While our survey was primarily of shop floor employees, our life sciences focus group believes these sentiments are also shared by middle and senior management.

> "We have already built up compliance introductions in recruitment."
>
> **VP Compliance**
> Greater China

1. Also known as the Millennial Generation or Generation Y, being those with birth years ranging from the early 1980s to the early 2000s.

How should life sciences companies respond?

Talent is high on executive and board agendas, with concerns mounting about an aging workforce, a shortage of skilled candidates and competition from other industries trying to find similarly qualified talent. Anecdotally, some life sciences companies are struggling to fill both executive-level positions as today's C-suite nears retirement and to attract quality young talent at the other end of the leadership pipeline.

Given talent is critical to life sciences companies' growth agendas, executives have an additional incentive to operate and be seen to operate an ethical business. Executives and managers throughout organizations must continuously set an example of ethical behavior and communicate proactively about it. This is particularly important to build loyalty in younger generations, which is essential to ensuring long-term talent retention.

60% vs. **74%** in life sciences

of respondents in Asia-Pacific believe bribery/ corrupt practices happen widely in their country

Case study: Bribery and corruption deter quality candidates

In response to allegations that unethical payments were being made to HCPs, EY helped a life sciences company to review the expenses associated with HCP interactions. A number of employees were identified with unexplained questionable claims, resulting in the employees involved leaving the company. Because of the incident, the client experienced difficulties in attracting candidates of the correct caliber and level.

In such situations, companies should not only conduct compliance risk assessments and reviews, but also reinforce the importance of ethical behavior with frequent communications, interactive and localized training, and ongoing monitoring.

"In a highly competitive talent market, life sciences companies need to differentiate themselves to attract and retain talent. Among factors such as career prospects and the employee value proposition, one significant factor is ethical leadership. Everything else being equal, talent would go for a company that has a strong reputation and ethical values embedded into its culture."

Lawrance Lai
Partner
Fraud Investigation & Dispute Services, Singapore

Internal policies, processes and procedures – are they working?

In response to increasing regulation and enhanced local enforcement, life sciences companies have strengthened their internal controls. But some policies and systems are not working as well as they should – especially whistleblower hotlines.

Since our last APAC Fraud Survey conducted in 2013, more APAC organizations have established codes of conduct, anti-bribery and anti-corruption (ABAC) policies and training. All of our focus group representatives say their organizations have revisited their compliance programs and policies in the last two years.

Yet, not all of these initiatives are achieving their objectives. In life sciences and other industries across the board, survey respondents consistently agree that their ABAC policies are irrelevant and need to be more effective.

1 in 2

respondents in Asia-Pacific say ABAC policies are irrelevant and ineffective

"There needs to be more than just a code of conduct. It needs to be trained out, understood by all, and have compliance enforced. Senior leaders need to 'walk the talk'. All people within the business need to not only comply with the Code of Conduct but act within the spirit of the Code in an ethical manner and in day-to-day decisions they make. Compliance and Ethics Officers play a crucial role in ensuring ethical decision making is part of ordinary business."

Regional Compliance Manager
Asia-Pacific

Codes of conduct are in place but not always followed

Across all industries, more than 80% of respondents say their organization has a code of conduct. But 44% believe it has little impact on how people actually behave. A quarter of all respondents report that their colleagues do not comply with their organization's code of conduct.

Life sciences companies can increase the relevance of and adherence to codes of conduct by translating them into local languages and making training more effective. This will require more frequent and shorter localized compliance trainings augmented by compliance reminders via multiple channels. For example, informal reminders can be built into regular meetings and anonymized real life compliance stories can be disseminated through newsletters and intranet blogs.

