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The Platform Approach to Solving Compliance Challenges in the Life Sciences Industry

Why Treating FCPA and the Sunshine Act as Two Sides of the Same Coin is a Winning Strategy

Life Sciences companies are particularly attuned to the value of thinking in new and innovative ways. Many novel drugs and innovative therapies trace their roots to a scientist who thought differently and took a new approach to treating a disease. Unfortunately, the IT organizations of those companies labor under operating constraints that haven't allowed the same level of innovative thinking for creating internal information systems.

These constraints tend to guide life sciences IT teams to buy individual IT systems to tackle specific problems. This often means selecting separate commercial off-the-shelf systems for each individual need, with those systems providing most (but not all) of the specific functionality required. This leads to "application sprawl," a tangled web of brittle integrations to maintain, and applications that aren't ideally suited for their purposes.

But when life sciences IT leaders think innovatively and leverage state-of-the-art technology, they discover a route to solving multiple business challenges through a single software platform while bringing a new level of collaboration to the enterprise.

INTRODUCTION

Recent fraud and abuse cases have drawn attention to how the life sciences industry conducts business with health care providers (HCP) and foreign nationals. Non-compliance with regulations can not only result in severe penalties, but also criminal prosecution and a damaged corporate reputation. This negative exposure has led to unprecedented regulatory oversight and the creation of legal requirements, such as the Physician Payments Sunshine Act, for increased transparency in payments to HCPs and government officials outside of the United States.

To avoid prosecution for violations of the Physician Payments Sunshine Act and Foreign Corrupt Practices Act (FCPA), life sciences companies must put in place meaningful global compliance programs that prevent, detect and respond to potentially improper interactions with HCPs and government officials in real time. Both of these laws require a great level of data tracking and management on a wide range of both financial and non-financial transactions. Many life sciences companies have historically collected this information. The problem is that this information is tracked across disparate systems, in non-uniform ways, and without sufficient detail to meet compliance requirements. This creates barriers to analysis and timely action. Under this scenario, reporting is difficult if not impossible. Companies need to take a more proactive and comprehensive approach to ensure a consistent and measurable degree of compliance from a global perspective with easy reporting.

When companies approach compliance programs, they tend to view the requirements of specific laws separately, and buy or build a new IT system for each set of regulations. Such single-threaded thinking leads to "application sprawl" with employees spending considerable time entering information into a number of different systems. In addition to both employee and organizational inefficiency, this approach often results in:

- Lower quality of data
- Higher expenditure of effort on the part of employees to remain in compliance
- Added expenses in maintaining the various systems
- The need for significant resources to reconcile data across systems

Clearly, there is a need to move beyond a narrow single-threaded approach, especially when the timely need for data to avoid even the appearance of impropriety is a high-priority business imperative. The quality of record keeping for compliance is not positively associated with the amount of extra effort required to capture the information, so the single-threaded approach is likely to have natural limitations in an environment of increasing regulation.

Developing innovative treatments for patients defines what life sciences and related industries are all about. Innovation is the model for this industry, as underscored by daring scientists who developed translational pre-clinical models that challenged the status quo on how we treat and/or manage a disease. With advances in technology, the life sciences industry can adopt a similarly innovative approach in developing more robust compliance programs. These programs can report potential violations more quickly, while also reducing administrative burdens and delivering significant improvements in internal control provisions. Perhaps most important is that the aforementioned can all occur at a decreased cost across the entire spectrum of compliance reporting. This is only possible if IT leaders break from the single-threaded approach of the past and critically evaluate new software platforms. There is a new breed of software that can be leveraged across

a wide range of uses, and easily tailored to the reporting needs of an individual organization's unique processes from monitoring employee-HCP relationships that involve the provision of travel or hospitality to interactions with dualrole government officials overseas. To understand the platform approach in action, below we summarize two significant compliance risks facing life sciences companies. Avoid thinking about these two risks as distinct and you will begin to see the path to stronger compliance programs, reduced violation risk, and simplified systems with less investment required.

