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COMPLIANCE TRAINING INSIGHTS

In This Issue

COMPLIANCE EDUTRAINMENT:

TOO MUCH OF A GOOD THING?

These days, the standard safety presentation is delivered via video on most aircraft. Somewhere along the way, airlines decided this approach was an opportunity to express their creative spirit, and a bit of a competition developed, with the imagined spoils going to the company that produced the most entertaining safety video. That competition reached a new level when Virgin America rolled out its Safety Dance video. It boasted talented singers and dancers delivering the

FAA-required safety information. If the objective is simply to entertain, mission accomplished. However, if the objective is to educate passengers about safety protocol, we're not sure it hit the mark.



Continued on page 2 ...

Top 10 Compliance Training Mistakes

PAGE 3

MEDICAL DEVICE MOMENTS

"...medical device training related to the Anti-Kickback Statute needs to include topics such as improper discounts and rebates."

PAGE 3

COMPLIANCE EDUTRAINMENT:

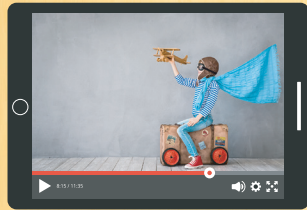
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Compliance training has evolved and a number of techniques are now utilized to deepen engagement and learning. Similar to the airline safety videos though, the learning suffers when those techniques are overused or misused.

Here are **three tips** to keep your compliance organization from falling into the Edutrainment Trap:

1. Use Interactivity Intelligently: The interactivity itself is often overused in online compliance training. Of course, a well thought-out level of interactivity is important, but overloading the interaction on every screen only serves to distract the learner from the salient points. When covering critical topics like off-label marketing and privacy, interactive exercises and games should be integrated intelligently, and in a manner that doesn't cloud the learning with unnecessary messages. Interactive elements should serve a purpose, and not just be included for the sake of entertainment.

2. Remember that Acting Counts: If live actors are used, make sure the subject matter remains the star of the training. Oscar-quality acting isn't necessary for the training to be effective, but there's a fine line between amusing amateur acting and just plain bad acting.



When the goal is to communicate the seriousness of a topic like the Anti-kickback Statute and its implications, amateur acting will derail any hope for effectiveness, as the learners pay more attention to the acting. Similarly, the more conversational the dialogue, the better. If the narration sounds like someone is reading a law journal or compliance policy, learners will tune out.

3. Include Targeted Imagery: Images and graphics are sometimes misused or overused in a way that distracts from the core objectives. There is truth to the phrase, "a picture is worth a thousand words" and well-placed imagery is certainly more engaging than an overabundance of text on screen. But when the objective is to ensure the learner can "demonstrate an understanding of the payments that need to be reported under the Sunshine Act," pretty pictures only go so far. Relevant images and graphics that reinforce key concepts and support learning objectives are needed.

A balance of imagery, text, and interactivity keeps training interesting and is a necessity in today's complex regulatory landscape. Understanding which techniques are most effective is the key to developing effective and highly-engaging training.



Our list of the top 10 compliance training mistakes we've encountered when evaluating curricula.

1 Not refreshing the content regularly. Even if most of the content hasn't changed, the way in which it is presented, as well as the delivery method, should be updated.



2 Topic overload. Focus on the most important content for training and use other tools to supplement the training.

3 Reliance on one type of training. Blended is best.

4 Training is overloaded with legalese. Use plain English as much as possible to avoid confusion.

5 Too much content in one course. People retain information better when it is presented in smaller chunks. Break down those 45 – 60 minute courses into more digestible bites of 25 – 30 minutes.

6 Too many words on the screen. A screen packed with text leads to cognitive overload. Only show main points on screen with engaging graphics, and leave the rest to the narrator.



7 All substance, no style. Content is important, but so are engaging graphics and interactivity. Learners want to be active participants in their training.

8 All sizzle, no steak. An overabundance of graphics, videos, and music also leads to cognitive overload. If the bells and whistles don't help the learning, your message is lost.

9 Not considering the goals for the training. "Checking a box" isn't a goal. Determine and define the learning objectives before you begin to write the content.

10 One size does not fit all. Include examples, scenarios, and case studies that are relevant and applicable to the targeted audience.



MEDICAL DEVICE MOMENTS

The largest False Claims Act settlement with a medical device company occurred earlier this year. Shire and its former subsidiary, Advance BioHealing, were accused of paying kickbacks in exchange for purchases of the product, Dermagraft. Among the "usual kickback suspects" (e.g., lavish gifts, meals, and sham speaking agreements), the government also cited the company for paying kickbacks in the form of rebates. The news serves as a good reminder that medical device training related to the Anti-Kickback Statute needs to include topics such as improper discounts and rebates.

Rebates and discounts can fall under the Statute's "Safe Harbors," if they are not offered as inducements to buy product. The OIG's *Compliance Guidance for Pharmaceutical Manufacturers* can be a useful tool for medical device trainers when creating training to address the risks these (and other) arrangements represent. The guidance provides explanations of how rebates and discounts can implicate the Statute and how to structure them in a compliant manner. Both are important points to cover in training.

Even though the OIG's guidance was written for pharmaceutical manufacturers, it's a must-read for medical device compliance trainers looking for the most up-to-date anti-kickback content.

