

Compliance Today – December 2018 Creating a culture of compliance

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In my first decade as an attorney, I've had the unique privilege of being the "first" to hold several compliance-related positions, and even aided in the creation of an office dedicated to clinical research compliance at a major academic medical center. For me, these positions were a blessing and, while overwhelming at times, provided the opportunity to mold the roles to fit my strengths and the needs of the organization. Whether you're being handed the keys to your dream job or taking over a position in a crunch, bringing a compliance plan that includes auditing and monitoring for a successful launch is no doubt daunting. I'm taking the opportunity to document my successes and failures below, so you can avoid any shortcomings and find success in your compliance efforts.

The true task at hand

First and foremost, you absolutely must embrace that you are not simply implementing or maintaining a compliance plan or a program. Rather, you're establishing a culture of compliance throughout the area you oversee. Any failure to fully recognize and plan from this pivotal point is almost certain to result in weak implementation. Thus, you're building, establishing, or maintaining a culture shift, which requires a more global approach and demands an investment by your organization to be successful. Of course, some of this shift falls to your role and other pieces fall to organizational leadership, but that is a discussion for a different article.

Being first or turning a program around

Remember to view your perspective as influential and positive, despite feeling as if you're treading uphill, no matter how much culture shift and compliance wrangling you or your organization are hoping to accomplish. You have the privilege to establish a new and improved manner of conducting compliance that builds on the good, discards the bad, and strives to grow. You're present to impart your experiences and learn from those within, so don't lose sight of every networking opportunity, coffee with a colleague, and truly touring your new role. Whether you've moved in-house or arrived fresh on the grounds, how positively you approach the role from Day One sets the tone loudly. One of the hardest moves I ever made was from one side of the table to the other within the same organization. Leaving previous bias outside the boardroom door is nearly impossible, and I challenge you to evaluate every step you make against any bias you believe you might possess. Knowing the pieces of any puzzle and how they interlock can make you an asset, but bias can and will cloud your judgment in tough situations when working with previous colleagues.

If you don't have buy-in, nothing will work

As foreshadowed, if you don't have organizational and employee "buy-in" to your shifting culture of compliance, you must work to build it. One hopes, given a role in compliance has been created and you're filling said role, that the organization has in essence made their commitment to a culture of compliance transparent.

This, unfortunately, is not always true, but even when it exists, you as the face of this new or improved compliance program must still garner the respect of the existing employees if you hope to lead the charge successfully.

In addition to the positive, unbiased attitude you must put forth, you must learn the infrastructure inside and out, in the most non-threatening fashion possible, to move a culture forward. Although admittedly ominous, this means your first few months absolutely must revolve around attending every stakeholders' functional meeting, small or large, and committing to as many coffee and lunch dates internally as possible. If you don't learn about the actual individuals you're working with and for, the infrastructure simply will not matter. Learning peoples' opinions, fears, ideas, and experiences sets the stage for how you will not only form your auditing and monitoring plan, but also how best to implement it. You may find allies and even volunteers in the most unlikely of circumstances.

Start at the pure and basic structural foundations

I promise to revisit this topic only this one, last time: structural foundations to compliance. If you haven't had the opportunity to review it in a while, you should visit the Office of Inspector General (OIG) website^[1] on the pillars of a compliance program. As I teach my students, you should look here, no matter your specific industry, to see how the federal government views compliance programs. The external federal compliance authorities are tossing you a softball here, so please, please knock it out of the park as such.

Hint: Mitigation directed at these exact pillars plays a huge role in resources and decisions in your program, as well as how you'll fare in a federal agency audit.

At this juncture, whether you're interviewing or already waist deep in the position, is also when you will strongly evaluate your organization's infrastructure and willingness to change. This analysis is multi-faceted, and while you might not find your organization as dedicated to change or compliance as you'd dreamed, hope is not lost. You use this information only to determine next steps, expectations, and your personal cost-benefit analysis. Factor what you find into your resource analysis and proposal, as well as the depth of your program and, if interviewing, your proposed compensation. Only you can decide how to best proceed in any given fact-finding mission, but remember, information is knowledge and thus power.

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