Compliance Training

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COMPLIANCE TRAINING INSIGHTS



In This Issue



IS OFF-THE-SHELF OR CUSTOM ONLINE COMPLIANCE TRAINING RIGHT FOR YOU?

During a recent compliance conference panel session, a chief compliance officer from a mid-sized pharmaceutical company proclaimed, "I only use custom for online training," and "off-the-shelf just doesn't meet my content needs." She explained that by using custom-developed training, she could target specific topics and include company-specific policies in a way that she never could with off-the-shelf.

Fair point, but she failed to take into consideration that well-designed off-the-shelf training provides a solid foundation of knowledge, which can then be supplemented with targeted, custom micro-learning as gaps and custom needs demand.

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QUICK TIPS

10 quick tips that will make your curriculum a better experience and simplify your training in the process!

MEDICAL DEVICE MOMENTS

If you're a medical device professional, you may be asking,

"why do I need to be concerned about a program targeted to prescription drugs?"



BUY OR BUILD?... Continued

Start with Off-the-Shelf

Small to mid-sized life sciences companies need training covering core topics like off-label promotion, transparency, gifts and meals, and adverse events, but the training resources and budgets for their compliance departments, which often consist of a staff of one or two, are limited. Instructionally sound, industry-focused, off-the-shelf training is an effective way to roll out core compliance training, without draining your limited resources and time.

Off-the-shelf training, even when tailored to include your policies and contact information, can be deployed more quickly than a custom training course. Review times are shortened and less demanding, and when a need for training on a specific topic is identified, off-the-shelf gives you the flexibility to deploy the training while the topic is still top of mind for your learners. In addition, industry-focused off-the-shelf content is typically developed by someone with expertise in commercial compliance. Therefore, your time isn't consumed with being the primary subject matter expert.

A Time and Place for Custom

But, there is also a need for custom online learning in a compliance training curriculum that addresses all of your organizational risks and helps build a positive compliance culture.

Steven Just, Ed.D., educational psychologist, and former CEO of the assessment company, Pedagogue, writes: "To learn, you must cognitively act upon the learning materials; and to retain what you have learned, you must actively re-engage with the learning repeatedly over a period of time." Starting with off-the-shelf, then mixing in smaller, more cost effective, custom mini modules and interactivities (video scenarios, games, assessments) over time supports on-going behavior change — a key objective in the world of





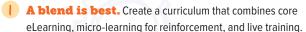
commercial compliance.

Summary

While custom online compliance training should certainly play a role in the ongoing execution of your compliance training plan, launching a foundation of targeted, off-the-shelf courses to address important topics to a broad audience represents a rational, quick-to-implement, and cost-effective starting point for any life sciences company's compliance training curriculum.

COMPLIANCE TRAINING OUICK TIPS





- Remember the WIIFM (What's In It For Me?). When training on laws or regulations, be sure to explain how the material affects the learners' job or duties.
- **3 Use classroom time wisely.** Make sure learners understand the basics through eLearning, then use classroom time for applying the knowledge.



- Keep it fresh. Routinely review training materials to update case studies and exercises.
- Use competition carefully. Some may not respond favorably to competitive training.
- **Reep it connected.** Tie the training to relevant company principles or values.
- Watch your words. A picture is worth a thousand words so limit the amount of on-screen text in courses.
- **Thin-slice your training content.** Break it into shorter, sharper segments to make it stick.
- 10 Have a little fun. Games and humor make your training engaging and fun.



MEDICAL DEVICE MOMENTS



The Bad Ad Program is managed by the FDA's Office of Prescription Drug Promotion (OPDP) and is designed to encourage healthcare providers to report pharmaceutical product ads that violate FDA guidelines. If you're a medical device professional, you may be asking, "why do I need to be concerned about a program targeted to prescription drugs?" Good question.

As part of its outreach for the Program, OPDP makes a training module publicly accessible to healthcare providers about how to identify the elements of a bad ad. Mock ads are used to highlight potential concerns, and while it may not seem relevant for medical device professionals, the module provides perspective into how regulators look for off-label promotion, omission of facts, and minimization of risk violations. This would certainly apply to Medical Device and is information your sales and marketing colleagues need to know.

Even though the OPDP Bad Ad training is focused on pharmaceutical promotion, the agency's HCP training module is a good source of information to help strengthen your compliance training and reduce your company's risk.

To see the OPDP Bad Ad Program training module, go to:

http://www.fda.gov/training/fdacontinuingeducationprogramsonmedscape

Medical device manufacturers are held to the same standards as pharmaceutical companies when promoting their products.