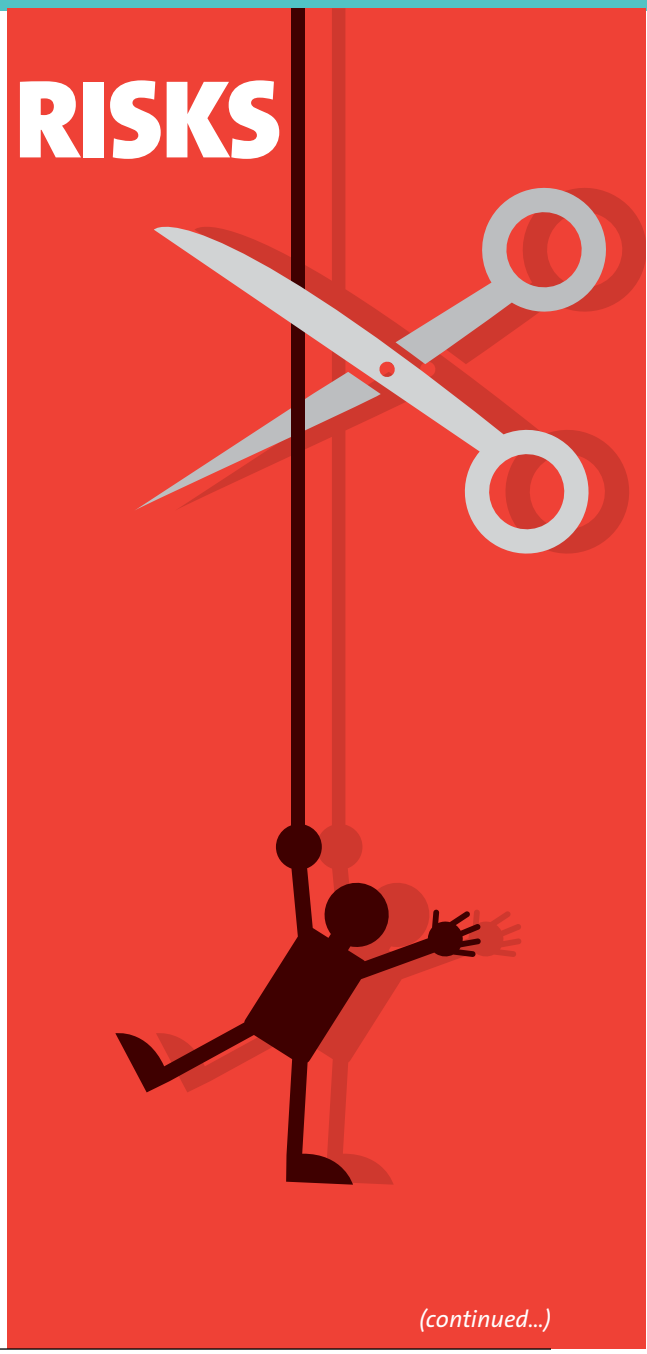
Health Care Compliance Communiqué

Q4 2015

THE COMPLIANCE RISKS OF DOWNSIZING



Reducing staff is often a necessary move for a company to reduce operating costs. The action may follow a serious economic downturn, such as the "Great Recession," a consolidation of facilities, the shutting down of nonproductive or obsolete plants, a corporate reorganization, or a merger or acquisition. Regardless of what the decision is called – downsizing, rightsizing or reducing redundancy – staff layoffs can pose significant compliance risks for any company. That risk is intensified for highly regulated businesses, such as those in the Life Science industry, which typically operate dispersed facilities and maintain supply chains that include dozens or even hundreds of organizations.

Many senior managers view staff layoffs, whether they are extensive or targeted, as risks to intellectual property, trade secrets or customer numbers. While those risks can be substantial, the risk to an organization's regulatory compliance is frequently minimized. That approach is dangerous, since consistent compliance with regulatory and legal requirements imposed by a growing number of government agencies around the world charged with monitoring anti-corruption compliance.

