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life sciences

CLIENT ALERT

# Department of Justice's (DOJ) September 2024 Update to Evaluation of Corporate Compliance Programs (ECCP)<sup>1</sup>

The guidance includes a few key changes to the agency's approach to evaluating the effectiveness of compliance programs. This is the first update the DOJ has made to the ECCP in 18 months<sup>2</sup> and in this guidance, they provide more specifics on key areas such as culture of compliance, artificial intelligence (AI), risk assessments, training effectiveness, and access to data.

Our takeaways on key new considerations from the guidance are as follows:

- > **Culture of Compliance:** Do companies have a culture of compliance that encourages and incentivizes its employees to report potential misconduct? Is the company committed to whistleblower protection and anti-retaliation? How often does the company measure the culture and effectiveness of compliance? What has the organization done to promote a culture of compliance based on the results of measurements taken?
- > **AI:** First, this guidance defines AI through the specific definition set forth in the OMB memo<sup>3</sup>. Additionally, the guidance asks various questions regarding how companies assess and manage emerging risks related to AI, including risk assessments regarding the use of new technologies, and governance and training on AI tools.
- > **Risk Assessments:** Does the company deploy its compliance resource in a risk-based manner? Do companies regularly review their risk assessment process to account for new and emerging risks as the company's risk profile evolves? Does the risk assessment process incorporate "lessons learned" from the company's own monitoring and investigations? *Is there a feedback loop from auditing, monitoring, investigations?*
- > **Training Effectiveness:** The DOJ repeatedly emphasizes that compliance activities be "tailored" to the particular organization, and training is no exception. Is training "landing" appropriately based on the needs of the relevant employees and does it address internal and external risks? Is the company measuring the effectiveness of its trainings?
- > **Access to Data:** Does compliance have access to timely data across the company to measure the compliance program's effectiveness? With this access, is the company leveraging data analytics to create efficiencies in their compliance program?

The Epsilon Life Sciences team can assist you in providing actionable ideas on how to implement, evaluate, and/ or enhance these areas in your compliance program.



1. <https://www.justice.gov/criminal/criminal-fraud/page/file/937501/dl?inline>

2. <https://www.justice.gov/opa/speech/file/1571911/dl>

3. <https://www.whitehouse.gov/wp-content/uploads/2024/03/M-24-10-Advancing-Governance-Innovation-and-Risk-Management-for-Agency-Use-of-Artificial-Intelligence.pdf>



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