

# Maintaining a Culture of Compliance

In order to sustain compliance it must become a core component of every company's training, sales processes, and incentive programs

The focus on off-label promotion in the biopharmaceutical industry is at an all-time high and shows no sign of slowing down. The current regulatory landscape includes record settlements, a heightened focus on prosecuting individuals, and trends toward more intrusive corporate integrity agreements.

The result of these actions has had a positive effect on the industry in the form of increased focus and commitment towards evolved compliance programs and policies, and improved codes of conduct, education, and training. Despite these advances, however, recent statements from Department of Justice (DoJ) prosecutors cite their concern that current compliance policies and principles are not translating to appropriate field conduct.

Companies must "mind the gap" and ensure that the principles outlined in their programs translate to conduct in the field, according to Sara M. Bloom, assistant U.S. attorney for the District of Boston, and Mary E. Riordan, senior counsel in the Department of Health and Human Services' Office of the Inspector General.

The heightened enforcement coupled with the industry's commitment to compliance leaves many wondering why this gap between policies and conduct continues to exist.

As companies, both large and small, try to ascertain the origin of the problem, there are several areas that may be at the source of this gap.

## A SILO MENTALITY

In many organizations an inherent tension exists between commercial and compliance teams due to misaligned perceptions and differing goals. Individuals on the commercial side often view the compliance team as "the police," while the compliance individuals may view the commercial team as "potential mavericks." These views could result in cooperation, communication, and alignment between compliance, legal, and commercial teams that are not as developed as they could be.

Aligning goals, missions, and incentive plans so that they are more consistent between these two groups is a good step

ized training on FDA laws and regulations. While knowledge of FDA laws, regulations, and corporate policies are vital components of a successful compliance training program, knowledge training alone will not lead to behavioral change.

Transfer of training is defined as the extent to which the training that is provided translates to application within the work environment. In her article, "A Process Approach to the Transfer of Training Part 1: The Impact of Motivation and Supervisor Support on Transfer Maintenance," Marguerite Foxon analyzed over 30 articles and identified inhibiting factors to training transfer that she grouped into four categories.

**1) Organizational Climate Factors:** The failure of supervisors (and, to a lesser extent, colleagues) to encourage or reinforce the behavior that is desired is the most common organizational climate factor that inhibits transfer.

Is the all important "tone at the top" perceived as simply a ringtone? The tone at the top has to resonate in not only words, but in actions and beliefs. The perceived level of support and modeling of the desired behavior by leaders at all levels of the organization is one of the most important

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in the right direction. Training designed to elicit behavioral change may also be necessary to demonstrate how partnering can actually give them a competitive business advantage.

## TRANSFER OF TRAINING

According to government prosecutors, current compliance training is not being transferred to compliant field conduct. It is easy to understand why when you look at the various forms of training that organizations are implementing. Compliance training is often company wide computer-

influencers of transferring desired conduct. Compliance has to be truly viewed by the commercial organization as an integral part of daily business and not as a one-time event. When this occurs, compliance will become a competitive advantage.

**2) Training Design Factors:** The most common inhibitor in design is content that is too theoretical or not practical enough for the individual levels of trainees.

In order for a positive transfer of compliance training to occur, the training should be relevant to the end user

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and should be customized to specific job responsibilities and tasks performed. The training should include relevant real-world case studies and workshops that are specific to the level of the individual and should incorporate myths and misperceptions of violative behaviors and their consequences.

**3) Training Delivery Factors:** The aspects that surround the lack of transfer due to the delivery vehicle include inappropriate delivery method, inappropriate delivery style, and low credibility of the trainer.

While remote testing and training has its place, it is often hard to gauge the level

of interest and engagement of the learner. Capturing and maintaining interest while having the learner identify with the personal and professional relevance of the topic is the goal to successful transfer or application of the training.

**4) Individual Learner Characteristics:** The largest inhibiting issue that affects transfer is low learner motivation and the inability to see the personal relevance of the training.

In order to obtain commercial readiness for compliance and make the topic relevant to the end user, colleagues must first change two vital beliefs. The first is that the regulatory environment has changed. The government is not only criminally prosecuting companies for off-label promotion, but also individuals. There is a large void of real-world education on just how prevalent individual prosecution is and what the consequences may be.

The second belief that needs to be changed is that an organization can be effective *and* ethical. Leaders often fear that too much compliance education will paralyze their sales force—when, in fact, effective compliance education will empower a sales force. Colleagues that embody these two beliefs will be more effective at engaging in compliant promotion.

### WHAT SURROUNDS PROMOTION

To ensure that a culture of compliance is sustained, it must be a core component of every company's training curriculum, sales processes, and incentive programs. With the evolution of more subtle off-label violations, now may be the right time to enhance and advance the training curriculum that you currently have in place.

Organizations and training departments need to keep up to date on the changes in the regulatory landscape and government trends as they pertain to off-label violations. The violative behaviors of today have moved from blatant off-label promotion to more subtle behaviors. Companies must ensure that their sales forces understand what the subtle violative behaviors look like, as it is these behaviors

that put managers, representatives, and companies at risk.

Organizations also need to evaluate the sales processes and incentive programs that surround promotion. Sales processes should support compliant behavior and help integrate compliance into daily activities. Incentive programs should encourage and reward compliant sales success.

### UNDERLYING COMPANY CULTURE

Is there a legacy culture with a “no excuses mentality?” Are the qualifiers for promotions and/or leadership awards overtly dominated by performance? The true measure of a leader is one who does the right thing at all times, not just when their performance is high.

Quota goals need to be aligned with the on-label sales potential of the product. In the past, conflicts arose because, in some scenarios, sales goals were higher than on-label potential. Quota teams may have had a broad view of sales potential because they simply looked at competitors' overall potential versus doing one more divedown to match up indications.

As a commercial leader the pressure to make your numbers cannot outweigh the pressure to do what's right. You have to ensure that your leadership is rewarding the right behavior and sending the right message. Just because something is considered right by the culture of an organization, it may not be so by the DoJ.

### MINDING THE GAP

The ongoing fines and violations accentuate the need to mind the gap between compliance policies and compliant field conduct. This gap can be caused by a variety of sources, as discussed above. With the reputational damage that the industry is under, and the increasing focus on prosecuting individuals, now is the time to assess these areas and mind the gap to ensure a successful transfer of compliance policies and training to field conduct. This will allow companies to responsibly deliver information on their products and continue to create a better quality of life to the patients that the industry serves. **PE**