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Asia Pacific Life Sciences Compliance Survey 2018

Executive Summary

Key findings

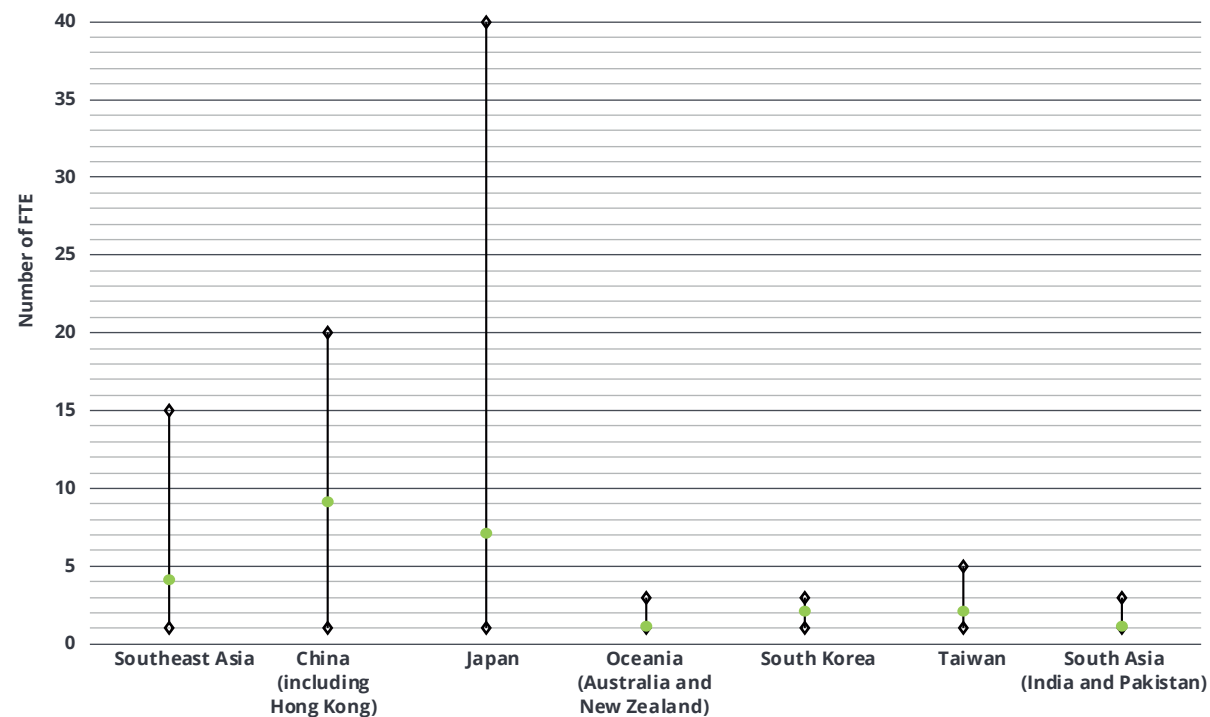
- 01. Compliance function benchmarking** – The majority of Life Sciences companies in Asia Pacific (APAC) have compliance reporting into an independent regional/global function. However, high variability exists in local country team sizes and compliance headcount is not always reflective of local market risks.
- 02. Compliance culture** – A lack of strong ‘speak up culture’ is a high risk in APAC countries with high corruption ratings as compliance incidents may go undetected. The lack of a strong speak up culture is likely due to the fact that most companies do not have an established system of including compliance measurables in the KPIs which define employee bonuses.
- 03. Compliance maturity** – Although compliance maturity is fast improving in APAC, risk articulation and identification and Life Sciences industry understanding are considered emerging capabilities.
- 04. Compliance monitoring** – Compliance monitoring in APAC is still relatively immature. A minority of Life Sciences companies rate their compliance monitoring programs as ‘world class’ and over a quarter of respondents from Pharmaceutical companies shared that their company has not completed a risk assessment in the last 3 years.
- 05. Third party risk mitigation** – Third party risks are significant across many APAC countries, however active mitigation of these risks is under-developed. Third party monitoring programs are widely rated as in need of improvement and more than half of Life Sciences companies are not regularly auditing third parties.
- 06. Emerging trends and regulations** – Support for innovation and use of analytics are becoming a core part of the compliance officer role. However competencies in these areas are still emerging, showing a gap in skill sets to adapt effectively to these changes.

Compliance function benchmarking – structure and size

The importance of independent and well resourced compliance organisations has been recognised by the majority of Life Sciences companies in APAC. Smaller companies may not need large teams due to low volume of activities, however there poses potential conflict of interest in cases where the business is responsible for compliance.

