



Commercial Compliance

Compliance Monitoring: Take your program from policing to a proactive partnership

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Influencing individual compliance decision making

Compliance is more than just a buzzword these days. It is a critical component in pharmaceutical companies' operations and obligations under an increasingly complex series of global regulatory requirements.

The roots of this new vigour in enforcement go back to 2010, when the U.S. Department of Justice stepped up scrutiny and oversight of The U.S. Foreign Corrupt Practices Act (FCPA) in the healthcare industry. Consequently, the past decade has seen many other countries make great advances in reinforcing their own anti-bribery anti-corruption (ABAC) laws, such as the United Kingdom's Bribery Act, China's Anti-Unfair Competition Law and France's Sapin II, all designed to stamp out improper influences on prescriber behaviour with extraterritorial reach.

Increasingly rigorous enforcement practices mean that companies with findings of non-compliance of these rules have had to pay hefty financial penalties and withstand reputational damage that comes from being thrust into an unflattering limelight.

Pharmaceutical companies have spent the past several years investing in technology and resources to design compliance programs. These programs vary in efficacy, however; some are too ambiguous to be truly useful at compliance risk mitigation, while others rely on overly restrictive controls that take away decision-making autonomy — creating an “us versus them” division within the company between Compliance and end users that don't treat attaining and maintaining compliance as a true partnership.

One benchmark behavioural science study (Behaviour and Compliance in Organisations, Financial Conduct Authority 2016) shows that, whilst credible deterrence

is an important component of an effective compliance strategy, adopting an overly-engineered approach can yield unintended consequences that blunt the effectiveness of these programs in achieving enterprise-wide compliance.

Rather than relying wholly on a rule-based approach, companies need to create an operational infrastructure that encourages individuals to self-regulate and bring moral considerations when confronted with ethical ambiguities. This means equipping decision makers with tools rather than rules. Instead of concentrating on complicated didactic policymaking, companies should prioritize measures that show program effectiveness and evolve the way stakeholders make compliance decisions.

Effective partnership with the business is one key aspect to an effective compliance program. Compliance officers who adopt a consultative approach and are both eager and able to understand the goals of the business are better able to ensure that existing protocols are still in line with the dynamic regulatory and commercial changes within the industry. In addition, focusing on monitoring will empower the people within your organization to make ethical decisions individually and allow them to understand that they are co-partners in the role of ensuring compliance.

Why is regular compliance monitoring important?

A well thought-out and managed compliance monitoring program enhances transparency, which has value beyond regulatory concerns: it improves outcomes for business partnerships, succession, and knowledge sharing across silos. Monitoring gives executives an unparalleled view across the scope of the company's operations and provides operational and commercial advantages.

By monitoring regularly and frequently, companies can identify areas of substantive risks and undertake mitigation strategies before any red flags manifest as regulatory violations. These "spot checks" or "soft audits" provide an extra level of protection to businesses prior to formal audits taking place.

Unlike formal audits, which are done retroactively to test transactions against established compliance standard operating procedures (SOPs), monitoring confers a greater degree of flexibility and responsiveness — a crucial element in a fast-moving regulatory climate.

Being able to adjust operations in real time reduces the burden of preparing for formal audits, since up-to-date assessments and relevant stakeholder feedback will be readily available. This enhances efficiency by cutting down on the human capital resources needed for preparation and document reviews and approvals.

From a commercial operations perspective, companies might find it challenging to make the case for ongoing monitoring when an established audit protocol is in place. In reality, monitoring is not a redundancy with auditing. Monitoring enhances the effectiveness of an auditing program and streamlines the oversight activities implemented across corporate silos.

While auditing is reactive, monitoring is proactive — and in the long run, proactivity is a better hedge against errors, violations and financial losses.



How does monitoring help measure and evaluate compliance program success?

Rome wasn't built in a day, as the saying goes, and companies should expect that their compliance programs will need to evolve and align to new business models and regulatory updates. Robust compliance programs can deliver "big picture" benefits that support and improve business performance and results. Some of these benefits, however, are often intangible and are not as simple to quantify as checking a box. Beyond ensuring compliance to established SOPs and protocols, a company should be able to evaluate its program and observe the following:

- A heightened awareness of compliance as an enterprise value and an understanding of actions that are monitored
- Development of an ethical culture in which "doing the right thing" is ingrained
- Greater autonomy and an increase in ownership of compliance protocols and adherence
- Ability to self-regulate and determine the correct decision. (Companies that observe this then have the

potential to eliminate certain approval processes or implement threshold-based approval to streamline operations, so they can focus their monitoring efforts on post-event oversight instead.)