Pharmaceutical Compliance IT Challenges & Solutions

	CHALLENGES	SOLUTIONS
PROCESSES	Multiple applications to satisfy various corporate compliance requirements	A single platform implemented globally to ensure compliance
	Manual & inconsistent processes across users and global affiliates	Automate processes with built-in business rules
SYSTEMS	Disconnected systems	Integrated systems based on Service Oriented Architecture (SOA)
	Cost & expenditure of effort to maintain multiple disparate systems	Easy to upgrade & maintain one platform on-premise or in the cloud
DATA	Inconsistent or poor data from multiple entries in different systems	Establish enterprise records with effective master data management
	Difficult to track & provide metrics for audit purposes	Efficient processes with metrics, analytics, and reports
MOBILITY	Access to data and reports is limited to corporate desktops and laptops	Access and enter data on any device, anywhere, anytime
	Prohibitive cost & resources to develop multiple mobile applications	Write once, deploy everywhere with mobile enablement

THE FOREIGN CORRUPT PRACTICES ACT IN LIFE SCIENCES

The FCPA criminalizes any person with a connection to the US that offers, authorizes, or gives "anything of value" to a foreign official in order to obtain an improper business advantage. This law has two main provisions, one that deals with transparency in financial payments and another that deals with bribery of foreign officials. While the government is focused on ensuring integrity in the American business system, the primary focus of this law appears to be the intent of the bribe regardless of the amount.

The legal definition of "foreign official" is broad and extends to any officer or employee of a foreign government-run healthcare system, or any department, agency, or any agent thereof. In many countries with national healthcare systems, any facility that provides healthcare, services, or treatment operates under the purview of the respective government. Therefore, any employee of that facility is considered a foreign official within the meaning of the FCPA. Another significant FCPA risk area involves clinical trials run in foreign countries where "consultants" can serve two roles, one as a clinical investigator on site, and the other as an agent of the government. Ultimately, in order to avoid violation of the FCPA, life sciences companies must relentlessly monitor relationships between their employees and HCPs, independent of how the foreign official is defined. Questionable practices in the life sciences industry are being scrutinized as part of broader FCPA enforcement, and violations are being met with record-setting sanctions and/or fines. Companies with poor compliance program practices run the risk of catching the attention of federal prosecutors. This puts the company, and in many ways, the entire industry, in danger. A single $10,000 unauthorized payment to a foreign official can cost a company millions

in fines and substantially more in remediation costs. Because of some of the recent egregious examples of corruption and bribery, US officials have repeatedly threatened to file charges against company executives — not just their companies — for FCPA violations.

While employees of pharmaceutical companies play a key role in FCPA compliance, recent trends suggest another key area of FCPA violation risk involves third parties. Anyone acting on behalf of a life sciences company can cause an FCPA violation. An effective practice for pharmaceutical companies is to perform risk-based due diligence in advance of contracting third parties as a necessary first step for FCPA compliance. This due diligence should include examining (1) the relevant experience a third party brings to the table, (2) the justification for selecting a third party, and (3) whether any possible FCPA risks exist. It is in the best interest of a life sciences company to ensure the depth of an inquiry is matched to the perceived risk, investigative best practices are followed, and all investigation documents are retained. Given the potential for conflicts of interest, it is common for life sciences companies to outsource due diligence efforts and put the investigative work into unbiased hands. This strengthens compliance, but increases the coordination, control, and documentation retention challenges. Life sciences companies also need to put in place an effective system for reporting and responding to questions and breaches in the field, including easy methods to report suspected illegal conduct.

THE PHYSICIAN PAYMENTS SUNSHINE ACT

The Physician Payments Sunshine Act requires all drug, device, and medical supply companies operating in the United States to report any payment or benefit given to an HCP. Some US states also have their own separate reporting requirements, and in many ways these data points represent new tools the government and local jurisdictions will have at their disposal in healthcare fraud cases, both in the US and abroad.

Compliance with this act presents challenges because HCP payments are usually recorded in different systems — meals and small expenses through expense reporting systems, unrestricted research grants through medical affairs systems, and honorariums for speaking through marketing event management systems. Simply linking these systems to reconcile the data can become an Achilles heel for a company when the HCP lists are not coded similarly and other data complications occur which require individual exceptions. The result of this approach is significant time and resource investment to fix problems that could have been avoided with a different approach.