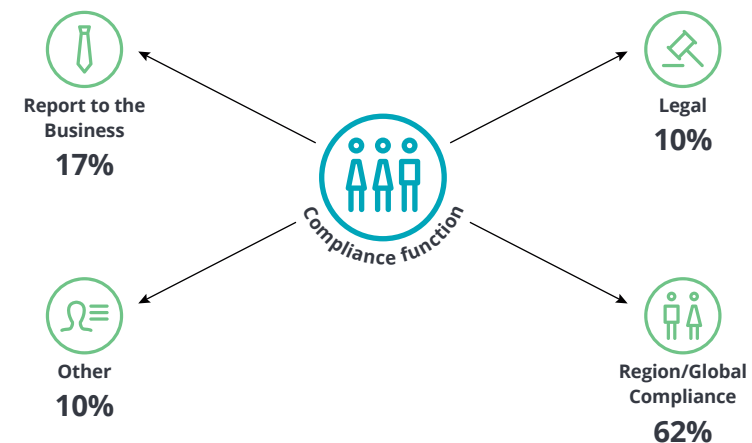
Compliance team size in APAC

- Team size is surprisingly small in India, where the largest local compliance team is 3 headcount. Given the size and risks in the market, this may indicate the low prioritisation amongst the APAC countries.
- China and Southeast Asia are high risk markets, however not all companies have large compliance teams. Medium size companies have a range in team size ranging from 1 to 15 in Southeast Asia and 1 to 20 in China.



Compliance function reporting lines

- The majority of companies have functional reporting into regional/global compliance. The exception is small companies where reporting is more often into the business. This may be due to limited resources to build an independent compliance function or little need due to low volume of activities.
- Local compliance reporting into Legal function is much more common for Medical Device companies, which is at 30% of companies compared to less than 5% in Pharmaceutical companies





Compliance culture and maturity

Compliance culture is driven by tone at the top and integration of compliance in daily operations. Whilst most respondents noted the importance of compliance in company strategic direction as well as the role of compliance champions and senior management, speak up culture and the use of Key Performance Indicators (KPIs) are still developing. This could pose significant risk in APAC countries if employees are not empowered or incentivised to speak openly about non-compliance incidents.

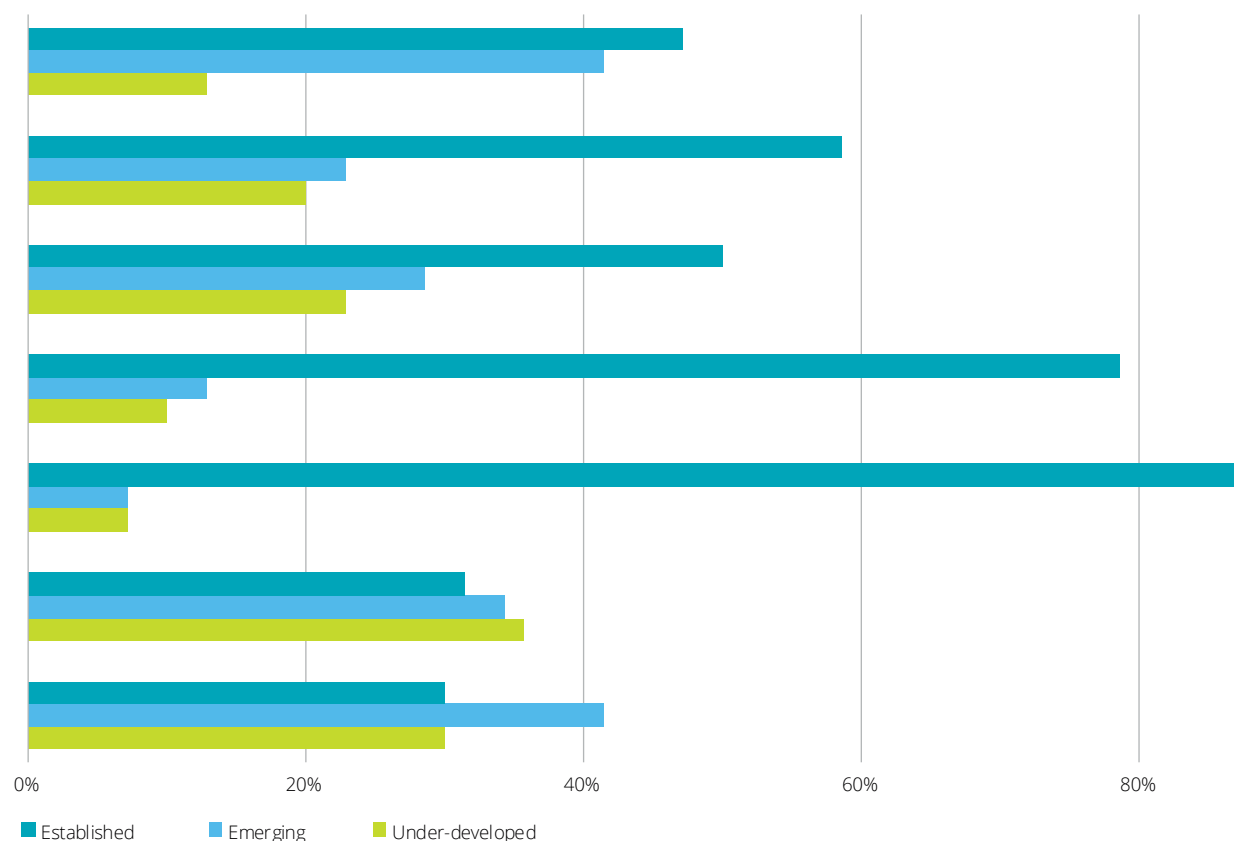


Factors of Compliance culture

Importance ranking

- 1** Compliance plays a major role in the strategic direction of the company
- 2** Compliance 'champions' exist within the organisation
- 3** Senior management is expected to regularly communicate with the organisation on compliance topics (at least quarterly)
- 4** Members of Senior Management are part of the Compliance Committee
- 5** All employees receive Compliance training when they join the organisation
- 6** Compliance measurable are part of performance metrics (KPIs)
- 7** Strong 'speak up culture'

