Life Sciences and Compliance in the Asia Pacific - Ripe for Automation?

In September 2019, we released an article in our Life Sciences Asia-Pacific series looking at company growth ambitions as a network of collaborators and the deep analytical tools therein for third-party oversight. While supporting top-line growth is important, the Compliance function also has a key role to play in driving a streamlined business. According to a KPMG survey of Chief Compliance Officers, Life Sciences is the top industry expected to make investments in improving its operations, with Ethics identified as the number one category to tackle first.

For the Compliance function the journey is evolving from emphasis on standardization, to integration of the first and second lines of defense through process convergence and real-time monitoring. This article looks at our observations in working with Life Sciences companies doing just that in the Asia-Pacific region. Life Sciences companies often face a fair amount of fragmentation and complexity in Compliance processes as well as inconsistency in policies across geographies. Not only are the costs and risks high, but moreover the business may not perceive of Compliance as a value-adding partner.

Take Novartis, a company with a stated vision to reimagine medicine with advanced therapies and to be a lead adopter in all-things digital. Compliance must seek to keep pace with the business, and to enable rather than inhibit. "Compliance is evolving beyond simply rules-based into a full Ethics, Risk & Compliance (ERC) approach," said Marcos Yuba, Ethics Risk & Compliance Officer for the Novartis Asia Cluster. "We need to understand the business, the products, the patient journeys, and even the science. At Novartis, the Compliance team aims to provide impactful advice to business partners."

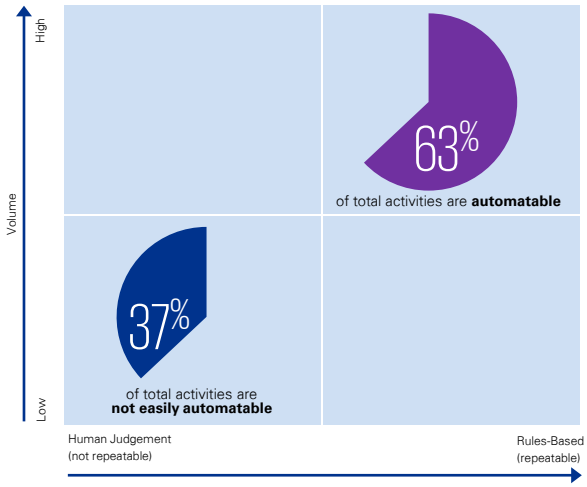
Leadership from Compliance functions have the power to take a pragmatic approach to effecting change – pick a few key processes to test automation techniques that gain buy-in from the business, calculate the cost-benefit, and scale the pilots through champion markets. Three common processes we've seen, prioritized based on risk, volume, and financial impact, are outlined in further detail below.

Process 1: Group Detailing

Life Sciences companies typically find that a majority of sales reps are organizing meetings with 10 or fewer HCPs. Yet the entire process may take up to eight weeks to arrange, from planning and registering to logistics and post-event administration. In addition, other KPMG observations about the group detailing process include:

- Duplicative entering of information, e.g. into CRM as well as local messaging platforms
- Manual reconciliation between budgeted and allocated spend
- Auditing inefficiencies being performed by both Compliance and Finance

Once the as-is process (and the challenges therein) are well documented, the next step is to assess the to-be potential based on two criteria – which sub-processes are more rules-based vs those requiring human judgment, and which sub-processes are high volume with repeatable tasks. Taken together, the criteria produce a spectrum by which to determine the ripeness for automation.



In the case of the Group Detailing process, KPMG has observed that up to 63% of the steps are automatable, including activities such as data entry for order information, HCP registering, and documentation upload.

At Novartis, interaction with HCPs is recognized as a daily, ongoing activity. The Compliance team found that by shifting away from the role of approver and into one of advisor, not only was the process more efficient but moreover the business took greater ownership over governance matters. "Technology helps us to mitigate risks and to anticipate the behaviors," said Yuba. "But it's also a mindset shift that goes beyond the technology."

Process 2: Standalone Meetings

This process relates to the promotion of products to HCPs and other healthcare stakeholders who are hosted independently of a congress. KPMG observes that the typical process takes around 11 weeks, involving planning and detailing, arranging logistics, event execution, and then liaising with Finance to remit payments. In addition, other common characteristics about the standalone meetings process include:

- Highly-manual, with many localized workflows and tools being used
- Lack of HCP crosscheck about ABAC status
- Various internal and external people are involved, causing complexity

Upon conducting the human judgment vs task repeatability analysis, KPMG has determined that 40% of the steps are automatable including external speaker engagement, creating POs, and value transfer disclosure.

Novartis has found a similar opportunity to create better business value here. In what they call "HCP end-to-end", the idea is to make the process consistent and streamlined for everything from selecting the HCPs, auto-generating the contract, use of e-signatures, and even allowing the HCPs to self-process the expenses and to trigger payment for their services via an app. According to Yuba, such innovation driven by Compliance has fostered a more proactive perception by the business to the point that Compliance are getting involved in pre-launch planning.