Whistleblower hotlines are underused

In a very worrying trend, the willingness to use whistleblower hotlines has decreased significantly since our 2013 APAC Fraud Survey and about half of the APAC respondents, and a mere 40% in life sciences, said that they would be prepared to use their company's hotline. This compares with more than 80% of respondents in our APAC Fraud Survey 2013. This sharp drop appears to be due to respondents being increasingly concerned about the insufficient legal protection and/or the lack of confidentiality for whistleblowers, a particular issue in the life sciences sector. However, this perception may not reflect reality. During our interviews with compliance professionals, each one of our life sciences focus group representatives reports that their company's whistleblower hotline promises confidentiality and all but one have reports handled by an independent party. Life sciences companies are setting up robust whistleblower processes but many of our survey respondents, the shop floor employees, are not aware of these processes or lack the confidence to use them.

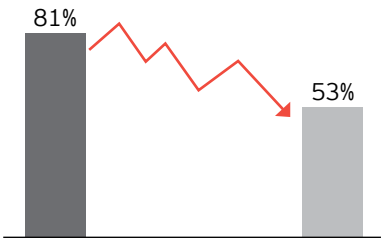
"It's all down to what degree the employee believes in the Code of Conduct and how well the control mechanisms work."

Compliance Director
China

2 in 5 respondents in Asia-Pacific say their code of conduct has little impact on how people actually behave

To address this issue, life sciences companies not only need to establish whistleblower mechanisms with proper protection of the whistleblowers that will result in more people "doing the right thing", but they also need to effectively and consistently communicate this throughout their organization. Whether or not there are protections in law, whistleblower policies need to reassure employees that they will get the protection and confidentiality they need. With a significant decrease in the use of whistleblower hotlines, companies need to be more proactive in seeking out issues before they escalate by making better use of corporate data to detect early signs of unethical behavior.

Figure 1
Decrease in the number of respondents prepared to use a whistleblower hotline in Asia-Pacific



Asia-Pacific Fraud Survey 2013

Asia-Pacific Fraud Survey 2015

Q: Which, if any of the following would characterize your willingness to use a whistleblower hotline: "I would be prepared to use it"

2013 Base: Respondents whose companies have a whistleblower hotline (245)
2015 Base: Respondents whose companies have a whistleblower hotline (828)

40% of life sciences respondents would be prepared to use a whistleblowing hotline

Case study: Whistleblower identifies third-party fee-stuffing

EY was engaged by a global medical devices company to investigate whistleblower allegations that the client's travel agency had inflated its fees for a national internal kick-off meeting – costing millions of dollars. An independent EY investigation discovered evidence of fee-stuffing (adding unrelated costs) as well as unsubstantiated items. At the conclusion of the investigation, the client terminated co-operation with the travel agency and also changed the way future events were organized to prevent the issue from re-occurring. This case not only exemplifies the importance of having an effective whistleblower program to bring out internal issues, but it also reinforces the need to quickly investigate, identify unethical behavior involved and take appropriate actions so that employees see that their allegations are taken seriously and confidentially.

"Whistleblower hotlines are a powerful tool to discover fraud, bribery and corruption, but they are less effective if whistleblowers are not comfortable using them. In addition to restoring confidence, life sciences companies need to leverage smart data analytics as a catalyst for meaningful discussions during field audits and investigations."

Emmanuel Vignal
Greater China Leader
Fraud Investigation & Dispute Services

Value chain – ethically aligned?

Life sciences companies are particularly vulnerable to fraud, bribery and corruption risks related to third parties. Yet few employees appreciate the magnitude of the problem. Robust third-party due diligence, comprehensive on-boarding procedures and ongoing monitoring are needed to manage this growing risk.

In their drive to reduce costs, grow revenue and remain competitive, life sciences companies are using M&A and joint ventures to find new synergies and cost saving partnerships. This leads to broader and deeper due diligence and monitoring being required to manage a more diverse portfolio of business relationships, each with varying cultures, on-boarding procedures and compliance controls.

Compliance risks are high in the life sciences sector, where distribution channels can include hundreds of distributors and sub-distributors that have direct relationships with HCPs and hospitals. In addition, HCPs who work at state-owned hospitals may be considered as government officials in the context of the U.S. Foreign Corrupt Practices Act (FCPA).