% of companies rating of their current maturity



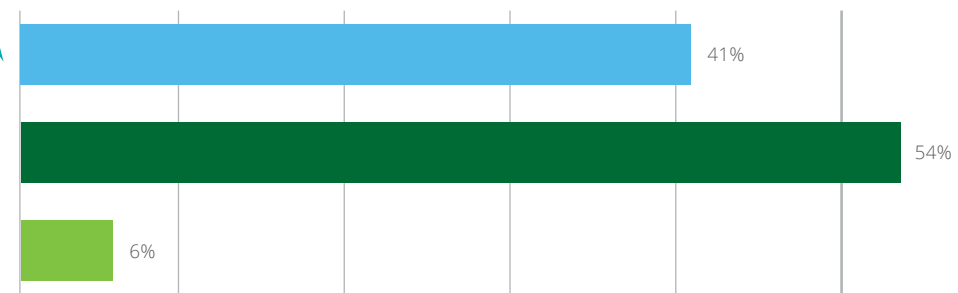
Tone at the top

In the majority of the Life Sciences companies management supports the compliance function with high level oversight of the program, and communicates with the organisation on compliance topics occasionally.

Management shows low/sporadic commitment to the compliance program and initiatives, and does not communicate with the organisation on compliance topics

Management has high level oversight of the compliance program, supports compliance function and communicates compliance topics to the organisation occasionally

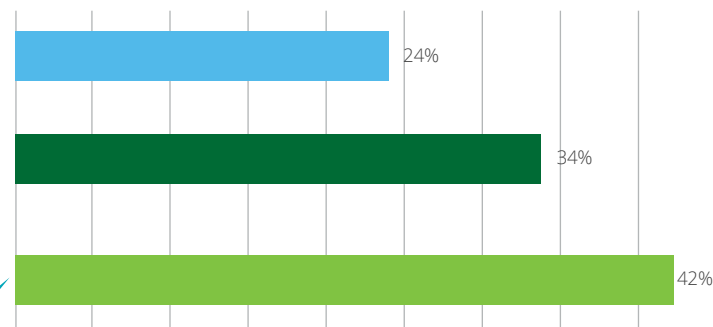
Management closely oversees the compliance program, regularly communicating on the importance of compliance and providing consistent support to activities and initiatives



Compliance function involved in management meetings and play a key role in business objective setting

Compliance function is consulted during business objective setting

Compliance function is informed of business objectives after they have been decided

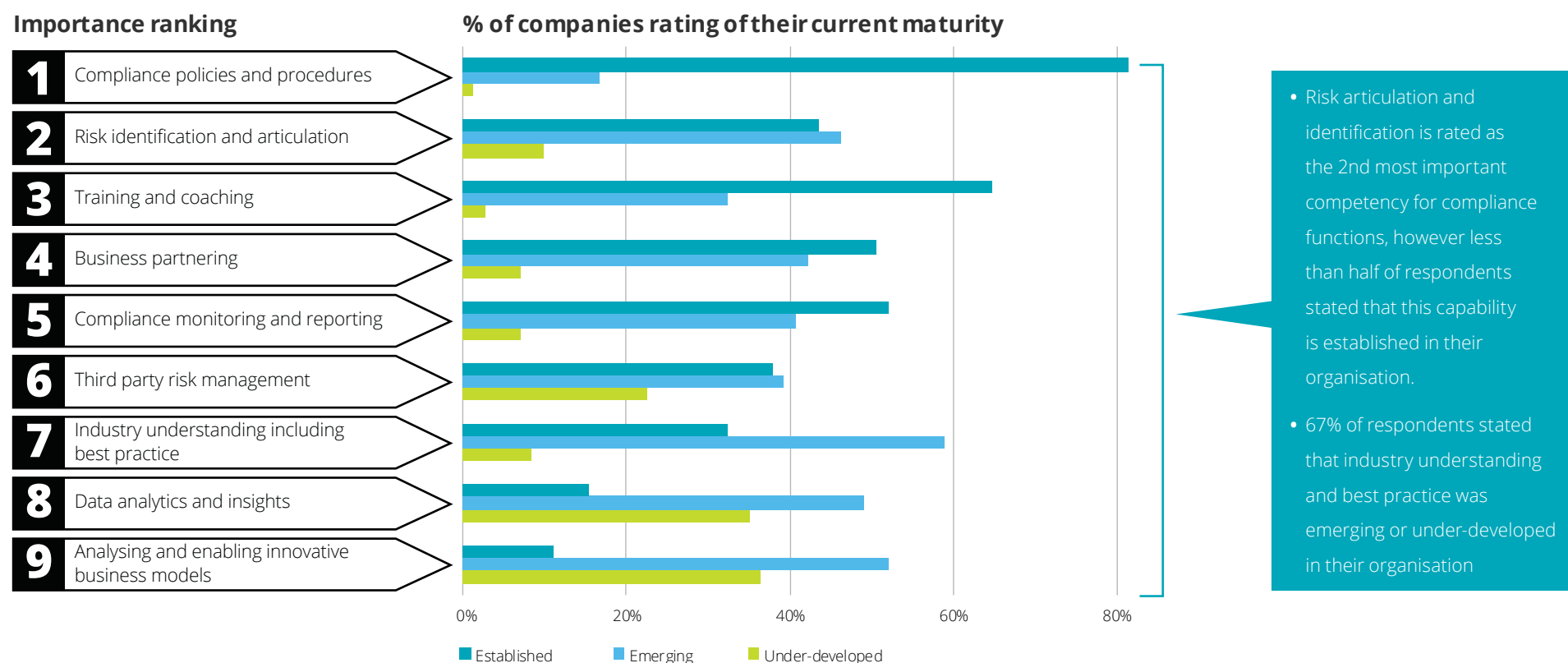


43% of respondents shared that compliance function is involved in management meetings and play a key role in setting business objectives, and an additional 34% of respondents shared that compliance function is being consulted. This shows that whilst the majority of companies consider compliance input critical to decision making, there are still a number of companies that do not involve compliance.

