

# ADDRESSING COMPLIANCE:

Strategies for finding the right chief compliance officer

Managing compliance always has been an important concern for life sciences companies, which operate under innumerable regulations governing their sales, product development and manufacturing activities. In the past several years, however, a number of forces — including globalization, the proliferation of new technologies and the increased scrutiny on companies by regulators, investors and the general public — have converged to elevate the compliance function within life sciences organizations.

More and more life sciences companies have created chief compliance officer (CCO) positions with broad responsibility to oversee compliance across the organization, including legal, ethical, internal, audit and risk management. While the demand for experienced compliance leaders continues to grow, the supply, for the time being, is limited. Over the next several years, the talent pool will continue to mature as more professionals develop expertise in the field. In the meantime, life sciences companies are carefully evaluating their requirements for the compliance officer role and, in some cases, making trade-offs to get the talent they need.

To complement our knowledge of the emerging profile of the chief compliance officer, consultants in Spencer Stuart's Life Sciences Practice spoke with senior executives experienced in compliance about the necessary background and personal qualities for the position, the challenges of recruiting compliance leaders and the considerations many organizations are making as they look to recruit talent.

### **The expanding role of compliance**

In the past, compliance efforts by life sciences companies were driven by government enforcement of specific requirements — such as healthcare funding guidelines or regulations governing the manufacturing and product development activities of pharmaceutical and medical technology companies. As such, most companies had informal compliance programs, typically housed in the legal department.

Over time, organizations formalized and, in some cases, consolidated compliance activities to respond to new regulatory requirements and heightened scrutiny of their activities by lawmakers, the enforcement community and the public. The role of chief compliance officer emerged to help provide structure to companies' compliance approaches, which were becoming more complex, and to ensure that companies identified and addressed potential risks and compliance issues.

### **Compliance in today's times**

Programs today take a more comprehensive approach to addressing compliance, and the compliance function typically is a stand-alone department in most life sciences companies. Chief compliance officers, meanwhile, are responsible for administering the program and developing the compliance infrastructure, methodologies and documentation standards. They also advise the board of directors on compliance issues.

One of the most important aspects of their jobs, according to compliance leaders, is partnering with the business to embed compliance into regular business operations and everyday activities. To do this, compliance leaders must provide the guidance and support to help the

organization achieve business goals, while maintaining appropriate vigilance on internal and external standards.

Valli F. Baldassano, executive vice president and chief compliance officer at Cephalon, likes to define the role by what it should not be. “A compliance officer is a risk manager, not a risk eliminator. A compliance officer is responsible for seeing what risks are coming down the pike and helping the company fashion ways to manage that risk. They shouldn't be approvers. When the compliance officer becomes the ‘approver,’ it takes the responsibility off of the business where it belongs.”

### **The emerging compliance leader profile**

To be successful, compliance officers must know and understand the range of regulations governing company activities and have the necessary business knowledge to identify potential vulnerabilities and establish priorities and objectives for measuring the effectiveness of compliance programs. They must anticipate emerging issues and use their influence to promote an ethical culture across the organization.

Given their range of responsibilities, what is the ideal background for chief compliance officers, if there is one, and what skills and capabilities are essential for success in the role?

### **Knowledge of the regulatory landscape and the business**

As a foundation, it is important that the chief compliance officer have a solid understanding of the industry's regulatory landscape and, potentially, knowledge of the Securities and Exchange Commission and Sarbanes-Oxley (SOX) requirements. With their knowledge of

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the law and regulatory frameworks, lawyers are one traditional source for compliance officers and remain in demand today for compliance leadership roles.

Lawyers with litigation experience bring the additional trait of being problem solvers, Baldassano said. “An individual who is rigid and has a real black-or-white perspective on everything isn’t going to be successful in the role,” she said. “An individual with a legal background has great training for this role because they can dissect problems and look for solutions. A good lawyer is solution-oriented.”

Chief compliance officers do not have to be lawyers, however. Individuals with knowledge of the business, whether by formal training, hands-on business experience or previous compliance roles, have proven to be successful when they are able to speak the language of management, relate the standards of the organization in terms that resonate with different levels of employees and understand the stressors that create risk for various positions within the business. As such, organizations increasingly are recruiting business or strategy consultants, functional compliance executives, auditors and business unit leaders for the role. Life sciences companies looking to recruit compliance officers also may look outside the industry to other highly regulated industries such as financial services or defense.

