

How pharmaceutical and life sciences companies can improve monitoring techniques to anticipate and mitigate compliance risk*

Effective compliance monitoring requires a combination of industry knowledge, accurate and available information, and risk-focused indicators to establish a program that not only identifies potential compliance issues but adds insight to business process improvement. A successful monitoring program incorporates compliance and business goals directly into its design. With the appropriate technological capabilities, the monitoring program can effectively measure an organization's compliance while delivering sustainable value to the organization.

Compliance is at a crossroad. Compliance programs have been quickly and progressively developing in response to a variety of drivers—settlement requirements, industry standards, government regulation. Regardless of the success companies have had implementing the "seven elements," few have had true success with establishing real-time, proactive monitoring programs that allow them to get ahead of issues and violations, reduce costs, and drive operational excellence to enhance compliance and create a competitive advantage.

Truly effective monitoring programs enable the organizations to identify emerging compliance issues before they become problematic. Shared monitoring capabilities leverage central data repositories to capture critical information from systems within each functional area and report anomalies back to responsible stakeholders according to pre-defined "monitoring drivers." Compliance or performance-based drivers include state reporting laws, Foreign Corrupt Practices Act mandates, external monitoring per corporate integrity agreements, third-party vendor due diligence and monitoring, corporate compliance policies, and internal financial and operational performance goals.

Monitoring drivers are supported by company-defined key performance and compliance indicators (key performance indicators [KPIs] and key control effectiveness indicators [KCEIs]). These indicators are embedded within functional area processes and governed by rules and parameters specific to each monitoring driver. KPIs and KCEIs are triggered by control violations or process deviations, resulting in immediate notification to assigned stakeholders.

Compliance Monitoring Challenges

Changing Risk Environment—The rapid pace of regulatory requirements leaves many organizations scrambling to keep up. Does your monitoring program have an innovative approach with the flexibility to accommodate a continuously changing regulatory environment? Does it provide value to business stakeholders?

Non-integrated Systems and Duplicative Business Processes—Many departments work in their own organizational silo, which drives additional spend to meet basic business demands and creates redundant efforts to meet monitoring and reporting requirements. Can your systems comprehensively address compliance monitoring and reporting requirements?

Low Automation of Monitoring—The volume of business activities that should be monitored can overwhelm the resources of most organizations. The failure to use technical capabilities to the fullest can decrease efficiency of data loading, validation, and monitoring of business activities. Does your monitoring program use data systems to the fullest extent possible?

How Can PwC Help Your Organization?

PricewaterhouseCoopers assists companies in developing leading-edge monitoring programs to increase compliance oversight and drive performance improvement within your organization. We leverage technology to collect, assess, validate, and report data

The seven elements of compliance:

1. Standards & procedures
2. Oversight
3. Education & training
4. Auditing & monitoring
5. Reporting
6. Enforcement & discipline
7. Response & prevention

from relevant systems and employ KPIs and KCIs to enable real-time monitoring of key compliance and performance drivers.

PwC's Performance Improvement professionals provide proven functional, industry-specific support skills in key areas including:

Compliance Monitoring Assessment and Design—PwC's Governance, Risk and Compliance professionals provide sound, enterprise-wide advice related to accomplishing a sustainable and disciplined approach to monitoring. We help enhance your compliance monitoring system and provide options for key performance indicators, monitoring criteria, and frequency. We assess your staffing resources, data sources, and quality to focus on leveraging your existing technology and capacity thresholds.

Compliance Monitoring Implementation—PwC's enterprise-wide monitoring implementation approach allows us to develop actionable and strategic reporting. We help enhance your monitoring program, identify attainable system synergies, and create a monitoring roadmap so you realize the benefits of consistent compliance monitoring.

Compliance Monitoring Performance Improvement—To achieve performance excellence, you must understand and improve the individual elements of your operation to create a stronger overall operation. PwC identifies opportunities to apply resources efficiently, lower costs, and improve service. We help you establish measurable targets, particularly around customer service, order fill-rate operating metrics, internal sourcing, inventory levels, operating and manufacturing costs, and trending analysis.

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Benefits You Can Realize

PwC's compliance monitoring and development services can help your organization:

- Create a sustainable and consistent compliance monitoring program for the compliance organization and business stakeholders.
- Reduce duplicative monitoring business processes across departments and streamline the ability to meet reporting requirements.
- Integrate process and systems to reduce costly and redundant projects.
- Increase data consistency and quality as information is sourced, transformed, managed and distributed to address monitoring reporting.
- Drive the automation and efficiency of data loading, validation, and auditing by focusing client's resources.
- Leverage the data and information required for compliance requirements to increase the effectiveness of business stakeholders through enhancing reporting mechanisms and other tools.

About PricewaterhouseCoopers

PricewaterhouseCoopers' Global Pharmaceutical and Life Sciences Industry Group (www.pwc.com/pharma) is dedicated to delivering effective solutions to the complex strategic, operational and financial challenges facing pharmaceutical and life sciences companies. We provide industry-focused assurance, tax and advisory services to build public trust and enhance value for our clients and their stakeholders. We draw on the knowledge and skills of more than 154,000 people in 153 countries from across our network to share their thinking, experience and solutions to develop fresh perspectives and practical advice.

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