Compliance functions are maturing in APAC with KPIs being used and compliance training being carried out widely. Many of the traditional competencies related to policies and procedures, training and monitoring are well developed however some critical areas such as risk identification and industry understanding are still emerging.

Compliance competencies

Importance ranking



KPIs

92% of respondent organisations use KPIs to measure compliance program effectiveness, however there is a wide variety in the indicators used. The most common are internal audit results and number of non-compliance incidents

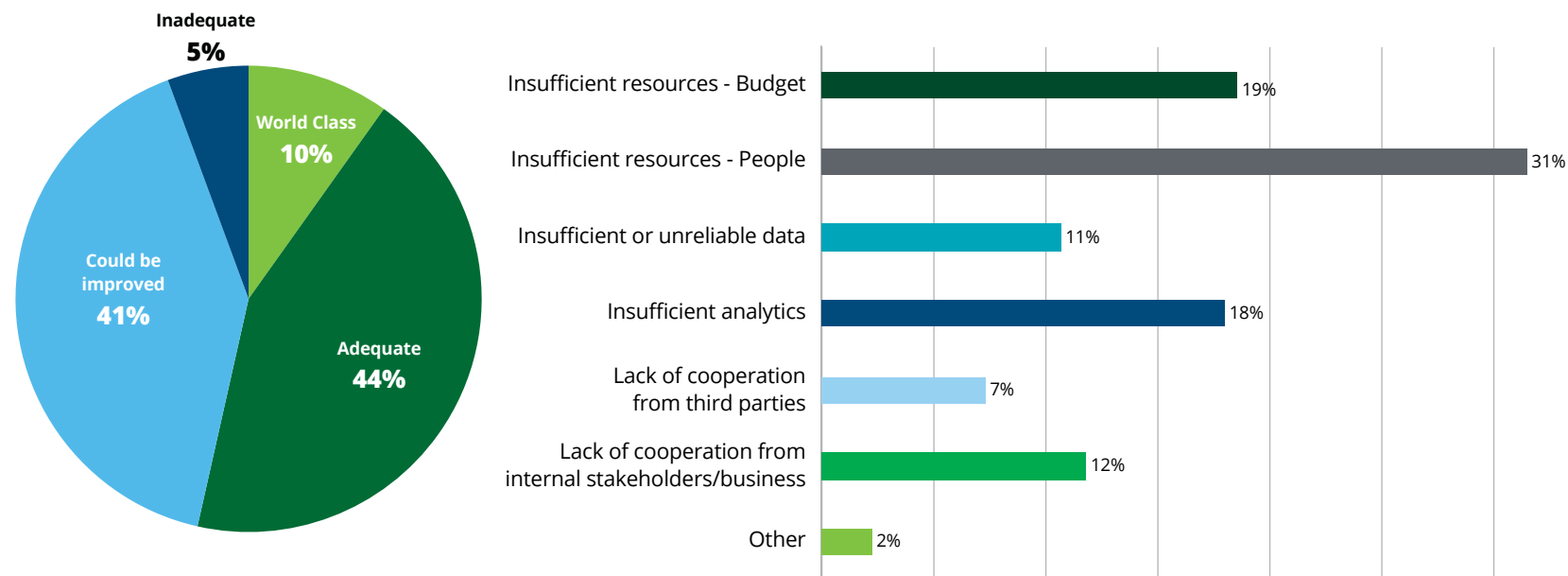
Compliance training

Non-compliance function employees in Life Sciences companies largely receive compliance training, however 42% of respondents shared that training is only carried out annually.

Compliance monitoring

Half of respondents rated their own monitoring programs as inadequate and could be improved. Despite respondents constituting 34% of large-sized companies (>50,000 people), only 10% rated themselves as “world class”.