#### **Cross-functional collaboration**

The ability to work with other departments is critical. Given that the chief compliance officer’s responsibilities often extend broadly across the organization, the ability to network, coach and champion programs by establishing positive, effective relationships with executives in key

functions is crucial to the successful implementation of compliance programs. Compliance executives not only manage direct reports but also work with other senior leaders throughout the organization to equip them to support compliance efforts and to recognize and respond to potential risks. Having experience as a manager may provide compliance leaders with additional credibility with business leaders.

“I see some very competent, capable individuals who are successful compliance officers and do not have legal backgrounds. But they are very good at organizing a task, mobilizing resources and assembling a team to advise them,” said Ted Acosta, leader of Ernst & Young’s fraud investigation and dispute services, health sciences practice. “A person who is able to operate and interact with the board of directors and senior management, but also can drill down and understand the business is probably the right profile.”

Kathy Schroeder, associate general counsel and chief compliance officer for Johnson & Johnson, also believes that a chief compliance officer must have a keen appreciation for policies, processes and systems and have a focus on prevention — rather than on putting out fires. “Someone who comes out of the quality function in pharmaceuticals or medical technology would be good. They understand how to design quality into the process from the beginning,” she said. “A compliance officer who does not have a passion for ethics and compliance will never be viewed as more than a figurehead.”

#### **Flexibility and adaptability**

Finally, chief compliance officers must be able to anticipate regulatory changes and help the organization adapt to new requirements and

### **Recruiting the CCO: Strategies for finding the right leader in a finite candidate pool**

As any life sciences organization that has searched for a chief compliance officer can attest, the pool of experienced and available compliance leaders is small. Because the position is relatively new, no well-developed career route to becoming chief compliance officer has developed. As a result, it can be difficult today to find an individual who possesses the complete range of compliance and sector expertise and the desired management skills for the role.

In light of the challenges of recruiting today, we offer several observations and considerations for life sciences organizations seeking to recruit a chief compliance officer.

- > In the past 10 years, the role of chief compliance officer has emerged as an important position at most life sciences companies. During the next five to 10 years, as the role matures within organizations and is increasingly recognized as a career option for promising executives, the pool of experienced and available compliance leaders will grow. In the meantime, companies will have to take creative approaches to finding compliance leaders.
- > Not every organization's compliance program is at the same stage of development. As a result, different organizations are likely to define the position differently and require a different mix of skills and expertise. To fill compliance officer roles, companies are tapping executives with a range of backgrounds and experience that varies depending on the nature of the company and the types of risks and compliance issues it faces.
- > In light of the scarcity of experienced talent, companies may have to make tradeoffs. Companies will have to evaluate each candidate's strengths and weaknesses based on his or her degree of functional expertise, breadth of industry and company knowledge and leadership capabilities. They also will have to consider what knowledge base is essential and what the CCO can learn on the job or through additional training.
- > Organizations also need to evaluate thoughtfully the advantages and disadvantages of each candidate's previous experience. Individuals with a compliance consulting background may have the most up-to-date knowledge of compliance issues and trends, but may have less industry knowledge or experience managing a compliance program. By comparison, a CCO from another company may have the necessary compliance management expertise, but may be less familiar with the cultural hurdles of the organization or the issues particular to the industry. Internal candidates, by contrast, know the organization, its compliance program, culture and people, but may be less experienced in management.
- > In some cases, life sciences organizations may want to consider tapping experienced compliance executives from other industries, such as financial services or consumer products, which have well-developed compliance programs. While these executives can be successful, management should be thoughtful about the level of domain expertise that is required to be effective in the role at their organization. Executives from consumer products companies, which have research and

development functions and must comply with food safety regulations, may have an easier time transitioning to a life sciences compliance role than a compliance executive from the financial services sector.

Finally, life sciences organizations should view the chief compliance officer role in the

same way they do any other senior-level position and employ the same talent development and recruiting processes they use for other key functions. Life sciences companies should identify promising compliance leaders and provide training and development opportunities to develop a strong bench of talent for the future.

expectations. Compliance leaders must be prepared to respond to new issues and challenges — ranging from evolving regulations governing off-label promotion of pharmaceuticals to managing compliance in multiple nations around the world, each with its own regulatory regime.

“I would say that compliance is a verb, it’s not a noun. The world is a pretty dynamic place for a life sciences company and so the key to our success at Schering-Plough is the fact that we’ll never become complacent in this area. We continue to evolve and review our compliance program,” said Brent Saunders, senior vice president and president of Schering-Plough Corporation’s Consumer Health Care business. Saunders previously served as the senior vice president of global compliance and business practices. “In fact, I see a benefit to appointing a new compliance officer every five to seven years. The program needs to be fresh, so someone new can bring a new perspective about the program — and assess for potential flaws and weaknesses, which will help the company avoid becoming complacent about compliance.”

