

## **Compliance Red Flags: What Companies Should Look Out For in Times of Change**

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### **1. Introduction**

Although we know that compliance is everyone's responsibility, we also understand that company personnel are focused on their primary roles and responsibilities, and because of this, compliance requirements may not be at the top of everyone's priority list. Addressing the myriad of compliance requirements can be challenging for any company, and especially so for those undergoing significant change.

While companies face compliance risk during all phases of the organisational life cycle, compliance risks are increased during significant times of change such as becoming publicly traded, transitioning from a "start-up" culture to a mature organisation, or undergoing significant internal growth and/or reorganisation. These changes often coincide with growth and/or increased internal turnover, and company personnel may be expected to take on additional roles and responsibilities for which they are not familiar. During these times, companies should look out for specific "red flags" to help identify areas to focus on and prioritise when developing or improving their compliance programmes.

This article focuses on risks faced by pharmaceutical and biotechnology companies, but the red flags and recommendations can also apply to companies in other sectors. Below is a description of various red flags that companies should be aware of, as well as tips and recommendations to address these red flags if they are identified to ensure that risks are mitigated before problems arise.

### **2. Compliance "red flags"**

Times of change in a company can be very exciting because they often signify growth and/or important milestones. They also coincide with increased compliance risk, especially for smaller companies with less developed compliance programmes. Examples of risk areas include data privacy, interactions with healthcare professionals, external communications, contracting, third party vendor management, procurement, and many others. Defined processes and written standards may not yet exist or may need to be updated to meet changing needs. The task of identifying, prioritising, and mitigating compliance risk can be daunting. Below are several red flags that can help identify specific areas of increased compliance risk for which companies should focus their immediate attention.

### ***2.1 Red flag #1: Wrong tone at the top***

The first red flag that companies should look for is the wrong “tone at the top.” No matter how willing the rest of the company may be to do things the right way, the wrong tone from leadership permeates the organisation and negatively impacts the culture. Acting in a compliant manner often involves additional work (e.g. creating written policies and processes and ensuring that these processes are followed), so without the support of leadership, it can be very difficult if not impossible to ensure that all company personnel perform their functions in a compliant manner. Doing the right thing for the right reasons is important and requires a courageous and high integrity leadership.

### ***2.2 Red flag #2: Lack of formalised review and approval structure for important decision-making***

Another red flag that companies should look out for is a lack of a formalised review and approval structure for important decision-making. A lack of formalised review for important decision-making can be problematic because ad hoc review and decision-making by personnel unfamiliar with certain rules or requirements may lead to unintentional violations of these requirements. For example, persons unfamiliar with applicable anti-kickback laws may enter into contractual agreements with healthcare professionals that do not contain the required information regarding fair market value, duration of agreement, and other necessary information, which may run afoul of legal requirements.

Several examples of decisions that should undergo formalised review and approval include:

- When and how to enter into contracts with healthcare professionals and vendors
- When and how messaging on social media platforms should be conducted
- How materials for training and external distribution should be reviewed
- How goods and services should be procured

By implementing a formalised review process for important decision-making, companies can ensure that legal requirements are met. A formalised process does not mean that the process must be long and complex. Rather, the process may be as simple as a basic flow chart that outlines the individual(s) or function(s) responsible for making various decisions within a process.

### ***2.3 Red flag #3: Lack of clear expectations and guidance in the form of written standards***

A third red flag for companies to look out for is a lack of clear guidance in the form of written standards. As described above, changes within a company frequently lead to new and increased responsibilities for personnel for which they may be unfamiliar. Without clear, written standards, companies open themselves up to increased compliance risk.

Examples of written standards that should be in place include:

- Monetary limits for employee business activities (e.g. business meals, travel, lodging, etc.)
- Monetary limits/budgeting for employee group activities (e.g. social events and gatherings)
- Standards/rules for conducting business travel
- Standards/rules for planning and executing employee group activities

If areas/activities are identified for which guidance/limits do not exist, appropriate guidance should be created in the form of written standards. These standards should also

be organised and stored in a manner that facilitates easy access (e.g. a central repository) and allows for periodic (e.g. annual) review. It is just as important to ensure that company personnel can easily obtain and review these documents as it is that they are developed. And as with decision-making procedures above, these standards should be disseminated and clearly communicated to all personnel who might be affected.

#### ***2.4 Red flag #4: Lack of oversight***

A fourth red flag is lack of oversight within an organisation. Even if decision-making structure and written standards exist, they cannot effectively mitigate compliance risk without oversight to ensure that the structure and standards are being followed. This is especially true during times of change, when structure and standards may undergo frequent and/or rapid modifications. Company personnel may be used to the “status quo” of doing things a certain way, and it can be difficult to make necessary procedural changes. However, with proper oversight, personnel will have the guidance and support to implement these changes.