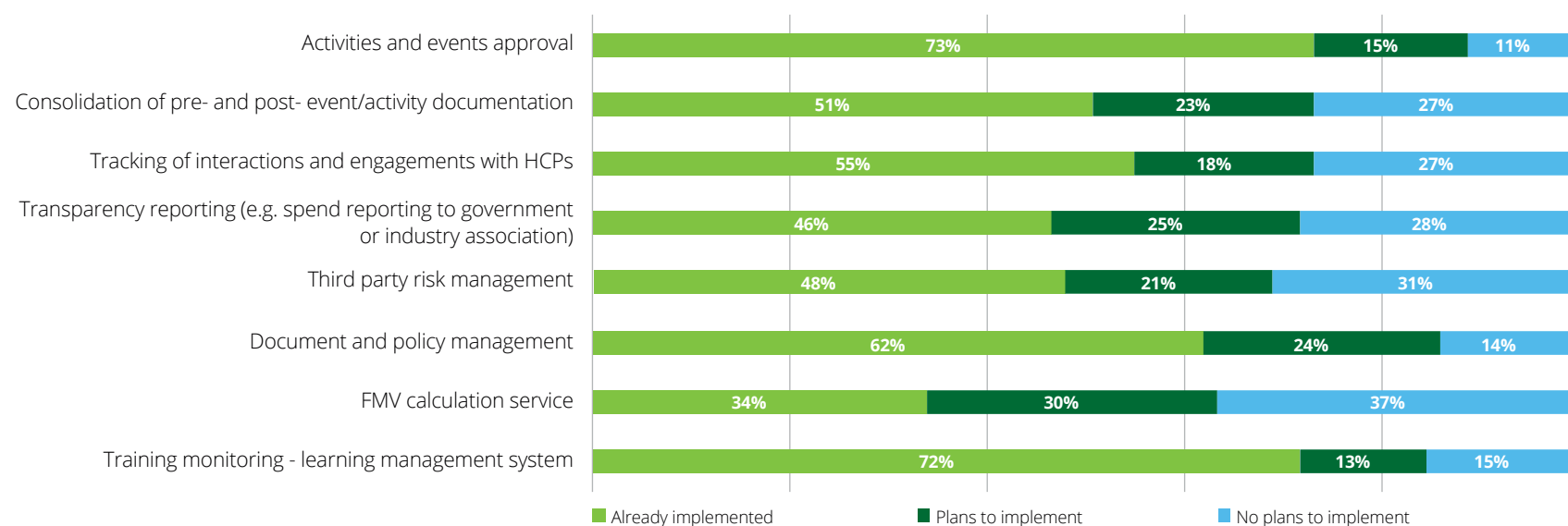
Barriers faced in achieving a 'world class' monitoring program



A larger company size implies a more vast/complex operations which would require more budget to monitor these operations. However, only 10% of respondents rated themselves as “world class”. Almost one-third rated “people-related resource limitations” as the key hindrance to evolving into a “world class”, followed by budget constraints and insufficient analytics.

Monitoring technology is typically used to manage standardised and voluminous transactions, with clearly defined compliance control points and strong documentation needs. However, for the least-prioritised items, the business case/investment may not be sufficient despite the underlying business risk. Technology may also not be available or sufficiently advanced to satisfactorily achieve their goals.

Status of implementation of IT systems and tools to support compliance



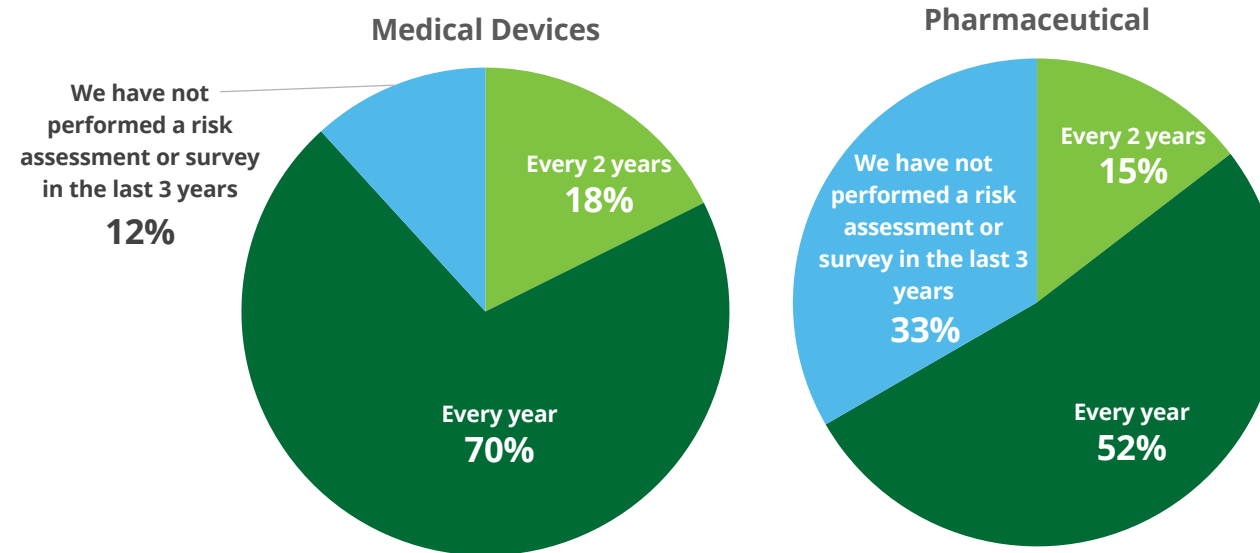
Top priorities in systems implementation (already and planned):

- Activity and Events Approval (88%)
- Document and Policy Management (86%)
- Training Monitoring (85%)

Least prioritised:

- Fair Market Value (FMV) Calculation Service (31%)
- Third Party Risk Management (28%)
- Transparency Reporting (27%)
- Consolidation of Pre- and Post-Event/Activity Documentation
- Tracking of interactions and Engagement with Health Care Professionals (HCPs)

Risk assessments help companies to prioritise and leverage resource allocation, however, industries contrast in their frequency of such assessments.



70% of respondents from Medical Device companies perform risk assessments annually compared to 52% from Pharmaceutical companies.