Process 3: Congress Sponsorship

Congresses are typically organized by third-parties, for which Life Sciences companies would provide funding for a booth, product promotion, and speaking roles. KPMG sees the process steps as being somewhat similar to those of organizing standalone meetings, yet in the case of congresses can take up to 15 weeks. Observations about the congress sponsorship process include:

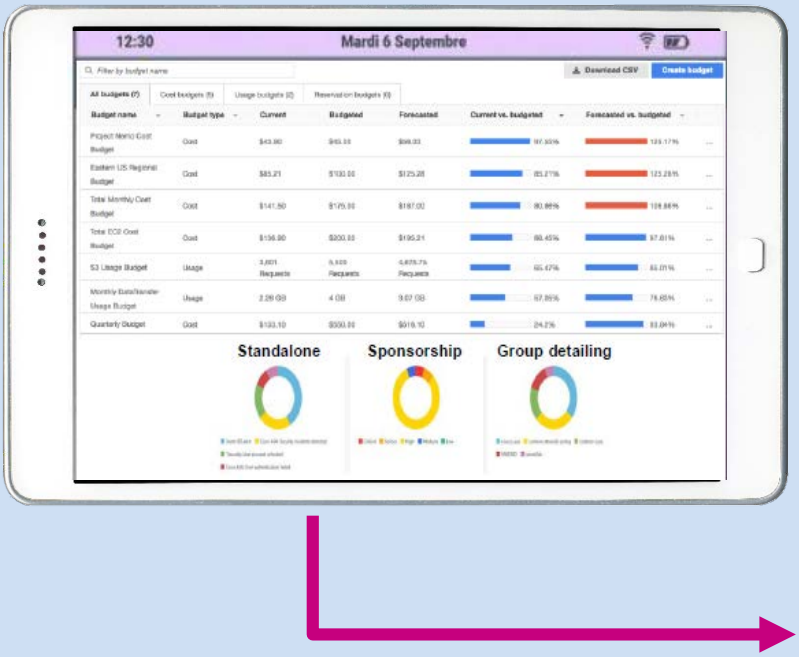
- Event organizer data is often incomplete and the input templates vary country-to-country
- Limited control over fair market value, and also lacking an archive of sponsor-related emails to audit
- Manual steps related to payment and contract preparation

Upon conducting the human judgment vs task repeatability analysis, it is determined that 60% of the steps are automatable including event registration, HCP communications, and receipts upload.

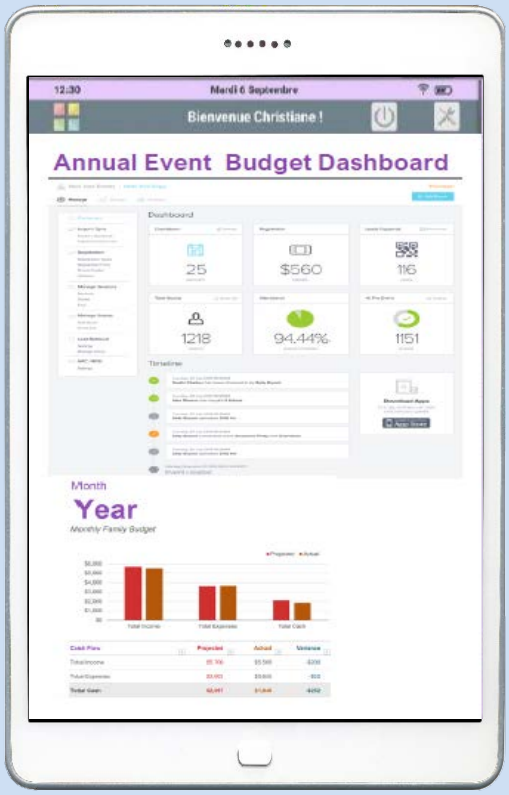
In the Novartis example, they are driving what is known as a "speaker pull" list of pre-qualified KOLs based on articles written, specialties, credentials, etc. Rather than inhibit the process, Compliance are then running analytics to monitor the high-volume interactions, and seeking to improve the cross-border transparency.

As automation work gets underway, KPMG and Life Sciences companies are already thinking ahead toward embracing digitalization for user experience. From event planning through to management and closure, the automation workflow could be facilitated by interactive dashboards and mobile-friendly tools like the below:

Annual Event Budget Planning



Approved Annual Event Budget



Zoom-in on the China landscape

China is quite often the largest market for Life Sciences companies in the Asia-Pacific region, and one of the most complex. China may represent a fragmented, difficult landscape for employees to understand. KPMG's observations about ambitions for Compliance in China, in line with a company's broader growth targets, include simplifications, transparency, and cost reduction.

KPMG-led Compliance innovation projects in China typically involve in-country sessions across numerous functions – Marketing & Sales, Operations, Medical, Procurement, Supply Chain, Finance, among others. The same three processes outlined above can be covered. For the China market, KPMG has seen a much higher automation potential, in some cases beyond 70%.

Near-term steps ripe for automation in China include data extraction, form filling, communications, and cross-platform integrations, especially WeChat. This is driven by a high volume of rules-based activities that are being undertaken. For many Life Sciences companies, China can account for hundreds of events, and thousands of sponsorships and detailing each year.

The time for automation is now

Post automation, according to KPMG experience, Life Sciences companies can expect investment payback within two years and cumulative savings in tens of millions of dollars. Not just in headcount rationalization and process streamlining, but also in the opportunity cost of doing nothing – the risks are just too high.

Five principles have emerged from the experience:

1. **Enhanced Compliance** – building stronger controls and workflow, relying less on human judgment, and reducing the need for manual training exercises
2. **User Experience** – paperless, fewer spreadsheets, automated notifications
3. **Standardize & Simplify** – regional consistency, automation of high-volume / low-risk activities, improving the key controls
4. **Data Accuracy & Retention** – central repository for all events, more insightful management reporting, better commercial decision-making
5. **Productivity Savings** – formal cost-benefit analysis, hard dollars but also efficiency gains, optimize the risk monitoring investments

Most importantly, the use of automation means more time for the Compliance function to focus on its strategic work. And with more robust data to actually track the ROI of risk monitoring activities, there is great appeal to the Commercial part of the business in measuring the marketing impacts.

"In Compliance, we need to get better with data and to articulate the story to the business," said Yuba. "Decision-making ultimately happens at the front line, so the business must know what to do in the moment. The cultural shift is a journey, it takes time."

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With Thanks

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