

Guest commentary

Commercial compliance training needs to be a collaborative effort, say industry veterans

By Dee Mahoney and Mary Holloway

Federal and state agencies continue to target pharmaceutical, biotech and medical device manufacturers for what the agencies deem to be unlawful promotion. To make matter worse, the Food and Drug Administration (FDA) has called for more frequent prosecutions of “responsible corporate officers” (RCO) under the federal Food, Drug and Cosmetic Act. Under the RCO doctrine, also known as the Park doctrine, colleagues in FDA-regulated companies can be charged with strict-liability misdemeanor offenses even when the individual did not participate in, or even know about, the underlying misconduct.

Clearly, there has never been a more important time for companies to improve the quality and the impact of their compliance training. Organizations must ensure that their compliance training methods are resulting in a successful transfer of training, which may be defined as the degree to which trainees incorporate the attitude, behaviors, knowledge and skills they gained in training to their jobs.

Existing Compliance Training Programs

The majority of pharmaceutical, biotech and medical device companies rely on their compliance departments to design, deliver, and fund compliance training for their sales teams. Compliance training needs to cover much territory: all the standards and regulations that govern pharmaceutical sales, including good promotional practices. The training that is being delivered, however, is not having the desired impact on field sales colleagues. As co-founders of DMH, a consulting firm that specializes in behavioral-based compliance training, we have observed three reasons why this occurs:

Improving Compliance Training Programs

I. Compliance Training Design

Compliance professionals are experts on the laws and policies that govern promotion, but they are usually not well versed in training design or the

principles that lead to a successful transfer of learning. Because compliance teams usually have a legal mindset, it is often difficult for them to understand the mindset and motivation of sales professionals. As a result, the compliance training delivered, while functional, is often not specific or relevant to commercial colleagues.

In order for field professionals to “hear” the message and successfully transfer training to appropriate field behavior, the compliance training content has to be practical, professionally relevant, and customized to specific job responsibilities. It should include pertinent content and interactive real-world case studies and workshops.

It is imperative that compliance teams work with training, regulatory and commercial colleagues to design training that will have the desired impact on field behavior.

II. Compliance Training Delivery

There is an inherent distrust that tends to exist between commercial sales teams and compliance professionals. This often exists because commercial colleagues view compliance professionals as the police versus partners in effective and ethical promotion. In addition, training is often delivered in a legalese language versus a language that translates to everyday selling behaviors.

Training has to be delivered in a language that sales teams will understand. The more compliance

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colleagues can partner with commercial sales and training partners in their presentation efforts, the more likely that the message will be met with open ears and will result in an increase in trust and engagement.

III. Shortchanged Compliance Budgets

In our experience, compliance departments are routinely underfunded for design and implementation of sales training. We have observed four reasons why this is occurring

1. Considering the 100+-year history of pharma companies, compliance is a relatively new functional department. Compliance lacks the historical record of success tied to budget monies which other departments have. Additionally, new compliance budgets are funded by taking from another department's budget, making that a difficult sell.
2. Legal and regulatory professionals typically staff biotech and pharma compliance departments. In their previous roles, sales training was funded by sales. So, they are unaccustomed to fighting for the amount of money necessary to conduct effective behaviorally-based sales training that sticks.
3. Compliance is perceived as a non-revenue generating department. Hence, their training budgets are small in comparison to sales training budgets. Because compliance is considered a "cost center" vs. an opportunity to better the company and the sales department, it is usually among the last to see any money.
4. Lastly, to complicate matters further, many pharmaceutical and biotech manufacturers have experienced budget cuts and layoffs in recent years.

If a company is truly committed to integrating Good Promotional Practices into the business and delivering effective training, then compliance needs to be a collaborative effort. Sales leadership, training professionals and regulatory experts must work with compliance to develop and fund compliance training for sales professionals. So what can you do to better support your company's commercial compliance training?

Executives: At budget planning sessions, allocate

"earmarked" resources for compliance departments to ensure funding for behavioral-based compliance training for your sales teams.

Sales: Since field sales representatives are responsible for the majority of off-label compliance violations, sales should be willing to support this funding. In addition, commercial leaders should know that they could be held liable for unlawful promotions committed by sales teams, and even face misdemeanor or felony convictions.

Compliance: Be bold. Familiarize yourself with your company's products, sales techniques, market challenges, and brush up on effective training and communication methods that will motivate your sales team to partner with your organization.

Make sure your corporate leadership understands the importance of your role and the resources you need (be realistic) to do your job.

Compliance can save companies from ruinous publicity and potentially millions of dollars in fines. It is time for everyone to get on the same page and realize that a compliance department does not ensure compliant behavior, unless they have the support and means to do so. ■

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DMH BioPharm Advisors LLC is a training and consulting firm that partners with biopharmaceutical and device companies to develop and deliver commercial compliance training solutions and curriculum.

For more information about DMH BioPharm Advisors, visit: www.dmhbiopharm.com or e-mail DMH at info@dmhbiopharm.com

Dee Mahoney and Mary Holloway are writers for Good Promotional Practices, a forum for establishing best collaborative practices in life sciences sales, marketing, compliance and regulatory. For more information, visit: www.goodpromotionalpractices.com.