Surprisingly, results for pharmaceutical companies are polarising. 1 in 3 Pharmaceutical respondents have not done a risk assessment in the last three years (vs 1 in 8 or 12%) of the Medical Device respondents.

Third party risk mitigation

In Asia Pacific third parties, particularly distributors, are relied on by many Life Sciences companies. Monitoring of these third parties has been largely rated as inadequate or in need of improvement, and 23% of respondents stated that competency in their organisation is under-developed in this area. This gap poses significant risks for Life Sciences companies in the region.

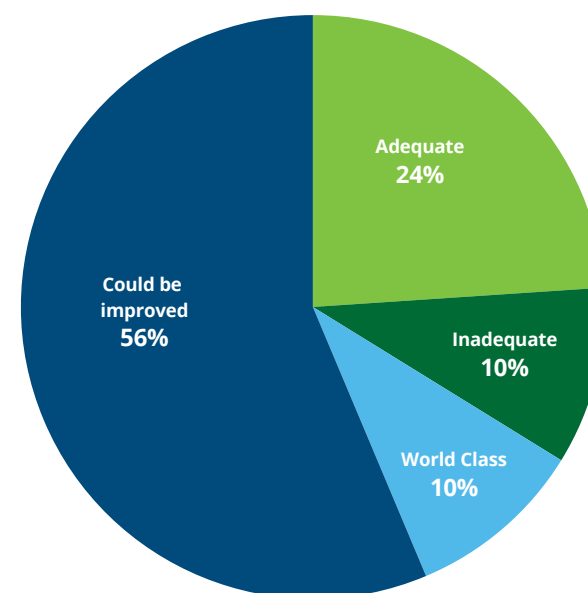
Frequency of third party audit



In terms of execution of third party audits, we found that organisation in **China completed their audits most regularly** (36% annually).

Japan had the highest number of responses stating that organisations had never audited third parties (32%).

Rating of Third Party Compliance Monitoring Programs

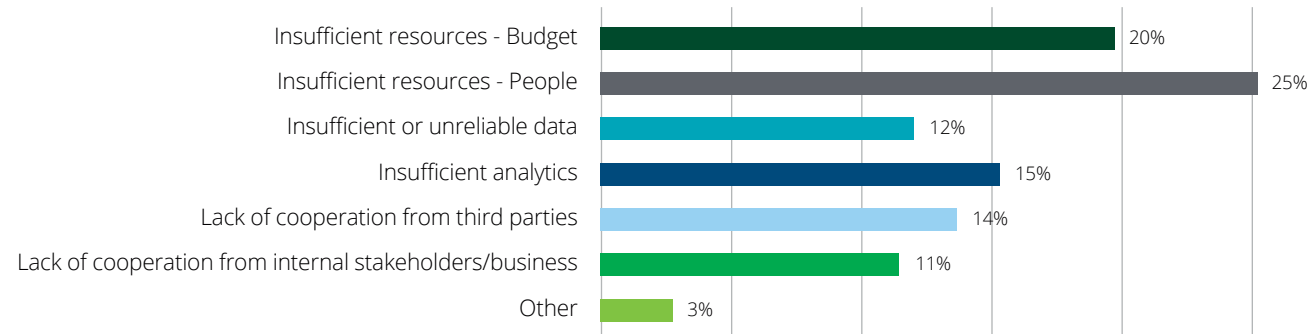


Over 66% of companies rated their third party compliance monitoring programs as inadequate or in need of improvement.

23% of organisations stated that third party monitoring competencies were under-developed in their organisation

Life Sciences companies are limited by insufficient resources to improve their third party monitoring programs. This is reflected in low levels of training being provided and the fact that most organisations do not frequently audit third parties. As a result Life Sciences companies may not be effectively identifying and addressing potentially significant third party risks.

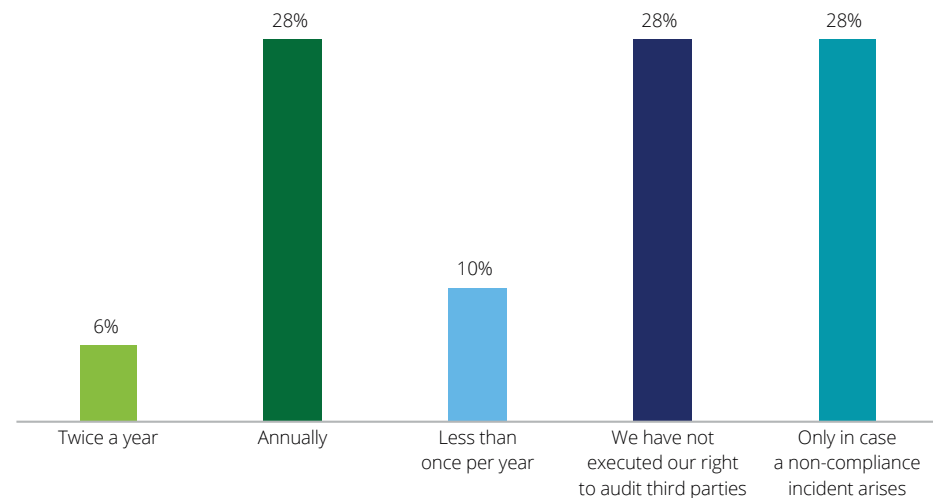
Organisational barriers for a 'world class' standard third party compliance monitoring program