The US Foreign Corrupt Practices Act (FCPA) may be the best-known of international anti-corruption laws, but it is far from the only legal challenge for global Life Science companies. The UK's Bribery Act and a rapidly growing number of anti-corruption laws enacted by countries from Brazil to China and Canada put Life Science companies under the compliance spotlight. When staff layoffs are implemented, regardless of location or number, corruption risks increase and compliance often suffers. It is imperative for Chief Compliance Officers to recognize and communicate the most important of the compliance risks to corporate officers who will ultimately carry responsibility for the noncompliance of their entire enterprises.

(continued...)

Recognizing Compliance Risks

There are multiple compliance risks, some of which easily slip over into operational and product quality risks. Anticipating those risks can help compliance officers respond proactively through careful competency analysis, targeted training and program monitoring. Areas of particular risk are included.

1. Often, "non-revenue producing" departments are hit hardest by staff layoffs driven by the need to cut operational costs. At the top of that list are departments including compliance, training and human resources – the very functions critical to consistent compliance. Reduced personnel, particularly in the compliance department, may result in key responsibilities being reassigned to legal or HR departments, which may also be feeling the pinch of layoffs. Even if HR escapes staff reductions, the existing personnel will be saddled with additional responsibilities, for which they are untrained.
2. A large-scale or untargeted staff reduction virtually requires that remaining employees take on the responsibilities of their absent colleagues, often being required to perform jobs for which they are untrained. The lack of job competency is especially risky in areas with increased exposure to corruption. Examples of increased risk include procurement, with a potential increase in conflicts of interest situations; bookkeeping and accounting, where unfamiliarity with "red flags" in expense reports or contract performance may allow small mistakes to escalate into large problems; supply chain management, which requires consistent monitoring of the compliance status of supply partners; and even routine business functions responsible for arranging travel schedules, office space, local licenses, customs papers and building permits. Although personnel reassigned to these functions have undoubtedly received generalized training in anti-corruption including the FCPA and Bribery Act, they may never have encountered the number or type of corruption risks to which they are now exposed and required to address.
3. Determining who knows what – and the level of competency required for each employee – is almost a "start over again" challenge for compliance officers. Unfortunately, conducting a thorough needs assessment may not be in the new budget, leaving compliance officers with few reasonable choices. Responding to the unknown, simply rolling out the generalized anti-corruption training that all employees routinely receive is unlikely to be effective since it lacks focus on the specific, in-depth needs of reassigned personnel. Relying on the knowledge of remaining personnel may be even less effective unless an earlier assessment has identified a high level of competency by those individuals who remain in the organization. Those employees can be called on to share their knowledge, but it is important to remember that they are not trainers, nor are they likely to have available time to take on that additional function.
4. The emergence of anti-corruption laws in countries where the company may have operations poses an additional layer of compliance challenges. Layoffs or plant closures may be restricted under local laws. Even if those challenges are met, the reassignment of key personnel to facilities in other countries or functions can create a training risk with the additional challenge of language and country-specific knowledge. Beyond those specific issues, the laws of individual countries pose vastly different compliance challenges. The FCPA, for example, prohibits the offering or giving of anything of value to a foreign government official for the purpose of obtaining or retaining business. Alternately, the UK Bribery Act prohibits giving or receiving bribes to or from any organization including private companies and government agencies. A number of countries have extreme penalties for violations of their anti-corruption laws and countries such as China have been very vocal about their focus on global Life Science companies for potentially corrupt behaviors. These differences in law, approach, enforcement and focus demand competency by employees located in those countries. Just as important, employees or third parties charged with overseeing supply partners, product quality and service performance must receive specialized training in their responsibilities and liabilities under local and cross-border laws.
5. The reduction of company staff often has the effect of undermining the confidence of remaining staff in the company, its stated mission and its compliance policies. That loss of confidence is particularly likely when layoffs avoid the upper levels of management. The message, however unintentional, is that employees on the ground are easily dispensable, that the bottom line is the only thing that counts, and that cutting costs is the overriding driver of corporate policy. That attitude, if left unaddressed, is a virtual breeding ground for irresponsible or even non-compliant behavior. Counteracting those attitudes will take more than a repeat of the same slogans and ethics training programs that preceded the layoffs.

