Are You Ready to Build a Culture of Quality?

It’s difficult to imagine a pharmaceutical company that wouldn’t want to build a culture of quality throughout its organization. Most companies say they are committed to quality. Many even make the pursuit of quality part of their corporate mission statements. But we often meet senior leaders of pharmaceutical firms who are willing to invest in quality systems and processes, but not the deeper work of organizational culture change that is necessary to support quality initiatives. Unfortunately, without a true culture of quality built into the DNA of your organization, most quality improvement projects will fail.

Before a company develops any quality system or process, its management must take a deep and honest look in the mirror and ask a simple question: Do our leadership actions demonstrate that quality is our highest priority? If the answer is “No”, management is not cultivating quality at the deepest levels of the organization.

The best designed, most sophisticated quality systems can be subverted by employee behaviors driven by an organizational culture that is not aligned with a quality doctrine. In some cases, undesirable behaviors are unknowingly encouraged by the organization’s own policies and programs. As an example, we, at Becker, have seen bonus plans that reward employees for meeting regulatory market clearance and product launch milestones. When these milestones are met, everyone celebrates and employees are duly rewarded. Yet, there is no accountability when the new product has to be recalled six months later because of a design or manufacturing defect. This communicates a powerful message about the company’s true priorities: Obtaining market clearance is more important than assuring product quality. Other personnel practices such as salary adjustments, promotions, and informal recognitions can provide similar incentives for inappropriate behaviors.

Leadership behavior speaks volumes in communicating the company’s real values and, in turn, creating the company’s culture. Consider these questions:

- Does management override the Quality Assurance Unit’s decision to withhold a product release?
• Does management cut funding of the quality function before, or to a greater extent, than other functions?
• Does management recognize and reward quality achievements as enthusiastically as financial successes?
• Does management effectively balance its financial imperatives with its commitment to quality?

While there are many ways to build a culture of quality, it always starts at the top. Management must “walk the talk” and model the company’s quality values. Among other things, we encourage each member of the senior management team to have at least one performance scorecard element linked to a quality metric. Our goal is that the company’s executive management team will have a vested interest in the company’s quality metrics, just as it has a vested interest in the company’s financial performance.

When companies face threatened or actual enforcement action by the Food and Drug Administration (FDA), they are often desperate and willing to do “whatever it takes” to address quality issues. But, this must go beyond marshaling the internal and external resources to design and document a new quality management system. Failing to address organizational culture issues almost inevitably leads to failure, which may then lead to even more aggressive and draconian enforcement actions. FDA files are replete with companies that have invested millions of dollars attempting to comply with FDA quality system requirements, only to fail and succumb to FDA enforcement action. FDA attributes what it calls “corporate culture” as the root cause of most compliance problems.

A company’s ability to effectively develop and successfully implement effective quality management systems requires a supportive organizational culture. If it does not honestly evaluate and address its organizational culture when reengineering its quality systems, it risks failure and frustration. Creating competent quality systems on paper is the easy part. Bringing those quality systems to life in the organization is the real challenge. Employee behaviors during execution almost always trump the best designed quality system.
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