

How is compliance evolving to address emerging risks?

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Executive summary

Life sciences companies are experiencing an escalation and expansion of business risks. Compliance teams are, in turn, facing increasing pressure to monitor, identify and remediate such risks. They are responding by evolving their organization, practices and mindset and embracing advanced technology, to deliver greater efficiency and strategic insights. This is elevating the function's role from business support to business enabler.

A rising tide of risk

The life sciences sector is facing a rising tide of risk. Regulators continue to introduce new regulations or enhance old ones, including the UK Economic Crime and Corporate Transparency Act, which introduces a new corporate criminal offence of failing to prevent fraud. Disruptive technologies are creating further challenges, such as ever more sophisticated cyberattacks. They are also creating opportunities – like efficiency-yielding automation and the innovation potential of artificial intelligence (AI). Yet such opportunities, if not handled well, can themselves generate further risks. Compliance teams must rapidly react and adapt to manage this evolving array of risk. To identify how they are rising to the challenge, EY surveyed compliance leaders and data analytics specialists from nine global life sciences businesses*.

A broader compliance role

The compliance function's role is expanding. While teams continue to focus on detecting and mitigating risk, ensuring regulatory compliance, and managing reputational risk, their responsibilities are growing. They are now more frequently asked to provide insights that help organizations improve processes and controls, guide business activities and make informed strategic decisions.

Technology and data analytics are providing the tools to deliver such insights. Analytics, for example, can enable companies to see and contrast organizational trends and themes, informing future actions and priorities. Possessing these insights has elevated the significance and stature of the compliance function. One function leader describes this change as, "the shift from being seen as a controlling function, gatekeepers of everything, to being more of a business partner, aligned and agile with the business' objectives".



More effective ways of working

Compliance teams are moving away from traditional structures and ways of operating for greater efficiency. Eighty-two percent of function leaders say they have "centralized" delivery models, often with a global unit overseeing a centrally devised program, supported by regional or local teams. The primary reason for this is to achieve a consistent approach where needed. Another key driver is the ability to look at a consolidated view of outcomes through the same lens. Such global-local partnerships are now widespread, as companies shift from a uniform, top-down monitoring approach. Almost three-quarters tailor their programs, checklists and protocols for each review, working in collaboration with local teams to reflect local regulations.

Review locations have also changed. Forty-five percent of compliance leaders say they now execute monitoring tasks both on-site and remotely, with 27% doing so entirely remotely. The move to hybrid and remote monitoring was expedited by COVID-19, which spurred an acceleration in the development of tech and processes to enable electronic access to vital compliance data. This approach has delivered increased efficiencies and reduced travel, helping compliance teams to better manage their budgets.

Compliance is increasingly delivered with external help. Forty-five percent of surveyed companies outsource part of their monitoring programs, with 80% flagging efficiencies and lack of internal resource as key drivers. The need for specialist expertise is a prompt for 40%.

The evolution of the compliance function along with its tools and methodologies, has inevitably influenced the skill set it requires of its people. Compliance leaders now need to be able to interpret data as well as risk, with remote reviewing requiring language capabilities and understanding of local nuances. Such skills are likely to become even more essential.

The promise of technology

As their remit becomes broader and more complex, function leaders are turning to advanced technology and data analytics to enhance efficiency. Indeed, tech is central to compliance leaders' top three objectives for 2024. "Expanding and integrating data analytics and technology into monitoring" ranks beside such traditional goals as "maintaining and improving current monitoring practices" and "adapting to new risk and business changes."

Our life sciences cohort uniformly harnesses rules-based analytics to support monitoring, with 70% deploying machine learning tools, and 60% using robotic process automation and AI.

Some are pushing boundaries in using analytics for risk detection and mitigation by, for instance, using advanced behavioral techniques to identify teams more likely to initiate non-compliant events, with the aim of early intervention. Compliance teams are also using technology for centralization, automation, and digital workflow and case management.



Challenges within the tech promise

Technology is not a cure-all, however. Life sciences compliance teams, in common with other functions and sectors, are facing fundamental challenges, such as inadequate and inconsistent datasets and outdated legacy infrastructure. Although optimistic about the advantages technology will deliver, few are currently reaping the optimum benefits. Indeed, compliance heads identify "technology and innovation" and "data availability" among the key challenges of the past two years.

Many struggle with sourcing, collating and linking good, accurate data, often due to limited system integration. Such challenges can result in compliance teams following up on breaches rather than preventing them. Most function leaders would like 60% of their programs to be proactive, so equipping their businesses with the insights to prevent non-compliance. Currently, only 43% achieve this goal.

Compliance leaders realize that tapping the full potential of advanced technology and data analytics will not be a quick fix. Although most consider their monitoring programs to be "fairly mature", they acknowledge there is room for improvement – particularly around technology and data analytics. The majority anticipate it will take up to five years before they fully leverage analytics to identify patterns, trends and outliers; use AI to increase efficiency, automate and identify future risks, and apply technology for more frequent and real-time monitoring.

Toward greater collaboration

Compliance team members must now work more collaboratively, as different functions seek data from compliance to unlock insights that help in managing risk and making informed decisions within their respective areas. Ninety percent of data analytics professionals say other groups access their analytics platform: one business surveyed incorporates learnings from third party compliance monitoring into supplier risk profiles. Compliance leaders believe this union between different teams will only grow over the next three to five years.



Maintaining compliance's upward trajectory

Life sciences compliance teams are evolving in line with the risks they face; embracing advanced technology and data analytics and developing more flexible, risk-centered organizations, ways of working, and new skills. This has improved their efficiency and strategic value. Below we suggest ways for maintaining this upward trajectory:

- ▶ Balance centralization and local nuance.
- ▶ Approach current and future talent needs strategically in partnership with HR.
- ▶ Cross-pollinate ideas and experience.
- ▶ Approach technology methodically. Identify the main challenges first and then consider how IT might help.
- ▶ Make sure tech includes safeguards for proper, effective and objective working.
- ▶ Ensure the organization has a technology ethics policy.
- ▶ Support the development of a corporate culture of integrity.

*The data for our research was collected by telephone interviews with compliance leaders and digital analytics professionals from nine global life sciences companies between 20 November 2023 and 19 January 2024. Participants were invited by the EY organization, with Ipsos conducting the interviews. All data is unweighted.

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