What You Can Do

In the best of all worlds, compliance professionals could simply request – and receive – a larger budget to address the challenges posed by staff layoffs. That isn't going to happen very often. Instead, the message is likely to be, "Do more with less." While that message isn't always helpful, compliance professionals may have existing resources that can be drafted to address the compliance challenges of downsizing. Here are some suggestions:

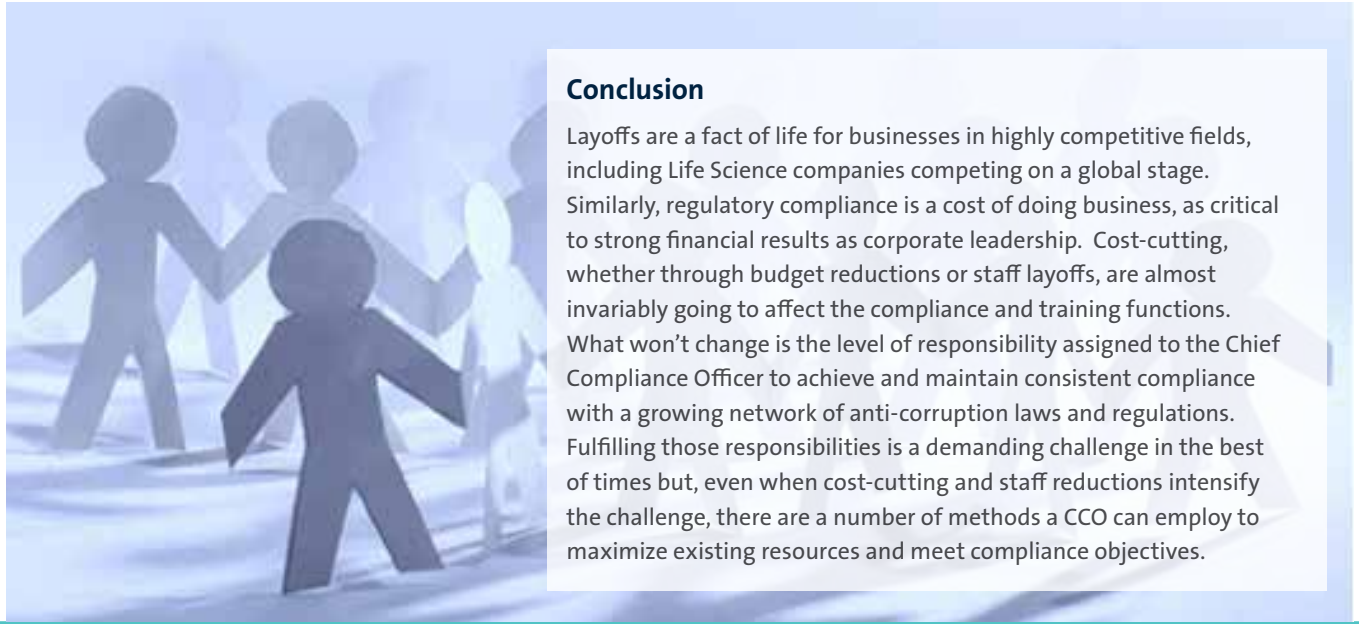
A. **Rally your allies.** It's likely that each department with a finger in the compliance pie is suffering the same downsizing of personnel and budget as is the compliance department. Business functions including Finance, HR, Operations, Legal and IT to name just a few, all have a stake in ensuring compliance with anti-corruption laws. Each department may have resources that, when combined or reutilized, can provide partial answers to the larger question.

B. **Review your own assessments.** Review the information you already have from recent needs assessments or competency audits. Familiarize yourself anew with the information those resources contain and which elements could be repurposed.

C. **Call on HR for mutual benefit.** The HR department is likely to have the best, most in-depth information about the layoffs – where they occurred, the job functions that suffered the greatest losses, even the length of time of key personnel who were downsized. Cross reference that information with your own needs assessment to assist in determining knowledge gaps and specific training needs such as site-specific translations.

