



Sales & Marketing

An underused strategy to reduce costs, increase efficiencies

by Illysa Levins

By Illysa Levins, Center for Communication Compliance

In this economic downturn, clients and their promotional agencies are actively looking to reduce unnecessary costs and increase efficiencies. One underused strategy: save money and time by investing in regulatory compliance testing.

Business case based on data

The business case for testing is based on statistically significant results from a survey conducted by Rx Compliance Report at the 2010 Drug Information Association conference, attended by regulatory professionals employed by industry. 76 percent of respondents stated that as many as 40 hours per month would be saved if materials were prepared by promotional agency teams with a certified understanding of regulatory compliance. Testing is the certification tool of choice.

Based on these findings, the dollars add up quickly when you do the math. The following calculations take into account salary levels of regulatory professionals and agency team members, the 12 promotional review cycles in a year, and the fact that multiple agencies work on one brand.

Promotional agencies with certified mastery over fundamental compliance information can save \$100,000 or more per year per brand by reducing the number of pieces that need to be redone because they are not compliant. Drug or device companies can save twice as much per brand, per year, by working only with agencies that have passed a regulatory compliance test.

These numbers do not include the time saved by other members of the promotional review team (e.g., legal, medical, marketing). Nor do they take into account the money saved on nonstarters that don't reach the execution phase because they are rejected in the proposal stage as violative.

"Testing is part of our ongoing professional development curriculum in the United States, Europe, and Asia to help reduce risk and save clients money as an informed, efficient, and vigilant agency partner," says Laura Schoen, president of Weber Shandwick's global healthcare practice.

The review of promotional materials will always result in some level of rewrite. The process is inherently complicated and requires the utmost scrutiny to ensure that violative materials do not get distributed. But many agencies are already doing their best to use compliance testing to reduce the amount of time and resources that rewrites consume. At CAHG, key staff will be tested on an annual basis as a condition for employment, "to transfer regulatory knowledge more quickly and help streamline the communications review process," according to agency CEO Scott Cotherman.

And Siren Interactive President Wendy White has found that testing has helped reduce unnecessary rewrites, "because we know how to submit materials that are prepared with FDA regulations in mind."

But not everyone has been so far ahead of the curve. "Some agency programs are so noncompliant coming in the door that they not only increase risk, but create extra work for everyone involved," says former FDA official and compliance officer Michael Misocky. "Wasted time in completely rewriting materials means fewer materials going through the system, which reduces business opportunities for the brand."

Reduced turnover costs

Employee loyalty is another value-add for agencies that implement testing, which creates professional development opportunities. With testing, supervisors can inform employees about their current progress in order to help each team member set goals for improvement. They can also implement spot training where necessary. This investment attracts top talent and can retain staff longer, thereby reducing turnover costs.

Reduced legal fees

Although inefficiencies are clearly an issue for the industry, reducing risk of litigation is a top priority. "FDA enforcement letters and settlements by the Department of Justice/OIG sometimes contain nuances of policy that are important for all companies to understand," says Wayne Pines, former FDA Associate Commissioner for Public Affairs and chair of the CCC Advisory Board. "Keeping up with these actions is critically important for all companies."

The DIA-fielded survey found that 77 percent of regulatory compliance respondents are concerned that promotional agency programs and materials could be a source of trouble in litigation.

Behavioral change is the holy grail

Testing increases mastery over the information provided in the training because it forces employees to pay more attention to the subject matter. By reviewing regulatory material to correct their mistakes on the test, employees retain vital information. They also become more reflective, a critical step toward behavioral change. Such change is the holy grail for an industry that must effectively operate within an increasingly demanding culture of compliance.

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