> "To mitigate risks from third parties, we conduct annual compliance training for our staff, include anti-bribery terms in master contracts and perform due diligence on vendors – including using independent parties to check their routines."
>
> **Country Compliance Officer**
> China

Due diligence required to manage third-party risk

All of our focus group representatives and more than 70% of life sciences survey respondents, 20% higher than the APAC average, think third parties are a significant risk to their business in relation to ABAC compliance. Not surprisingly, given the close relationships distributors have with HCPs, pharmacies and hospitals, life sciences respondents believe distributors pose the sector's biggest third-party risk. Even if due diligence is performed on a distributor, it will not necessarily have the compliance culture to conduct due diligence on its own sub-distributors.

Despite being aware of these issues, 72% of life sciences survey respondents are confident that their organization is effectively managing the fraud, bribery and corruption risks associated with third parties. However, we believe this confidence is optimistic. We frequently see third-party risks headlined in FCPA settlements and these risks are at the heart of a majority of cases investigated by our Fraud Investigation & Dispute Services professionals.

Traditionally, the high-risk third parties that life sciences companies have been exposed to included travel agencies, public relations agencies, event and marketing agencies that may offer bribes in the form of cash, stored-value cards or various incentive and travel programs to HCPs. Now, client payment concerns have broadened even further to encompass sources such as:

- HCPs being compensated to engage in market research focus groups
- Grants or sponsorships of questionable medical associations and societies posing as fronts for HCPs, hospitals or government health authorities

> "Risk areas in life sciences compliance include distributors, digital, multi-channel marketing, independent medical education, sampling, interactions with government officials and off-label marketing."
>
> **Compliance Director**
> Asia-Pacific

How should life sciences companies respond?

For new joint venture partners and acquisition targets, the amount of anti-corruption due diligence that can be performed in the context of a merger or acquisition is subject to negotiation between the buyer and the seller, and is often conducted under intense time pressure. Additional access is often gained between signing and closing. At the minimum, a detailed plan should be developed pre-closing to assist in identifying potential risks immediately after closing. If not a limited window (of 180 days according to the DOJ's Opinion Procedure Release No. 08–02 regarding Halliburton) exists to do so post-acquisition.

Once the transaction is closed and there is more access to data rooms, books and records, this is typically a good time for the acquirer to conduct a comprehensive compliance risk assessment to find potentially corrupt behaviour and determine how to handle such matters. In addition, the acquirer should put anti-corruption compliance high on its integration plan to include updating internal controls, policies and procedures, as well as training the acquired employees and, if possible, third-party intermediaries

Life sciences companies need to exercise control over their large number of third parties and sub-contractors. This requires robust third-party due diligence programs that go beyond "tick-the-box" public domain background checks. Such programs need to assess the business purpose for engaging third parties and the precise services they perform and be set up for ongoing monitoring.

With distributors, vendors and suppliers, stringent on-boarding procedures are highly recommended. Local distributors typically do not have the compliance culture to perform due diligence on their sub-distributors. In these cases, life sciences companies will need to conduct a risk-based assessment of their third-party relationships, and based on the level of risk, comprehensive due diligence may require compliance health checks and multiple management interviews on a distributor's compliance culture and business practices. This should include:

- Reviewing internal controls, policies and procedures
- Interviewing multiple and diverse third-party management
- Carrying out process walk-throughs to sample and test select processes
- Undertaking gap analysis to identify how to improve internal controls to better meet the compliance standards and culture of foreign companies

In addition to these on-boarding procedures, life sciences companies may consider mitigating the ongoing corruption risks posed by third parties with:

- Pre-contract and recurring periodic due diligence and acceptance procedures
- Contracting provisions with anti-bribery representations and warranties
- Vendor certifications and anti-corruption training
- Special payments review and approval for high-risk vendors

Finally, life sciences companies need to step up their monitoring of sales representatives, who have frequent interactions with HCPs, health care organizations and third parties, in connection with promotional activities, continuing medical education and other scientific/medical research, grants and sponsorships such as clinical trials and post-marketing studies.