D. **Make your case to the Operations and Quality department** about the interconnections between their business responsibilities and compliance with anticorruption laws. A growing issue for quality and operations personnel is counterfeit drugs and adulterated products. Although these problems might appear to be outside the realm of anti-corruption compliance, the US Department of Justice has successfully made the case that adulterated products (often the result of poorly managed supply chains) violate the False Claims Act. It's worth noting that FCA settlements are among the highest imposed by the DOJ and risk the company's participation in federal healthcare programs.

E. **Spend time rebuilding morale.** Something as simple and cost-effective as implementing a competition program among departments that have suffered losses and may have notable knowledge gaps could prove beneficial. The competition might build on the mentoring model, challenging each department to pass a test on compliance topics targeted to that group. "Old timers" may be willing to work with reassigned, less knowledgeable employees as a means to win the challenge. The top team or department could win a company-paid pizza lunch or, if the challenge is individual, a coupon for two for dinner at a local restaurant. The technique not only promotes cooperation among employees, but also may help to counteract negative feelings about the company.



Conclusion

Layoffs are a fact of life for businesses in highly competitive fields, including Life Science companies competing on a global stage. Similarly, regulatory compliance is a cost of doing business, as critical to strong financial results as corporate leadership. Cost-cutting, whether through budget reductions or staff layoffs, are almost invariably going to affect the compliance and training functions. What won't change is the level of responsibility assigned to the Chief Compliance Officer to achieve and maintain consistent compliance with a growing network of anti-corruption laws and regulations. Fulfilling those responsibilities is a demanding challenge in the best of times but, even when cost-cutting and staff reductions intensify the challenge, there are a number of methods a CCO can employ to maximize existing resources and meet compliance objectives.

WHY "COMPETENCE" MAKES MORE SENSE THAN COMPLIANCE

Although still in the minority, a growing number of businesses are abandoning the traditional "compliance as an end goal" approach to corporate policy. Instead, they are replacing that approach with a competency focus, viewing compliance as a logical consequence of the larger competency model of corporate policy and practices.

Often, the competency model is most obvious in the areas of quality and operations, where the payoff is not only compliance, but improved cost efficiency and higher assurances of product quality. Despite the traditional application, the model might be adapted to the needs of Chief Compliance Officers, offering new tools to move beyond routine compliance to a higher level of employee competency and corporate performance.

Understanding the Competency Model

At first glance, the word "competency" justifiably could be seen as a legitimate expectation by any company manager. In this application, however, the model represents a three-tier approach of escalating knowledge, application and mastery. For Compliance Officers, the competency approach to the FCPA might be adapted as follows:

Stage 1: (Entry/Support) Employees learn and can express the importance of the FCPA and its impact on various business functions and the company as a whole.

Stage 2: (Fully Functional/Independent) Employees understand the regulatory accountabilities and implications of FCPA-related behaviors and are able to apply new regulations from a compliance perspective to their own responsibilities through new or revised procedures. Critically, employees can integrate compliance practices into the work practices of their departments and can work with co-workers to promote an understanding of how compliance can benefit them.

Stage 3: (Expert/Master Performer) Employees are knowledgeable about major changes in the thinking and practice of applicable regulations. They will take a proactive role in incorporating regulatory practice into good business practice and take action about how regulatory compliance becomes embedded into the company culture.

(continued...)

WHY "COMPETENCE" MAKES MORE SENSE THAN COMPLIANCE *(Continued)*

Applying the Competency Model

Applying the model of competency requires a commitment from every level of the organization. It also requires an understanding of the time period over which results can be expected and a commitment of the necessary resources to develop essential programs and tools. Different levels and types of training are required.

