



Life Sciences Compliance in Asia

**How the Evolution of Asia's
Compliance Landscape is Driving
Uncertainty**

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The Evolution of Asia's Compliance Landscape is Driving Uncertainty

For many Life Sciences organizations looking to enhance their compliance programs, regulatory uncertainty can make it challenging to identify where to prioritize their compliance efforts.

Markets across Asia hold substantial growth opportunities for Life Sciences companies, however their varying regulatory regimes mean compliance is often tedious and time consuming.

There is a need to track and comply with multiple laws from different geographies – for instance, while compliance with the Foreign Corrupt Practices Act is critical for most companies, we have seen the emergence and bolstering of domestic anti-bribery and anti-corruption laws in several Asian countries.

In China, the Unfair Competition Law was revised in 2016 to further define commercial bribery and include fines of 10% - 30% of illegal sales. In Korea, a dual punishment system exists whereby both Life Sciences companies and Healthcare Professionals can be held liable for improper benefits or bribes.

This situation will continue to evolve; in particular, within the ASEAN region there are Other recent developments, including anti-counterfeiting tactics and e-clinical trials (details on the next page) have also brought about increased uncertainty for compliance efforts in Asia.

Yet many of the organizations we speak with recognize the need to “stay the course” in this time of uncertainty. It is important to remember that while changes to specific regulations are anticipated and are already occurring, compliance is broader than any one regulation. Further, the tenets of good risk governance, conduct, and culture are already entrenched in the expectations of regulators and consumers globally.¹

Additionally, Asian and global regulatory trends support better corporate governance and risk management, not reversals of it. Therefore, management's overall commitment to instilling and enhancing a culture of compliance within their organization and their vision to further strengthen governance, compliance, and risk management as part of their risk-based strategy should continue to guide them forward.

A continued focus on the larger compliance picture and emphasis on how to enhance one's effectiveness, efficiency, and agility through tactical efforts remains a strong course of action for Life Sciences organizations.

¹Source: Compliance Week, Compliance Officers Scratch Heads as U.S. Trumps Brexit, Paul Hodgson, November 22, 2016.

Recent Developments in Compliance

Anti-Counterfeiting

The International Medical Products Anti-Counterfeiting Taskforce estimates that in regions of Asia, over 30% of medicines on sale can be counterfeit. This heightens the risk of product recalls and potential for damage to a company's reputation.

To combat counterfeiting, many governments are adopting serialization and requiring companies to implement compliance reporting systems that provide regulators with supply chain data. Developing a cost-effective serialization program necessitates a thorough understanding of country-specific regulatory requirements, and building of cross-functional capabilities of people, processes, technology and third parties.

E-Clinical Trials

E-Clinical Trials leverage technology to automate clinical development processes. According to market research by Global Industry Analysts, the Asia Pacific market has the fastest growth in this area. China, India, South Korea and Taiwan are particularly attractive locations for clinical trials, since costs are relatively low and there are large patient populations.

The introduction of new technologies for clinical trials in turn brings increased compliance and regulatory challenges relating to data privacy and security. As seen during recent global incidents involving malware and ransomware, many companies remain relatively weak in terms of cybersecurity. This becomes especially concerning when viewed in conjunction with the increased collection and use of "big data", including where organizations capturing a wide variety of data not strictly classed as "health" data, for example income or marital status, in order to link these factors to healthcare issues.

In the event of a data privacy compliance breach, companies may find themselves the subject of class action lawsuits, which are now regularly arising following large reported breaches. Such breaches are of significant concern to Life Sciences companies due to the sensitivity of the data that could be involved.

The Compliance Journey

Companies today face many challenges in their compliance journeys. The pace of regulatory change is swift. Key stakeholders within compliance, legal, and internal audit at major life sciences organizations are becoming increasingly concerned about the effectiveness of their global compliance programs. Most recognize that these programs have become increasingly complex and are seeing their workloads rise as the business and regulatory environments evolve. And they are concerned that they may not be protecting against risks in a manner that meets the needs of the organization.

The Compliance Investment

For some organizations, compliance costs and inherent risks have dictated significant changes in product offerings and business operations. However, many are now viewing compliance as an investment and not simply a cost. These organizations are realizing that business and operational value, such as better quality data and an improved customer experience, can be derived from anticipating risks and meeting regulatory requirements. This makes compliance an increasingly integrated part of the business investment strategy.

KPMG's Compliance Program Framework



Advancing in the Compliance Journey

A framework for compliance encompasses multiple components that drive prevention, detection and response across the three lines of defence.

KPMG has developed a proprietary compliance program framework that consists of eight components, with culture and accountability at the core.

The importance of culture and tone from both the top and middle management should not be underestimated. Leading compliance programs that are plagued by cultural issues will still have problems. Similarly, a good culture can help organizations minimize misconduct while reducing the impact of compliance issues.

