



Leveraging tech-enabled solutions to support OIG Compliance Program Guidance implementation for life sciences companies

Contributors: Jack Tanselle, Juan Tessi, Jessica Vermillion, Emma Campbell

In November 2023, the US Department of Health and Human Services (HHS) Office of Inspector General (OIG) released its latest version of “General Compliance Program Guidance” (GCPG)¹; a voluntary set of directives specifically designed to assist companies in the management and oversight of their compliance program.

The GCPG notes the enhanced expectations placed on company leadership to understand risks impacting their business and manage them through active oversight. Also in 2023, Generative AI (GenAI) emerged as a major topic within the media and many board rooms, capturing global attention and sparking new or accelerated discussions about transformation as companies and individuals explore its potential to

revolutionize business and society. Compliance programs require agility and resourcefulness to assess and mitigate risk as business strategies naturally evolve and as the OIG and other regulatory bodies periodically update their expectations for achieving an effective and sustainable compliance program. In this article, we explore how GenAI can enhance risk assessment and monitoring to help mitigate potential risk in an era characterized by rapid

¹ <https://oig.hhs.gov/documents/compliance-guidance/1135/HHS-OIG-GCPG-2023.pdf>

technological advancement and a growing appetite for automation. **Let's take a closer look at two practical use cases:**

1. Compliance Risk Assessment

Enhancing risk scanning to help accelerate the company's compliance risk assessment (CRA) process and arm the compliance team with near real-time analysis for a potential proactive response to company risks and provide benefits to companies grappling with economic challenges, resource needs, and budget constraints.

What the GCPG says:

The GCPG highlights that an effective compliance program involves quarterly reports to the Board on the company's effectiveness in addressing and resolving identified risks through the Compliance Committee and its expectations for using data analytics to assist in identifying company risks.

Our experience:

A formal CRA process is integral to determining that the company has its finger on the pulse of risks and can formalize plans to mitigate identified risks efficiently and effectively. We regularly interact with global companies who are challenged to balance the rigor and frequency of risk assessment activities relative to resource needs and budget constraints. These companies are often looking for more timely and practical tools to aid them in executing more routine risk assessment activities, allowing compliance team members to focus on higher-order and more nuanced reviews. Regardless of potential impacts from unforeseen business changes, loss of staff, or budget cuts, compliance officers still need to demonstrate program effectiveness, raise awareness of potential gaps, and provide recommendations to leadership

on an ongoing basis.

Recommendations for consideration: Frequent assessment is crucial for a company to effectively plan and implement timely compliance related communications, training, and other resources to support the business. It is also important to provide Compliance with a proactive ability to develop mitigation plans to help address identified company risks and raise awareness for company leadership.

Integrating the strategic application of GenAI in outlining areas for assessment can help streamline efforts across functions such as Human Resources, Internal Audit, Compliance, Quality, and Procurement, potentially reducing resource constraints across the enterprise and helping to proactively identify enterprise risks. Given the commonalities across these functions, companies can collaboratively build GenAI use cases that support their respective areas, share the associated cost, and add value to existing enterprise risk management (ERM) and CRA processes for a reasonable cost that has the potential for large-scale benefit to the company.

Integration of GenAI can be incorporated at different stages of risk assessment:

- Assess a high volume of source information at a faster pace to identify emerging risks on a continual basis.
- Discover near real-time risk trends specific to the industry and where risk assessment gaps may exist, equipping Compliance or other functions with information earlier to help identify proactive mitigation strategies.
- Tailor recommendations based on source inputs relevant to the industry, select peers, and geographies considering the time-sensitive nature of the information.

The use of GenAI has the potential to provide cost efficiencies to a company, enabling more opportunities for company personnel to support business initiatives in a more strategic and proactive manner.

2. Continuous Monitoring

Analyze company data to identify potential areas of risk and inform the company's ERM and CRA processes.

What the GCPG says:

The GCPG's recommended expectations for companies include a compliance work plan that includes routine monitoring of compliance risks and monitoring the effectiveness of controls and risk remediation efforts. Companies should identify various sources (i.e., both internal and external) to monitor and evaluate the Compliance program's effectiveness. The guidance highlights that identifying potential risks has been at the core of compliance programs and encourages companies to consider using data analytics to assist in identifying compliance risk areas.

