

Case Study: Corporate Integrity Agreement Vendor Compliance

For this case study, the client is a global pharmaceutical company that entered into a CIA. The scope of their CIA included their U.S. division and a number of their affiliates, as well as employees located in Europe and Asia. Intuition was engaged to rapidly design, implement and manage a system and process to meet the requirements for vendors (i.e., contractors, subcontractors, agents, and other service providers performing Covered Functions). Intuition was also engaged to address the requirements for the client's employees residing outside of the U.S. who were Covered Persons.

PROJECT CHALLENGES

The CIA implementation timeframes mandated by the U.S. Government were extremely tight, with possible serious business consequences for the client if the deadlines were not met. Within 90 days, the client had to identify all Covered Persons and ensure they were successfully screened against the U.S. Government Exclusion Lists. The client also had to deliver two hours of General Training to all Covered Persons and obtain a Certification from each individual attesting that he or she received, read, understood and would abide by the client's Code of Conduct. Within 120 days, the client had to ensure all Covered Persons completed four hours of Specific Training and then collect a final Certification from each individual attesting that all required training was received and complete.

Determining how to address these requirements for Covered Persons who were not the client's employees was a daunting task for the client. They began by using SAP extracts to filter through thousands of vendors to determine which Covered Persons. However, they soon realized that was just the first step in a series of processes that had to be quickly designed, staffed and implemented, which raised the following questions:

- After we identify the vendors, how do we identify each and all of the actual Covered Persons within each organization?
- How do we ensure Exclusion List screening is performed?
- How do we deliver training to the vendors? And to their sub-contractors?
- How do we track their progress?
- How do we capture the required Certifications?
- How do we ensure they complete everything on time?
- How do we know if they have new hires that become Covered Persons who must be immediately trained?
- How do we support the vendors – answer their questions and resolve their issues?
- Are we resourced to do all of this?

Compounding these challenges, due to the confidential nature of the discussions with the U.S. government before a CIA is announced, the client was unable to conduct the type of internal communication and advance planning that generally accompanies a project of this size. The compliance department had to obtain information on vendor activities from the business units before they could fully disclose the reasons why they needed the information. Though the basic data was extracted from SAP, the exact nature of the services performed by the vendor had to be verified by the business owner. As with any large company, thousands of vendors are engaged each year and points of contact change. Obtaining the information needed to accurately identify covered vendors was challenging and time-consuming. People were already working at capacity and the additional efforts required to implement the CIA were layered on top of everyone's already busy "day job."

SOLUTION



Week 1:

A two-day intensive kick-off meeting was held to review existing Intuition “playbook” detailing processes and communications and CIA Vendor Compliance Training and Certification portals that could be leveraged to manage CIA vendor compliance. The meeting included representatives from procurement, legal and compliance departments, as well as from the Commercial and Clinical business units. Through discussions with the team, how each component would be tailored to meet the specific needs and preferences of the CIA and the company was agreed and documented.



Week 2:

Robust operating procedures were developed describing all processes, communications and reporting that would be implemented to address the CIA vendor compliance requirements. In addition a technical specification document explaining how the CIA vendor compliance portal would function was developed.



Week 3-4:

All covered vendors were contacted and notified of what they would need to do within the next few weeks. The notifications were emailed on behalf of the client’s Chief Compliance Officer using their letterhead and explained each of the CIA requirements, as well as why the vendor was impacted. In addition resources were provided to assist the vendors, including Frequently Asked Questions and Quick Reference Guides and Intuition’s Senior Compliance Advisors personally contacted all vendors by phone to explain the requirements, the processes, answer their questions and offer assistance.



Week 4-5:

The vendor compliance portal was launched, available 24/7 from any computer using any browser. This portal required attestations from each vendor that Exclusion List Screening had been performed on all Covered Persons. It delivered the client’s General and Specific Training courses, which has been adapted and tested to ensure compatibility across diverse computer platforms. In addition, the portal also captured the required Code of Conduct Certifications and the final Certification from each Covered Person acknowledging that he/she has received and completed the required training.



Week 6-10

The client services team worked diligently to ensure that all CIA requirements were completed for 100% of Covered Persons working for the client’s vendors, including independent contractors and temporary workers. In addition, to ensure that all of the client’s employees residing outside of the U.S. who were Covered Persons completed their requirements as well.



Week 11:

A report was delivered to include in the Implementation Report for the Government. The report contained the summary data required by the CIA, as well as detail supporting data for all relevant records.



On-going through the term of the CIA:

As the new covered vendors were engaged the training and certification processes were immediately launched for them. All aspects of assisting the vendors through to completion of their CIA requirements were managed as per the documented processes. When a previously covered vendor was no longer performing Covered Functions (e.g., their contract is terminated or the type of work changes) a formal exemption process was initiated and managed through to completion. All exemption requests were reviewed by an appropriate person and, if approved, all associated documentation and records were archived for future reference as needed.

Finally, all CIA annual requirements associated with vendors were managed on an ongoing basis, ensuring they repeat CIA training and Exclusion List screening for active Covered Persons. In addition, an annual audit of Exclusion List screening to facilitate vendor readiness to comply with OIG requests that may be received was completed.