77%

of life science respondents believe distributors are the most significant risks

"The current areas of significant risk from a life sciences compliance perspective are internal controls on interactions with HCPs, spot checks and data manipulation."

Compliance Lead
Greater China

"To mitigate risk we use third-party frameworks, supplier risk management frameworks, due diligence and fair market values, supplier security reviews, distributor audits and quarterly business updates about high-risk third parties."

Compliance Director
Asia-Pacific

Case study: Pre-screening employees' third-party payments lowers exception rates and raises awareness of compliance policies

To establish more effective control over recurring employee travel and entertainment compliance issues, many life sciences companies have started to scrutinize employee expenses even before reimbursements are made. To this end, EY was engaged by a client to pre-screen all employee expenses associated with HCP interactions. The client has since experienced a significant drop in exception rates discovered in these expenses, and has also reported increased awareness of the importance of compliance policy by its employees.

"Due diligence should not be a checkbox exercise. Its true value lies in its ability to protect a company's interest and reputation. It should be viewed as a small investment that pays big dividends by allowing key decision-makers to make critical and informed decisions."

John Tsai
Partner
Fraud Investigation & Dispute Services, China

On-site reviews (exercising audit rights)

Merely having an audit clause in contracts with third parties is not sufficient if this right is not exercised. Exercising this clause may identify any weaknesses in the compliance or business structure of the third party and, just as importantly, it gives the message to the third party that the life sciences company takes compliance with laws and the contract very seriously.

Recently published DPAs require companies to include right-to-audit clauses in their contracts with third parties. In general, due to the high risks associated with them, these reviews are conducted mostly on distributors. However, other high-risk third parties may also fall under the scope of these reviews (e.g., Clinical Research Organization (CRO), travel agencies).

Length and scope of the review

Depending on the size of the third party, the services it provides (promotional activity, merely distribution, etc.) and the sophistication of the third party, these reviews can take as long as a few weeks or as short as a few days. The length of the review is also related to the period in scope. If it is a new third party for which a review has never been done or has come through an acquisition, companies may choose to have a longer-scope period (e.g., three years). For larger third parties or longer-scope periods, companies may consider the use of forensic data analytics to increase efficiency and effectiveness of the review. On-site reviews comprise interviews and a financial review of data relating to the company's business. The process should not only focus on the third-party's business relating to the life sciences company and its compliance and financial framework, but also on the existing monitoring activities performed by the life sciences company on the third party and their effectiveness. An effective third-party framework must be easily achievable, consistently applied and documented, all of which would allow for the process to be audited or scrutinized by internal or external parties, should a need arise. Based on the laws and regulations in place, companies need to remember that it is no longer nice to have an effective third-party framework, rather a requirement to have one.

How can life sciences companies better monitor and mitigate risk?

To meet compliance obligations, avoid reputational risk and attract and retain top talent, the sector needs to harness proven corruption detection strategies, robust third-party due diligence, new analytics capabilities and continuously introduce new measures to strengthen the accounting and monitoring controls.

1

Internal controls and compliance

Life sciences companies should look for opportunities to strengthen their accounting and monitoring controls relating to interactions with HCPs, including travel and entertainment expenses, meetings, sponsorships, grants and donations. For example, organizations should consider establishing a pre-reimbursement review of expense claims, they should ensure that the accounting system provides an audit trail for each expense and vendor payment, the requestor, approver, settlement, and commission independent surprise checks at events sponsored by sales representatives. They should also review their compensation structures, with a view to reducing the portion of incentive-based compensation for sales and distribution, eliminate gifts to HCPs and implement monitoring systems for speaker fees and third-party events.