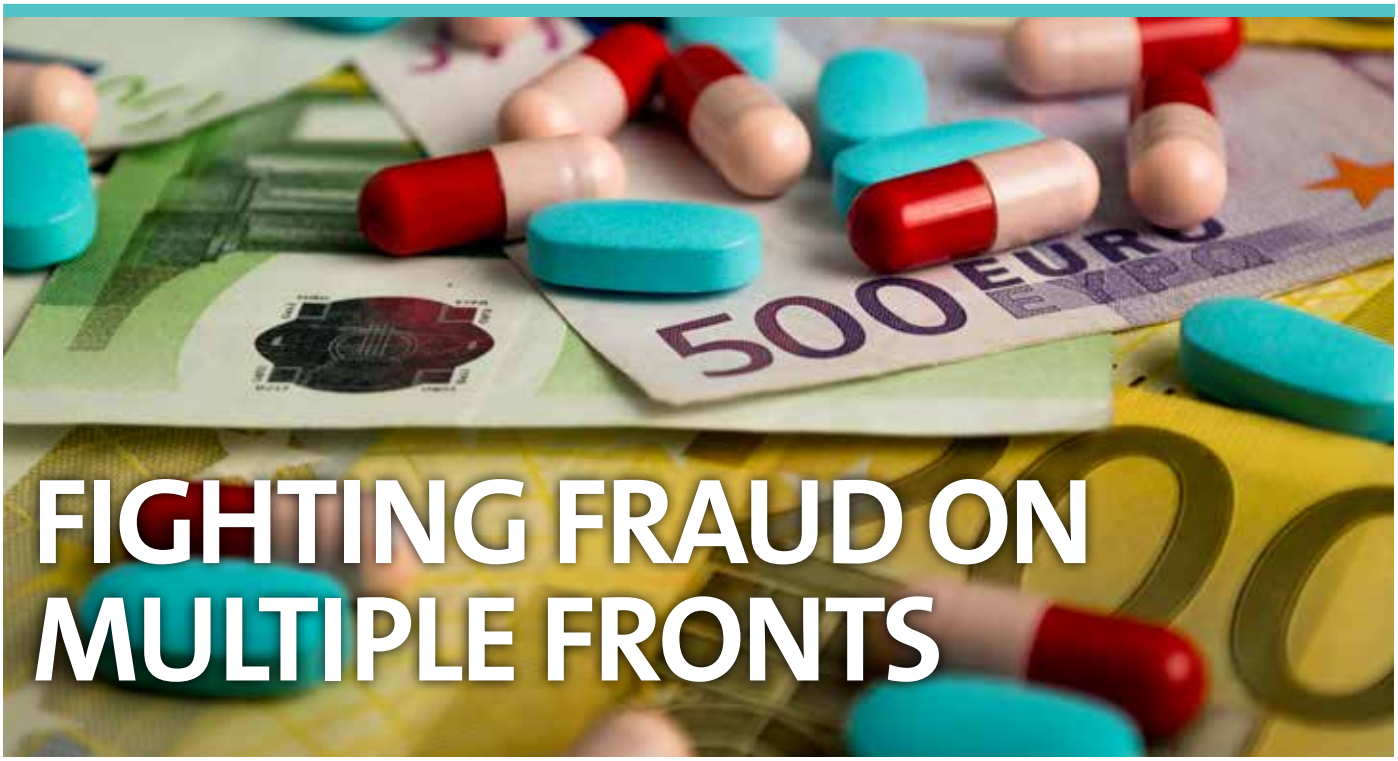
Stage 1: For example, this might require existing FCPA training that is supported by additional scheduled communication, reinforcement and unconventional training tools such as periodic texts, competitions and reminders.

Stage 2: Instructions would likely integrate online and instructor-led training as well as mentoring programs that use real-life situations to drive a deeper understanding of the law and its application. An innovative approach to instruction might also include day-long instruction under Master Performers in other company departments to demonstrate how the law integrates throughout the organization.

Stage 3: Involves a long-term commitment by the employee and employer to fully adopt the level of knowledge required to be proactive in incorporating regulatory requirements into good business practices and corporate culture. Stage 3 Master Performers should serve as mentors to Stage 1 and 2 employees, supporting them in their advancement to higher levels of competency.

Conclusion

Although many current headlines scream about corporate layoffs and budget cuts that may well affect compliance departments, the three-stage competency approach offers more than compliance. It is an effective talent management tool that can promote employee retention eager for an ongoing pathway to advancement. Just as important from a nuts-and-bolts perspective, improved competency produces more consistent compliance along with improved operations and possibly lower operational costs.