### **Centralized or decentralized? The compliance organization and reporting structure**

In light of the growing need to have an organization-wide approach to compliance, how are companies structuring the function and what reporting structures are most effective?

“Compliance can be very difficult and the challenge in achieving compliance, not just for the pharmaceutical industry, but for any industry, is making sure that the compliance effort is truly well positioned to succeed,” Acosta said. “That is an acknowledgment of who the individual reports to, what resources are available to him or her or the infrastructure of compliance, and what tone is being set at the top.”

Compliance officers say that no one organizational structure or reporting model is appropriate for all companies. Approaches are likely to differ depending on the organization’s state of compliance, the nature of the business and its culture. However, several chief compliance officers we spoke with said they favored centralized responsibility for compliance and a reporting structure that gives the role visibility and support at the highest levels. “Each company should do what’s right for it.

With that being said, I do strongly believe that the right way to do it is through a centralized function because there has to be a single point of accountability for the compliance program. There should be an individual who can act as the arbiter of the direction the program should head, and, lastly and probably most important, compliance should be developed in a consistent way across the company,” Saunders said. “Regulators don’t view companies as divisions or functions, they view them as companies. They expect us to be consistent in our application of our compliance programs. They expect that the left hand knows what the right hand is doing.”

**Key competencies for today’s chief compliance officer:**

- > Knowledge of the business (minimum of 10 years)
- > Familiarity with compliance regulations and best practices and SOX
- > Understanding of risk management and audit functions
- > Management experience (minimum of five years)
- > Ability to motivate and inspire people
- > Experience working cross-functionally and collaboratively
- > Strong communication and persuasion skills
- > Results orientation and problem-solving skills

Baldassano also favors the centralized approach. “Compliance isn’t necessarily a manufacturing policy or a clinical policy or a sales policy. Compliance is a mindset. You need to have that mindset across all of the components of your business. It can’t be different for manufacturing than it is for sales than it is for clinical.”

While she agreed that each company needs to determine the most appropriate model for its organization, Schroeder said a decentralized approach has the advantage of pushing responsibility for compliance out to the business

units. “It’s really important to have accountability in the businesses and to assure that they have skin in the game,” she said. “The business units are responsible for the compliance posture of their organization and we’re there to help them and make sure they are meeting our standards.” In a decentralized environment, “communities of compliance” can meet formally and informally to share best practices, training and ideas for different, customized approaches to addressing compliance issues.

Regardless of how the compliance structure is organized, compliance leaders believe that it is important that the chief compliance officer hold a very senior role whose mission is embraced by the CEO, even if it does not directly report to the CEO. Programs have much more impact when compliance is embraced at the top levels and integrity is integral to the culture of the organization. Leadership in this area should extend from the top down. Many compliance officers report to the general counsel, which is, at times, appropriate given that position’s natural interest in compliance.

“The ability to effectuate change increases tremendously when you’re part of the executive management team of a company. When you’re a direct report of the CEO, you’ll get a return phone call a lot faster; people will take what you’re trying to accomplish more seriously. You’ll get the resources and attention that compliance frankly deserves inside a company,” Saunders said. “On the other hand, it can’t be abused. You can’t use it to prosecute a dead horse or create more bureaucracy that creates inefficiencies in the system. You have to use it in the most appropriate way.”

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Said Baldassano, “Is it the death knell if you’re not reporting to the CEO? No, I don’t think it is. Compliance has to be empowered and in a position to effect change, so it’s really about the value that the CEO and senior management put on the compliance initiative. While I have a lot of criticisms of the Sarbanes-Oxley Act, one thing that it did emphasize was the tone at the top. You can’t have a successful compliance program without the right tone at the top.”

#### **About the authors**

**William B. Clemens, III**, is a member of Spencer Stuart’s Life Sciences Practice, focusing on senior-level executive searches for a range of functions, including sales and marketing, R&D, human resources, legal and finance, for biotechnology and pharmaceutical companies.

**Patricia J. Coleman** specializes in senior-level executive search assignments in Spencer Stuart’s Life Sciences and Legal Search practices. Her clients have included for-profit and nonprofit entities in the pharmaceutical, medical device, biotechnology, legal and healthcare arenas. Functionally, Patricia has completed assignments in senior executive management, finance, operations, sales and marketing, communications, technology, business development, human resources and other strategic leadership positions.

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