Compliance Program Continuum



For each program element, organizations should determine their target state, across a continuum ranging from fundamental to advanced compliance. As organizations travel along the continuum, they tend to focus more on prevention and detection and less on response, allowing them to move toward

viewing compliance as an investment and realize significant savings. Organizations further in their journey also transition to greater program centralization, integration, and sustainability.

Larger organizations, for instance, often have a large number of regulatory issues. The cost of self-identification, auditing, and investigations for these issues can be immense. However, a reduction in the number of issues can bring significant savings.

For most organisations, the compliance journey will be a continual evolution and alignment between regulatory requirements and expectations as well as the organization's risk profile, culture, strategic and financial objectives, and business operating models.

Participants at a KPMG Compliance Roundtable in Singapore (held in May 2017) cited the following activities they are or have undertaken as part of their compliance journey:

- Adapt the compliance program to different cultures and educate staff on expected behaviors.
- Building compliance objectives into HR processes (recruitment, performance management, staff development, employee exit interviews/feedback).
- Risk assessment programs should have a bottom-up and top-down element, with participants from key geographies, including senior executives, group and regional leaders.
- Periodic monitoring is common but organisations are moving towards red-flag analysis and continuous monitoring through data analytics. There is an opportunity to use predictive analytics to identify emerging risks, such as potential non-compliant behavior by sales representatives.

Three good practices for compliance programs in Asia

1. **Tailor global compliance policies to Asia.** Work with head office to understand local conditions, and develop a robust regional compliance program. This should include putting in place regional and local compliance officers and detailed procedures.
2. **Limit expenses and gifts.** For higher risk expenses, such as entertainment and gifts, require pre-approvals and set stringent expense limits.
3. **Implement a comprehensive compliance training program.** The training needs to be delivered frequently and timely, and endorsed via communications from senior management. Training should also be extended to third parties and business partners.

Asia Compliance and Culture Survey

To understand how organizations are responding to the changing compliance environment in Asia, KPMG Singapore surveyed Regional Heads of Compliance and Internal Audit from major multinational corporations in Asia regarding their compliance and culture related activities. The key findings of KPMG Singapore's Asia Compliance and Culture Survey are summarized below.

Profile of respondents (conducted May 2017)

The organizations participating in KPMG Singapore's Asia Compliance and Culture Survey operate in the following industries: consumer markets (18%); energy and natural resources (3%); financial services (3%); healthcare and life sciences (44%); industrial manufacturing (6%); and technology, media and telecommunications (26%).



Compliance functions in Asia lack maturity.

Over **54%** of Regional Heads of Compliance and Internal Audit in Asia say the actual maturity of their organization's compliance function partially reflects its desired maturity level. The remaining **46%** say actual maturity does not come close to desired maturity levels.



The key challenge for compliance is embedding governance and/or processes.

Regional Heads of Compliance and Internal Audit in Asia reported the following key compliance challenges: embedding governance and/or processes (**42%**), compliance program effectiveness (**33%**), managing rules and regulations in different regions/countries (**17%**), resources (**8%**).



Bribery and corruption compliance risks receive the greatest attention.

Regional Heads of Compliance and Internal Audit in Asia reported the following risk areas receive the most attention in their organizations: bribery and corruption (**33%**), third party oversight and management (**25%**), health, safety and the environment (**25%**), behavior and culture (**17%**).



Line-of-business management needs to take further ownership of compliance.

Only **15%** of Regional Heads of Compliance and Internal Audit in Asia thought line-of-business management took sufficient ownership of the compliance culture and agenda. Another **77%** felt there was partial ownership, while **8%** thought there was no ownership of compliance matters.



Actual organizational culture does not sufficiently reflect stated culture or values.

15% of Regional Heads of Compliance and Internal Audit in Asia said actual culture reflected stated culture and values, while the remaining **85%** thought there was only a partial match of actual and stated culture and values, or they did not know.



Behavior of middle management is the main challenge to culture.

Regional Heads of Compliance and Internal Audit in Asia reported the following key challenges to achieving the desired culture within their organizations: behaviour of middle management (**39%**), targets/pressure on senior management (**31%**), targets/pressure on middle management (**15%**), tone at the top (**15%**).



Risk, compliance and internal audit functions are working with the business to manage culture.

50% of Regional Heads of Compliance and Internal Audit in Asia said they were extensively working with the business to monitor and manage culture, and the remaining **50%** were doing so in a more limited manner.



About KPMG

KPMG helps life sciences organizations further develop and enhance their compliance programs with the intent to help increase effectiveness and efficiency, expand compliance integration, and enhance strategic business decision making.

KPMG's services are customized according to your organization's regulatory requirements, objectives, business, operations, and jurisdictional reach. We help organizations fundamentally reassess and retool their compliance governance, compliance culture, and business and risk operations. This includes helping our clients align their compliance programs to the specific requirements of their industry and jurisdiction, anticipating regulatory changes, and understanding the practices of their peers.

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