FIGHTING FRAUD ON MULTIPLE FRONTS

DOJ's appetite for pursuing bribery and corruption in the Life Science industry is well-established, with particular emphasis on enforcement of the Foreign Corrupt Practices Act, which has returned billions of dollars to the US Treasury in penalties, fines and disgorgements. Now, DOJ has partners who are taking some of the weight for enforcing anti-corruption laws. The US Securities and Exchange Commission (SEC) is flexing its muscles in enforcing the FCPA through the books and records provision of the law while foreign counterparts including the UK Serious Fraud Office (SFO) are taking a more proactive role in the fight against global corruption through the UK Bribery Act. As a result, the number of DOJ enforcement actions of the FCPA dropped over the past couple of years, giving some observers the idea that DOJ has lost some of its enthusiasm in the fight against corruption, bribery and fraud in the Life Science industry.

DANGEROUS IDEA. DOJ remains hungry and continues to aim its eye on the global Life Science industry, but it now shares its anti-corruption appetite with its foreign counterparts, the SEC, and US State Attorneys General, all of whom remain eager to catch companies and individuals engaging in illegal activity. Just as important, pharmaceutical and medical device companies have reason to refocus some of their own compliance attention to DOJ's enforcement of laws including the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Sherman Act and the Travel Act to name just a few of the laws showing up with greater regularity in DOJ's enforcement actions.

(continued...)

FIGHTING FRAUD ON MULTIPLE FRONTS *(Continued)*

Compliance Is NOT "Either/Or..."

Compliance officers know that compliance is not an either/or proposition. FCPA compliance is no more important to the health of a Life Science company than is compliance with the FCA or AKS. CCOs also know that there are a number of other laws and enforcement agencies that can lead to serious violations and subsequent enforcement consequences.

- A medical device company settled allegations of violating the Trade Agreements Act, which applies to where its products were manufactured. In this case, the company sold products in the US that were manufactured in Malaysia, which did not have a trade agreement with the US. The Trade Agreement Act requires manufacturers to certify that the products they trade to the US originate only in the US or a country with a signed trade agreement with the US.
- A global pharmaceutical company resolved FCA violations stemming from its off-label marketing and promotion of several drugs for uses unapproved by the FDA.
- A medical device company paid nearly $10 million to resolve allegations of paying kickbacks to physicians as a means of inducing them to use their devices.
- A pharmaceutical company and its subsidiary agreed to settle allegations that they made payments to a physician to entice him to write prescriptions of their drug to Medicare and Medicaid beneficiaries.
- A global pharmaceutical company and its subsidiaries settled allegations of violating the False Claims Act by promoting drugs for unapproved uses and paying kickbacks to physicians.
- A medical device company entered into a settlement to resolve allegations that it knowingly sold defective heart devices to health care facilities.
- Violations of FDA's Good Manufacturing Practices (GMPs) have become an area of great interest to the DOJ. Beyond the expected product recalls, several companies and their top executives have been hit by serious enforcement actions with penalties and, in one occasion, a consent decree barring the company and its top executives from making or selling a medical device that had been manufactured in a facility at which FDA noted significant quality violations.