Our experience:

We regularly interact with global companies looking for assistance in evaluating their compliance program's effectiveness against an ever-evolving regulatory landscape and identifying areas of risk that may require tailored guidance or additional controls, such as continuous monitoring. Compliance programs should be nimble to adapt to updated or new guidance and quickly assess potential risks within their business. Expanding business opportunities in emerging markets, mergers or acquisitions, or product innovation also requires companies to

evaluate and monitor potential impacts and risks to the business in a proactive and agile way that supports business growth while protecting the company from undue risk.

Historically, monitoring and the resulting analysis can be costly and not fit-for-purpose as they are often used in a reactive model rather than strategically designed and embedded within business operations. In addition, when paired with GenAI-enabled risk assessment, as discussed in the prior section, utilizing GenAI to support continuous monitoring can help yield a capability greater than the sum of its parts for more dynamic and efficient risk identification cycles.

Recommendations for consideration:

An extensive array of factors within a company's internal and external risk landscape can be relevant to the monitoring and formulation of corresponding mitigation strategies. Utilizing GenAI to analyze such information may help significantly reduce resource burden, potentially minimizing impacts as the business evolves and increasing the ability to efficiently evaluate a large set of data from multiple sources. The outputs from real-time continuous monitoring with GenAI can positively impact a company's CRA process, potentially making it more dynamic and informative. The possibilities for relevant compliance use cases are many.

A few examples include:

- Supporting the traditional analysis associated with the evaluation of third parties to identify potential red flags or areas for further vetting. Evaluating company policies and contracts for outdated arrangements and/or processes.
- Extracting, processing, and analyzing large sets of health care provider (HCP) transparency data to provide insights through identifying spend patterns and trends; and evaluating a company's alignment with transparency regulations to help tailor training and communications to potentially mitigate against issues of non-compliance.
- Integrating automation strategies into a company's compliance and reporting hotline service to identify potential risk trends and define the geographies or areas of the business that may require additional training, monitoring, and oversight.
- Monitoring the company's electronic communications (e.g., emails, group chats), speaker presentations (e.g., recording in-person or virtual presentations, transcribing them and then leveraging GenAI to assess compliance with company policies), and product or marketing information to help identify language that is unclear or could be misconstrued as false or misleading.

Conclusion

The new age of GenAI brings upon a transformative era, revolutionizing traditional processes and propelling

us toward increased efficiency and innovation. Exploring avenues to incorporate GenAI into the strategic evaluation of compliance programs has the potential to provide significant value to companies in providing real-time risk evaluation and help equip Compliance and other functions to remedy swiftly and proactively.

Although establishing GenAI capabilities is a significant technical undertaking requiring specialization and cross-functional collaboration, it is one that Compliance does not have to pursue in a vacuum. Many companies layer Compliance use cases onto broader enterprise GenAI initiatives, allowing IT and similar functions to focus on the core technology and Compliance to focus on their subject matter specialty.

There are many opportunities to leverage GenAI to aid compliance programs. The CRA process and continuous monitoring are logical starting points, as they feed into one another in a positive feedback loop and are used as the compass by which a compliance program pivots and expands its strategy to align with business objectives and make certain the compliance program is aligning its obligations under regulatory requirements. By utilizing the capabilities of GenAI, the potential to enhance processes, identify critical risk areas, implement mitigating solutions, and alleviate resource constraints appears more attainable than ever.

Contact Info:

Jack Tanselle
Managing Director
Risk & Financial Advisory
Deloitte & Touche LLP

jtanselle@deloitte.com

+1 317 319 8237

This publication contains general information only and Deloitte is not, by means of this publication, rendering accounting, business, financial, investment, legal, tax, or other professional advice or services. This [publication or presentation] is not a substitute for such professional advice or services, nor should it be used as a basis for any decision or action that may affect your business. Before making any decision or taking any action that may affect your business, you should consult a qualified professional advisor.

Deloitte shall not be responsible for any loss sustained by any person who relies on this publication.

As used in this document, "Deloitte" means Deloitte & Touche LLP, a subsidiary of Deloitte LLP. Please see www.deloitte.com/us/about for a detailed description of our legal structure. Certain services may not be available to attest clients under the rules and regulations of public accounting.

Copyright © 2024 Deloitte Development LLC. All rights reserved.