Examples of areas for which oversight should be in place include:

- Procurement
- Interactions with vendors and other outside entities
- Interactions with healthcare professionals
- General business expenses

If areas lacking oversight are identified, persons within these business functions should be identified as responsible for oversight and given guidance on how to provide the necessary oversight. These persons responsible for providing oversight may set up a periodic review (e.g. monthly, quarterly, etc.) of activities within their purview. During these periodic reviews, responsible persons may meet with those who conduct the activities to ensure that procedures are being followed and to address any questions or concerns. Responsible persons may also modify existing guidance or create new guidance to address additional and/or changing company needs.

For example, if a company’s marketing team regularly engages with outside vendors, the marketing leader should ensure that she/he understands these engagements and that the engagements comply with applicable company policies (e.g. contracting policy, procurement budget/limits, fair market value, etc.). The marketing leader may meet with marketing team members for periodic updates on vendor engagements, and the marketing leader may periodically attend vendor meetings.

### **3. Tips and recommendations for addressing red flags**

Before addressing any red flags, it is important to remember that procedural changes can be difficult for those who have become used to a certain way of doing things, and changes may be met with resistance. Therefore, it is vital that companies clearly communicate not only what is changing, but the rationale behind the change and why it is important for the company. This messaging should also be incorporated in company-wide compliance training, which should encourage and facilitate open lines of communication within the company to ensure that all company personnel are empowered to be a part of the compliance process.

#### ***3.1 Use audits to identify red flags***

Even before a formal auditing and monitoring programme is established, targeted audits can be used to identify the red flags described above. For example, audits can be used to measure and review current processes and determine how personnel are operating in real-time. Audits can also be conducted to determine how current processes align with proposed standards to identify any gaps in the proposed process and provide training to inform personnel of changes that need to be made.

### ***3.2 Clearly outline roles and responsibilities***

During times of change, company personnel often find themselves taking on additional roles and responsibilities and encountering new requirements. With the addition of these new responsibilities, personnel have less time to complete tasks and may not want to spend any additional time developing written guidance regarding the expectations for these new roles and responsibilities. However, the initial investment in time that it takes to outline the expectations and processes that coincide with these changes will pay dividends in the long run.

Company personnel cannot be expected to meet standards and comply with processes that do not exist or are not adequately communicated and distributed. By making the initial time investment in developing guidance for new roles and responsibilities, company leadership will save time in the long run by ensuring that company personnel have the tools and knowledge to do things the right way.

### ***3.3 Develop basic standards for important decision-making***

As described above, times of change in a company often coincide with company personnel taking on new responsibilities beyond their primary roles. This is especially true for smaller companies and teams, where each team member is very busy, often “wearing multiple hats” and juggling many projects. The responsibilities that come along with these new projects can be unclear. As a result, team members may not be aware of which decisions should undergo formal review and approval, and important decisions may be left to ad hoc, undocumented, approval.

Once a decision needing formal review and approval is identified, the personnel who should be responsible for making these decisions must be notified. These personnel should then create, at minimum, a basic written review and approval process (e.g. basic flowchart) to include specific roles or individuals who must be included in the review process and the time required for each step of the review. This process should be disseminated to everyone in the company who has been involved, or potentially will be involved, in a particular activity to ensure that all relevant stakeholders are informed of the new decision-making process.

### ***3.4 Establish processes for accountability and oversight***

As with a lack of standards for important decision-making, a lack of process for accountability and oversight can be problematic because without such processes, a company has no way to ensure that established rules and procedures are being followed, exposing the company to compliance risks. Establishing processes for accountability and oversight will ensure that the standards for decision-making are being followed and will also identify any other areas that need improvement.

For example, the individual or function responsible for providing oversight for the contracting process should periodically review executed contracts to make sure they comply with company standards and ensure that the process for reviewing and approving contracts is being followed. If discrepancies are identified, training can be provided to responsible parties, and any problems can be resolved before they become crisis.

### ***3.5 Establish and publicise open lines of communication***

Open lines of communication within the company, especially between those responsible for compliance functions and the rest of company personnel, are necessary to ensure that company members can ask questions and get help before problems arise. Additionally, open communication facilitates accountability and oversight by ensuring that important information regarding training and new or updated processes gets circulated to all relevant persons so that everyone is aware of current guidelines and expectations.

In order to facilitate open communication, members of the company who have lead compliance roles (e.g. members of the compliance department as well as members of other business functions who are responsible for ensuring compliance within their departments/functions) should engage senior management, executives, and board members to help communicate compliance initiatives and work with top level executive and board of director members to help them understand the value of compliance and build a reputation as an ethical corporate entity. This can be achieved by explaining to these senior leaders that being a compliance-focused company will lead to increased trust between employees and company stakeholders, improved operational efficiencies, and increased profit by reducing fraud, abuse, and other unlawful conduct—and all the associated costs with these wrongdoings.