2

Third-party due diligence

To avoid being associated with fraud, bribery and corruption, life sciences companies need to improve their integrity diligence and monitoring of third parties. This process should be a risk-based approach and tiered to ensure that more scrutiny is applied to third parties with higher risks. Companies need a robust, consistent and practical diligence process, but for high risk relationships, this diligence would include compliance health checks and risk assessments that may involve using third-party audit rights within vendor contracts to review books, test transactions and conduct interviews with management. With increasing difficulty to obtain information on companies in various regions, these health checks and risk assessments are becoming the norm in having a better understanding of third parties, as well as helping reduce compliance gaps and improving compliance culture throughout the value chain.

"Companies should invest in establishing a robust and adaptive control mechanism that gives them comfort and assurance in the longer term. Merely stating, that other companies are doing the same things, is never a good defense in court."

Compliance Director
China

"We now have an increased focus on compliance, governance and risk management. We've embedded and strengthened the company's internal control framework and have a greater focus on management and independent business monitoring."

Regional Compliance Manager, Asia-Pacific

3

Whistleblower hotlines

Whistleblower hotlines are an essential part of a broader fraud, bribery and corruption risks management framework. They are often the first channel of complaint for employees and other stakeholders. But they will only be used if employees are confident that their reports will be dealt with in a confidential manner and that they will be protected from retaliation. It is critical that mechanisms and processes are transparent to all employees through training and communications. However, it is equally, if not more important, that whistleblower allegations are handled with care, as companies need to respond quickly and diligently to investigate and find the root cause to be able to act appropriately. Having an independent third party allows for more confidentiality as fewer insiders are involved, but it also allows for companies to leverage more resources in handling such time-sensitive matters in a highly professional manner. Mistakes in handling whistleblower allegations could be costly from diminishing confidence in such an important compliance component to legal recourse.

4

Big data and forensic data analytics (FDA)

With a significant drop in the use of whistleblower hotlines, life sciences companies need to rely more on other methods to capture unethical behaviors in a timely manner. To proactively detect fraud and corruption in a scientific way, rather than relying on random sampling, companies should leverage FDA, which is increasingly being taken up by companies as well as regulators. This multi dimensional analysis integrates risk scoring techniques, data visualization, statistical analysis and text mining to analyze disparate data sources with large numbers of transactions. A comprehensive FDA solution is designed for the life cycle of detecting, investigating, tracking and resolving fraudulent activities.

One of the compliance officers from our focus group reported that their organization was not using FDA technology because of budget considerations. In fact, by focusing in-house resources on high-risk areas, FDA can help life sciences companies improve the efficiency and effectiveness of internal investigations, with the cost of prevention often significantly less than the "cure" required if a fraud is committed.

Contact information

Fraud Investigation & Dispute Services

Global Leader/EMEIA Leader
David Stulb
+44 20 7951 2456

Americas Leader
Brian Loughman
+1 212 773 5343

Asia-Pacific Leader
Chris Fordham
+852 2846 9008

Japan Leader
Ken Arahari
+81 3 3503 3292

Global Fraud Investigation & Dispute Services Life Sciences Leader
Ted Acosta
+1 212 773 3022

Asia-Pacific Fraud Investigation & Dispute Services Life Sciences Leader
Emmanuel Vignal
+86 21 2228 5938

Asia-Pacific contacts

Australia/ New Zealand
Rob Locke
+61 28 2956335

China
Emmanuel Vignal
+86 21 2228 5938

Indonesia
Stevanus Sianturi
+62 21 5289 5000

Malaysia
Joyce Lim
+60 374 958 847

Philippines
Roderick Vega
+63 2894 8342

Singapore
Reuben Khoo
+65 6309 8099

South Korea
Chris Fordham
+852 2846 9008

Sri Lanka
Averil Ludowyke
+94 11 2463500

Taiwan
Chester Chu
+88 62 2757 2437

Thailand
Wilaiporn Ittiwiroon
+66 2264 9090

Vietnam
Saman Bandara
+84 4 3831 5100

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ED None

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