The largest barriers to the improvement of third party compliance monitoring is lack of resources (budget and people), whereas lack of cooperation from internal stakeholders was the lowest barrier



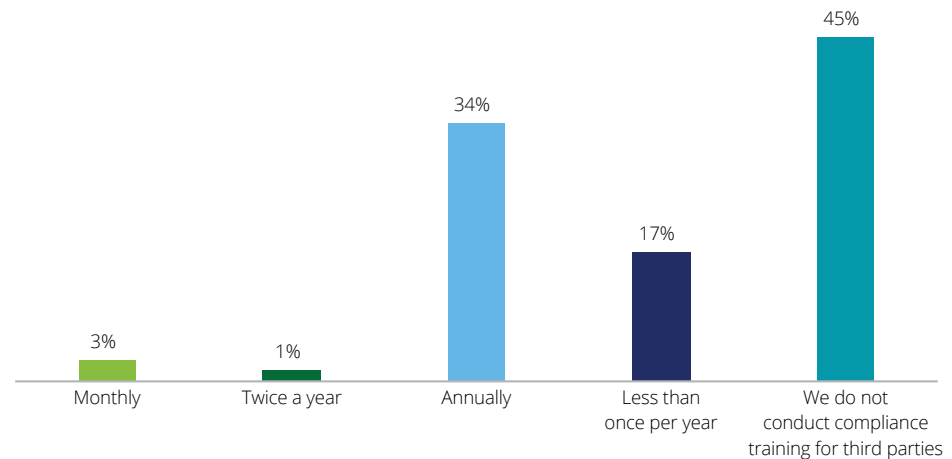
Execute the right to audit third parties



More than half (i.e. 56%) respondents stated that they execute the right to audit third parties only in case of a non-compliance incident or never



Third parties receive compliance training



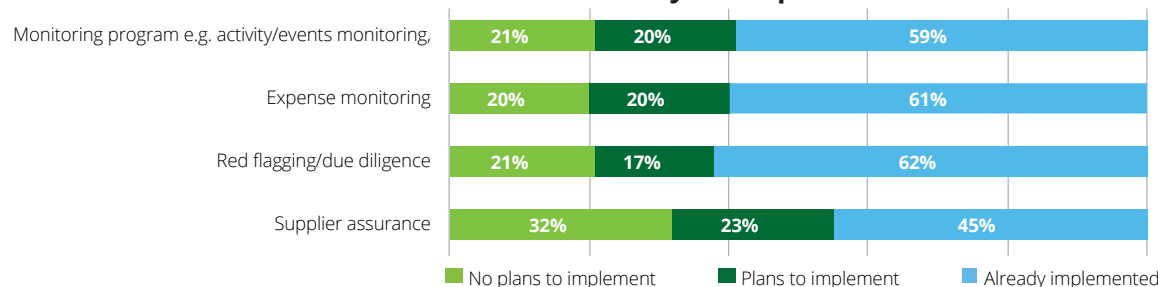
More than 60% of the respondents mentioned that their third parties either never receive compliance training or receive training less than once per year

Emerging trends and regulations

As the Life Sciences industry in APAC develops, support of innovation and use of analytics are becoming a core part of a compliance officers role. However competencies in these areas are still emerging, showing a gap in skill sets of compliance to adapt effectively to these changes.

Data analytics

What is the status of analytics implementation across Life Sciences companies?

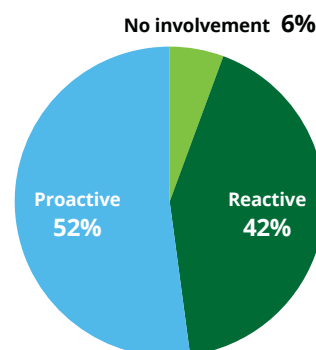


Use of analytics is growing in the Life Sciences industry, and the majority of companies have implemented or plan to implement analytics in core business operations. However, only a quarter of respondents rated competency in this area as developed for their organisation.

Data analytics and enabling innovative business models were rated as the least developed compliance competencies amongst respondents

Supporting innovation

The role of Compliance in supporting business model innovation



Life Sciences organisations are moving towards **innovative business models**, where the ways in which they interact with HCPs and Patients are evolving.

94% of respondents said they are involved in supporting these changes, however **37%** of respondents said that competency in this area was **under-developed**.

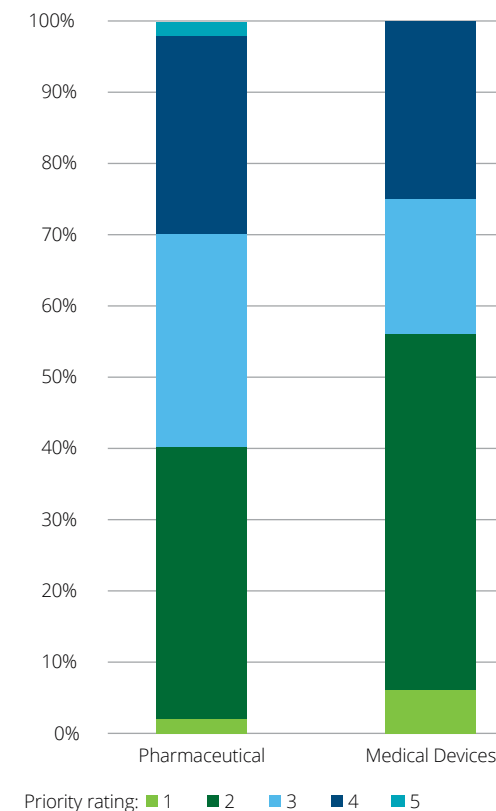
Anti-bribery, anti-corruption and policies relating to interactions with HCPs are the highest priority for Life Sciences companies. Respondents also noted adherence to transparency requirements was a priority, which is a reflection of reporting requirements in Japan, Korea and Indonesia.