While penalties for non-compliance are much smaller than the fines levied under FCPA, non-compliance can subject a company to a Corporate Integrity Agreement (CIA). The terms of a CIA are negotiated as part of a settlement with the US Government, which may seek to have the company excluded from participation in Medicare, Medicaid, or other federal health care programs. Such a ban is a disaster for most companies, making the direct and indirect costs of a Sunshine Act violation much higher than an FCPA fine.

To comply with the Sunshine Act, companies must create a "gold standard" for tracing any payment above $10 to HCPs. Theoretically, the simplest way to do this is to capture the spend from the system that recorded the business transaction, event, or activity where the value was provided to the HCP. That's simple in concept, but a challenge to implement across disparate systems. This leads companies to introduce entirely new systems to track Sunshine Act information, but that only increases the burden on users, which ultimately decreases the quality of data captured and increases non-compliance risk.

COMMON COMPLIANCE NEEDS, SEPARATED BY ORGANIZATIONAL SILOS

In many respects, the FCPA and the Sunshine Act are two sides of the same coin. Compliance with the FCPA requires verification that anyone receiving payment be vetted and evaluated for foreign government affiliation risk before the payment is approved. The Sunshine Act requires that all payments actually made to health care providers are recorded, tracked, and reported. Compliance with either one requires following strict processes and making information flows appropriately, whether through integration across systems or by hand entry.

In most life sciences companies, FCPA and Sunshine Act compliance are managed by separate groups, each operating within their own silo and using separate applications to achieve their compliance missions. Such splitting of systems increases costs and decreases user compliance because of the complexity and increased manual entry workload. The applications these groups put in use are often commercial off-the-shelf (COTS) software packages that require substantial modification to fit within the company's environment and existing processes. This makes these applications challenging to maintain and often impossible to upgrade without exorbitant fees. When combined, all of these negative elements put compliance on the bottom of the list for user priorities, and create an environment where compliance officers are as popular as tax auditors.

TACKLING FCPA AND SUNSHINE ACT COMPLIANCE THROUGH A SINGLE PLATFORM

Maximum compliance is achieved when the number of additional actions required by staff for compliance is minimized. The best solution is one that utilizes data collected in existing systems and processes and pulls it out for compliance examination and reporting. Rather than introduce another separate system, the most forward thinking compliance departments are deploying platforms that can easily integrate with existing accounting and other management systems, fill the "white spaces" that exist between systems where compliance information leaks out, automatically route investigative work tasks, and easily compile information for reports. With the right flexible platform, compliance staff can identify the logical points to collect required information and deploy a fix with surgical skill that results in maximum capture with minimal disruption.

As an illustration, let's look at an example of a life sciences marketing event with several international health care providers as featured speakers. The speakers will be paid honorariums so each needs to be vetted through an FCPA process. But that process only guides the organization as to whether or not those providers should be offered a contract to speak. Separate tracking needs to happen to determine if they actually spoke at the event and earned their honorarium. Tracking likewise needs to occur for all attendees because a free lunch was provided.

The event management system is the most likely system of record for generating the data required for compliance reporting. Unfortunately, information on who actually attended is often recorded on paper and doesn't get into the event management system without hand re-entry, which presents specific challenges. A targeted solution to fix this gap could come from wrapping the event management system with a flexible low-code platform giving it a mobile user interface so attendees can be tracked by checking their names off on an iPad application list. This check-in application could be integrated with the compliance application, allowing data of who actually received gifts of value to flow without additional user input. If travel expenses were paid, the work automation platform could integrate with a corporate travel system and pull appropriate records for Sunshine Act reporting.

ADDING COLLABORATION CAPABILITIES FOR EVEN GREATER COMPLIANCE

The single platform approach is just one aspect of the innovative thinking leading life sciences companies are bringing to broad compliance problems. Because many internal and external resources are involved in the FCPA investigation and compliance process, as well as Sunshine Act tracking, work automation platforms with built-in collaboration technologies can drive real advantage. These platforms enable staff to compile information, feedback, attestations, due diligence reports, and payment histories from multiple organizations into one secure location for review while maintaining security and auditability. An intuitive collaboration capability also allows investigations to be completed faster since most of the time required for an investigation is eaten up in the waiting between steps. Making collaboration actions available on mobile devices shortens average response times that much further. Rapid collaboration leads to faster decisions, reduced risk of improper payments, and improved response to requesters and the parties they want to engage.