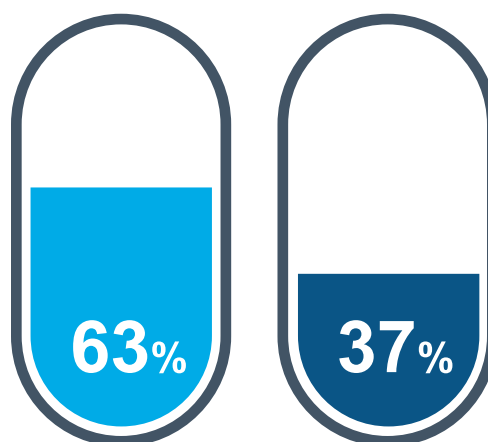
- Collaboration with compliance, and a perception shift in which compliance officers are partners rather than "police"
- A reduction in audit observations and risk reductions — both in the context of and apart from annual risk-assessment exercises

A well-rounded compliance monitoring program should strive to measure not only adherence to guidance and the effectiveness of established controls, it should also observe and consider the degree to which a culture of compliance is embedded into overall business operations. Doing this will allow for more holistic analysis and reporting of compliance activity and identify opportunities for both technical and behavioural change.

Advantages of Monitoring

- 1** Better tracking of budget through data analytics monitoring
- 2** Visibility into operations across departments and divisions both domestically and globally
- 3** Proactive real-time risk management, analyzing "why" and "how"
- 4** Enhanced external interactions with consumers and the public, protect reputation and main public trust
- 5** Defining and benchmarking best practices, improving communication with the board and investors

Monitoring Programs are now embedded in a majority of healthcare companies*



Implemented Regular Monitoring

As part of the Compliance Program at their organization

Rely on Audits

In addition to Regular Monitoring

*results obtained from recent 2019 Compliance Monitoring Roundtable

Make monitoring meaningful to the business

A key challenge for compliance is that it often may be viewed as a supportive or advisory role with limited impact on revenue generation. In reality, compliance officers and the third-party partners brought on board to help facilitate strategic compliance strategy are ideally positioned to be agents of change and to help build operational resilience within a business. This resilience can translate into better organizational responsiveness to environmental changes as well as more effective and efficient business practices and standards which help support an organization's bottom line.

Comprehensive and holistic compliance monitoring provides feedback on valuable insights around business activity such as aggregate spend on external stakeholders, awarding of grants or financial support for scientific education, and independent investigator studies. It also highlights opportunities on where and how to deploy resources to generate the highest return on investment. With that said, it's important to note that monitoring is not a static exercise. It is a dynamic system of checks, results, and continuous improvement. It must evolve with the organization and the external environment.

By applying a critical lens to what is observed, monitoring can help identify where to best deploy resources. Whether it is a need for improved guidance and controls or to support adaptive and behavioural change through training or other targeted improvement plans, monitoring can determine the root cause of its findings. Through effective monitoring, compliance helps to build a responsive and nimble business while ensuring optimal risk management and mitigation.

Highlighting key areas for improvement and working to address broader operational objectives helps a compliance professional transition from acting solely as a subject matter expert to becoming a "compliance coach" by contributing practical and applicable compliance direction to ensure business success. Working to embed compliance into the business mindset and building a compliance strategic plan that supports business goals will serve to demonstrate the value proposition of appropriate compliance investment.

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Putting a proactive compliance monitoring plan in place

Effective compliance is an inherently hard thing to measure, since the key marker of its success is the absence of regulatory scrutiny, violations, and penalties. As a result, it can easily be overlooked until there is an urgent need for intervention. Proactively investing in a strategic, comprehensive compliance framework can prevent legal trouble, financial penalties, and negative publicity.

Establishing a value-based monitoring program can help change the perspective of the compliance program by making it relevant to how the business operates. Monitoring enables proactive stewardship over various business activities, even across divisions or departments. Such cross-silo visibility gives a company the opportunity to course-correct in real time, streamlining audits when they do take place.

Successful compliance monitoring allows for timely reporting and feedback. Facilitating two-way communication is a key part of creating a corporate culture that prizes ethics, trust, and autonomy. This is what gives compliance professionals the power to act as change agents as the Life Sciences industry continues to evolve.

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