Outside the Box

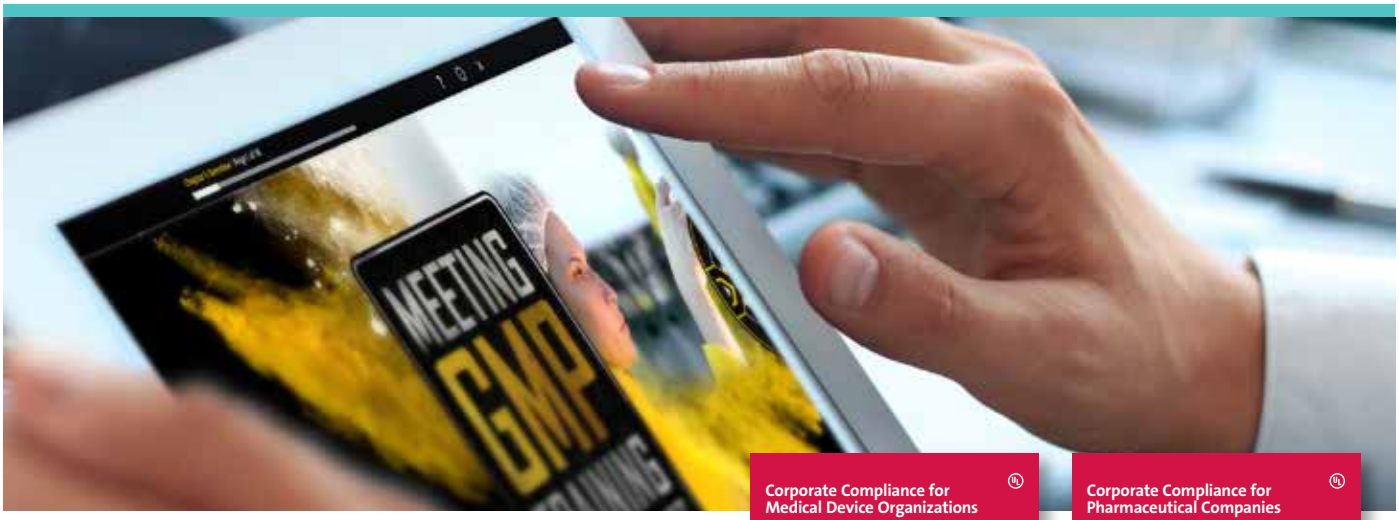
Laws including the FCA and AKS are two of DOJ's workhorses in attacking fraud in the health care industry. In recent years, DOJ has assigned greater responsibility and resources to its Antitrust Division for enforcement of laws that should be on the radar of Life Science companies. At the top of the list is the Sherman Act, which prohibits anti-competition actions including bid rigging, price fixing and market allocation.

In a review of one case, DOJ's Antitrust Division describes an agreement among competitors to fix prices and allocate sales volumes in the worldwide market. The product was citric acid, which is a common ingredient in products ranging from processed foods to pharmaceutical and cosmetic products. The conspirators in the case included companies from several countries and their executives who agreed to fix prices and allocate sales volumes among themselves and also agreed on a complex system to monitor and enforce the agreement. As a result of the conspiracy, list prices for citric acid rose by more than 30% to customers in the US.

Conclusion

Most recent antitrust cases have involved industries other than Life Science. Highly publicized, multi-company cases for violations of the Sherman Act have involved the automotive parts industry, the financial industry, LCD panels and freight transport. Life Science companies have not been targeted, but they may be vulnerable through their own or their suppliers' actions. Equally important, Sherman Act violations don't usually stand alone; criminal antitrust violations may have tag-along charges of mail or wire fraud, FCA violations, making false statements to a government agency or even tax evasion.

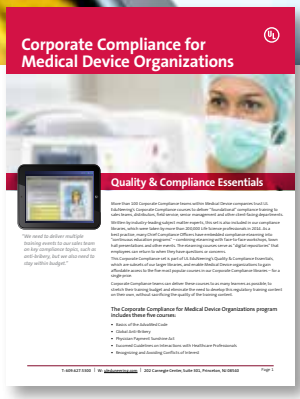
While FCPA and FCA compliance is likely to have more urgency for Life Science Compliance Officers, looking outside the box of the most common compliance challenges can provide a worthwhile "heads up" about the risks to all companies in conducting their businesses.



UL EduNeering's new Quality & Compliance Essentials program enables more Life Science organizations to gain affordable access to five of the most popular courses in our Corporate Compliance Library – for a single low price.

Our new articles, Quality & Compliance Essentials – Corporate Compliance for Pharmaceutical Companies and Corporate Compliance for Medical Device Companies highlight how Corporate Compliance teams can gain unlimited delivery to train sales teams, distributors, senior management and other client-facing departments using the top five Pharmaceutical & Medical Device Corporate Compliance Courses.

Each set contains five 40-minute courses, available as SCORM files for use on any compliant learning system. Other delivery options are available, including the use of UL's enterprise-wide learning management system, ComplianceWire® to deliver and track



Download Corporate Compliance for Medical Device Organizations for more details.

Download Corporate Compliance for Pharmaceutical Organizations for more details.

Contact UL for more information on which Quality & Compliance Essentials program best suits your organization.

Visit: ULEduNeering.com/QCE
Email: Pat.Thunell@UL.com

About UL EduNeering

UL EduNeering is a business line within UL Ventures Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council, and the Duke Clinical Research Institute.