Enabling performance through advanced monitoring and testing

A monitoring and testing solution for the pharmaceutical and life sciences industry
That is where a Managed Monitoring and Testing solution comes in. Managed Monitoring and Testing is an emerging outsourced or co-sourced solution for the risk, compliance, and control activities that commonly sit in a company’s “second line of defense,” including:

- Commercial Compliance
- Medical Affairs Compliance
- GxP Compliance
- IT & Data Privacy
- Anti-Corruption
- Third Party Risk Management
- Contract Compliance
- Financial Controls

Managed Monitoring and Testing helps companies “lift and shift” and/or advance their existing compliance and testing processes by:

- Aligning the entire monitoring and testing program to the company’s risk assessment and strategic priorities;
- Integrating with and centralizing a company’s existing (and often divergent) global monitoring and testing activities; and
- Applying advanced data analysis techniques (e.g., analytics, visualization, and surveillance), low-cost global delivery, and continuous process improvement.

The end product is a nimble, dynamic, and cost-effective approach that delivers better information to business leaders, helps them manage a growing list of organizational risks, and gives them the confidence to make decisions that drive innovation, growth, and profitability.

Pharmaceutical and life sciences companies at all levels of risk and business process maturity can benefit from a managed approach to monitoring and testing. For companies building their compliance infrastructure from the ground up, Managed Monitoring and Testing can provide a complete, integrated solution to what can be an onerous, day-to-day process—delivered quickly, with consistency and expertise, and at a lower cost than building it yourself. For companies with more developed compliance processes and culture, Managed Monitoring and Testing can present an opportunity to advance critical elements of monitoring and testing—e.g., commercial compliance activities, IT compliance, anti-corruption or key financial controls. By leveraging outside expertise, companies can increase productivity and consistency, and refocus in-house resources to more value-added activities like issue remediation, training or strategic business support, while potentially reducing infrastructure cost.

According to PwC’s 18th Annual Global CEO Survey,1 companies that look to outside sources for innovation ideas are more likely to be top performers in terms of revenue growth, profitability, and innovation. So ask yourself: Is monitoring and testing really in my organization’s wheelhouse, or could a specialized and scalable third party deliver better results at potentially lower cost?

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To move to the next level, pharmaceutical and life sciences companies are reviewing and evolving their processes and systems to deliver a more coordinated view of internal monitoring and testing across the second line of defense. Continued regulatory scrutiny and cost pressures require companies to better utilize data and reconsider resource models while maintaining or improving controls testing coverage. Partnering with a provider that specializes in Managed Monitoring and Testing can give these organizations immediate and greater access to skilled resources and technologies that enable that shift, thereby helping them move quickly to a more nimble, more proactive, and more cost-effective compliance and controls testing function. Within the complex and highly regulated pharmaceutical and life sciences space, the potential benefits can be multiple and long-lasting, such as:

- **Effective monitoring and testing prioritized to the business’s greatest risks.** A specialized provider brings the capabilities to analyze an organization’s risks, prioritize monitoring activities, execute analytics and testing, and support it with reporting and technology capabilities that make the test results easily available and analyzable.

- **Coordinated, standardized, and flexible monitoring and testing, across silos.** At many pharmaceutical and life sciences companies, monitoring and testing activities are spread across the organization, depriving leadership of a coordinated view and creating potential coverage gaps, duplicative processes, and excess cost. A managed solution can create monitoring and testing standards that are consistent and applicable across functions such as Sales & Marketing, Finance, R&D, and Medical Affairs, providing the flexibility to evolve and mature as compliance issues and operating conditions change.

### PwC’s Managed Monitoring and Testing Services Model

- **Risk Assessment**
  - Identify high-risk processes for ongoing testing. *Examples:*
    - Commercial compliance
    - Medical affairs compliance
    - GxP compliance
    - IT & data privacy
    - Anti-corruption
    - Third party risk management
    - Contract compliance
    - Financial controls

- **Key Controls**
  - Identification of key control objectives for high-risk processes

- **Data-driven Monitoring**
  - Advanced analytics technology to automate controls monitoring, where possible

- **Centralized Testing**
  - Ongoing scalable testing using low-cost global delivery, where possible

### Process supported by enabling technology

Continuous feedback to Risk Assessment and identification of controls remediation and enhancements
- **Additional talent where it’s needed and a restored focus on core processes.** The right provider gives companies the flexibility to supplement their teams by leveraging a flexible, globally sourced talent pool with deep industry specialization and capabilities in regulatory priorities, controls, compliance, and data analytics. Fully outsourcing or co-sourcing of monitoring and testing processes also takes pressure off of internal resources for whom monitoring and testing may be a secondary duty, allowing them to refocus on core processes and value-add activities like issue remediation, training or strategic business support.

- **Sustainable cost savings.** Through a managed solution, pharmaceutical and life sciences companies can leverage proven, leading methodologies and globally sourced compliance and sector expertise, all while potentially reducing their monitoring and testing costs and reducing the chance of costly compliance failures. An outsourced or co-sourced approach to monitoring and testing can produce significant benefits across the organization, leading to greatly enhanced risk and compliance monitoring, a more coordinated and standardized testing approach, more effective resource utilization, more bandwidth to focus on core business processes, and potentially greater return on monitoring investment. Given the desire to improve monitoring and testing to better grapple with today’s risks, along with the efficiencies that come with a managed solution, it is time for pharmaceutical and life sciences companies to consider an alternative that brings both the increased rigor needed today and increased flexibility needed in the future.
Gaining a new vantage point for controls and compliance

Diligent, recurring monitoring and testing is the backbone of an effective controls and compliance program, working every day to help identify and remediate weaknesses in controls and processes, and producing intelligence that can be fed back into management’s risk and controls assessment process to provide deeper insight into the organization’s risk profile and control posture.

But day-to-day monitoring and testing can also strain the bandwidth of organizational resources and dilute their focus on more strategic business processes. Creating a third-party outsourcing or co-sourcing relationship for those services is a potentially cost-effective way of alleviating stress in monitoring functions while also achieving a higher level of monitoring and testing maturity, with regular evaluation and updating of processes and controls.

Compliance and risk management will always come with some level of investment. The question is, when do you pay? Make the right investments on the front end and you are enabling your company to perform against its business plan with less risk of derailment. Wait and hope things fall into place, and you may be exposed to significant fines, payouts, legal costs, and reputational damage. Early, targeted investment is the strategic, cost-effective choice.

Pharmaceutical and life sciences companies should ask themselves:

• What is your level of risk and compliance program maturity?
• Are your monitoring programs effectively aligned to your key risks and executed in a consistent manner to produce the greatest coverage?
• Could a managed solution offer opportunities to optimize your controls monitoring and/or reduce cost of compliance?
• Are there human resource challenges to achieving effective controls monitoring?
• How well do you use your data and technology to drive testing and monitoring activity and measure results across the organization?

Contact information

For a deeper conversation about how PwC’s Managed Monitoring and Testing Services can enable the performance of your organization, contact:

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