Policies and regulations

Rating of prioritisation:

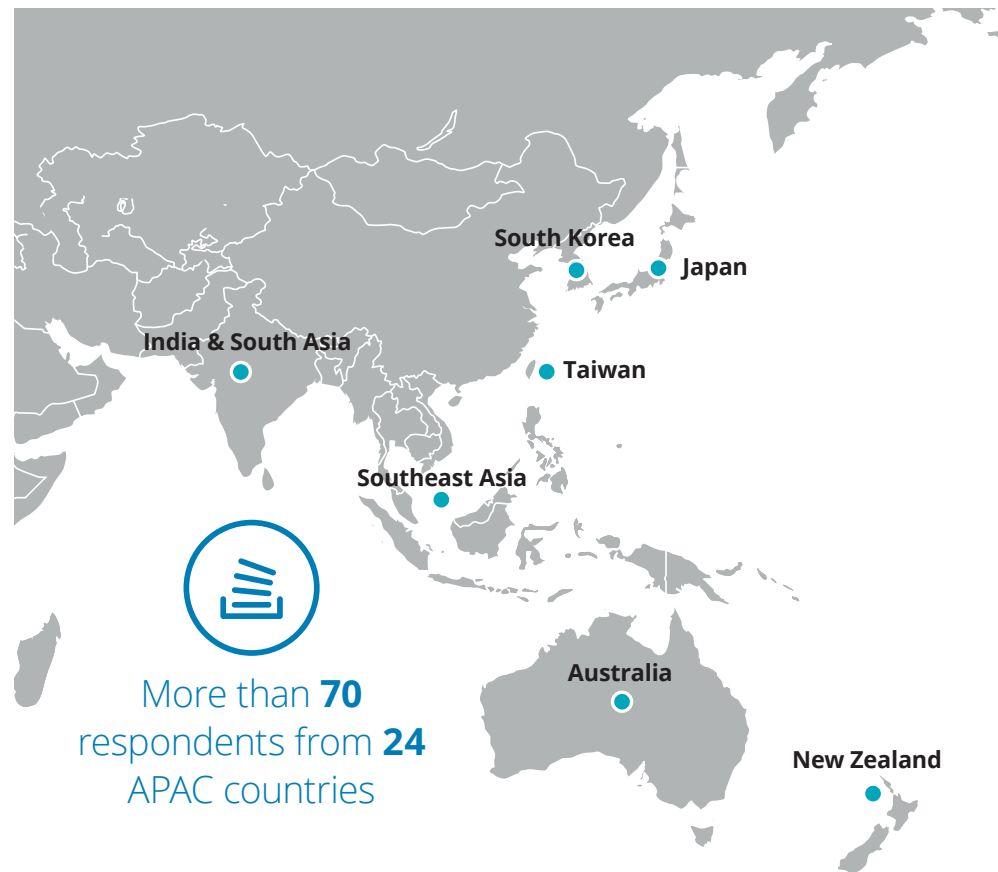


Regulations limiting direct sponsorships of HCPs are of higher concern to Medical Device companies compared to Pharmaceutical companies due to the recent updates to APAC Medical guidelines



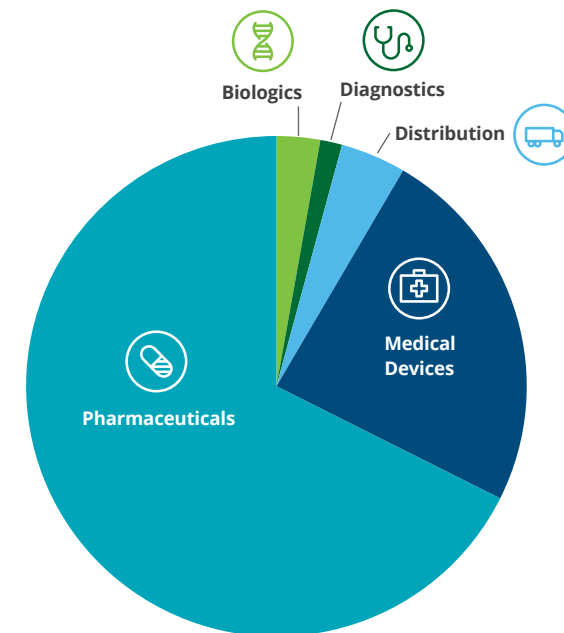
About APAC Life Sciences Compliance Survey 2018

Respondent demographics

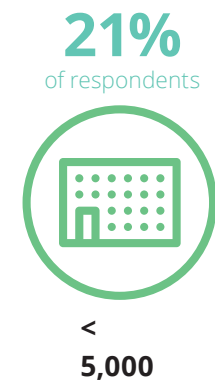


85% of respondents were Managers and or above

Respondents profile



Size of the organisation by number of global employees





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