#### **4. Conclusion**

Companies face a multitude of compliance risks that are ever evolving with the changing regulatory landscape, and these risks are amplified when companies undergo significant change. During these times, company personnel may take on new and sometimes unfamiliar roles and responsibilities. It is common that these periods of change coincide with growth as well as increased regulation and oversight. For example, when companies transition from privately held to publicly traded, they must comply with additional regulations under applicable global regulations (e.g. EU transparency directive, US securities laws). Similarly, when European companies grow to a certain size, they must comply with certain non-financial reporting requirements.

Ensuring compliance with these additional regulatory requirements may fall to company personnel who are not readily familiar with the applicable laws and regulations. By watching out for the red flags described above, companies can get a head start on identifying potential problem areas and implement processes and oversight mechanisms to proactively prevent problems from arising by ensuring that company personnel have the knowledge and resources to appropriately respond to the dynamic regulatory landscape.

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**Tatiana Akers** is a Corporate Compliance Consultant with over 12 years of Legal, Financial Services, and Compliance experience, specializing in the development and implementation of global ethics and compliance programs within the Pharmaceutical Industry. She has assisted pharmaceutical companies with the successful implementation and management of Office of Inspector General (OIG) mandated Corporate Integrity Agreement (CIA) obligations, including the development of CIA specific training; policy development; annual Independent Review Organization’s (IRO) system and transaction reviews; management and accountability certifications; board of directors resolutions; disciplinary guidelines; conflicts of interest, exclusion screening, and disclosure programs; as well as implementation/annual reports to the OIG. Mrs. Akers is also an experienced compliance investigator, partnering with various business functions to respond to, identify, and remedy potential compliance violations. She has a strong desire to integrate compliance initiatives and ethical practices cross functionally and via corporate leadership to ensure optimal compliance and operational efficiencies within organizations.

**Laura Hamm** is the Compliance Director at Aimmune Therapeutics. Before joining Aimmune, Laura was the Compliance Officer of medical device manufacturer Stryker's Neurovascular division, a nearly \$1B business, and Stryker's only global division. At Stryker, Laura oversaw all elements of Neurovascular's compliance program. As a global Compliance Officer, Laura has witnessed the evolution of international regulations, and recognizes the importance of cross-border collaboration to meet global business goals. Laura is passionate about integrating compliance into business DNA, and empowering business partners to achieve objectives with high integrity. Prior to industry, Laura was an educator in the California public school system, focusing on literacy in low-income communities.

**M. Fabiana Lacerca-Allen** has had more than 20 years of experience working for leading American companies such as Elan, Mylan, Bristol-Myers Squibb Company, Microsoft, Merck and AT&T. She has counselled and litigated in the field of international business transactions and international environmental law. She has extensive experience in the pharmaceutical industry in leadership roles in charge of legal and compliance teams. She has counselled and represented clients on a broad range of questions, including strategic business initiatives ensuring compliance with laws and regulations, and corporate policy. Ms. Lacerca-Allen has provided legal support and strategic advice on opportunities and trends in law particularly within the government sector, as well as with major and strategic corporate accounts. Fabiana has established policies and oversight on key areas of compliance affecting international markets, and she has been able to positively impact the perception of compliance, creating compliance training programs and relevant standard operating procedures and has been involved in validating and aiding due diligence in the compliance industry, frequently being requested as speaker and participant in forums. She has been recognized in the industry by Hispanic Executive Magazine in 2013, <http://hispanicexecutive.com/2013/fabiana-lacerca-allen/>; recognized as 2015 Women in Leadership, Inspiring Leaders: <http://www.theguardian.com/women-in-leadership/2015/may/12/know-who-you-want-to-be-kidnapped-with-and-four-more-tips-for-leaders>; served as Chair to the Bay Area Ethics & Compliance Association (BECA); and served as Co-Chair for CBI, an Advanstar company serving the Life Sciences industry. Ms. Lacerca-Allen was invited to join the Gioja Research Institute while she was a student researching on environmental law. She was recipient of 1992 UCLA's tuition waiver based on merit and recognition, and she represented UCLA in the Roscoe Foundation National Essay Contest submitting a paper on Global Warming.

**Aimmune** was created in response to a united call to action from the leading minds and key stakeholders in food allergy who met at an advocacy-sponsored research retreat in 2011 to reach consensus on the direction of food allergy treatment research. Among the outcomes of the retreat, the group concluded that a standard oral immunotherapy (OIT) approach needed to be established, and associated products needed to be developed. When no pharmaceutical company showed interest in developing an OIT treatment, the food allergy community formed Aimmune. Today, Aimmune is working to fulfill the 2011 shared vision of developing a peanut allergy treatment and making it available to allergists for patients worldwide.