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Four Strategies for Integrating Mobile Content within a Life Science Company's Compliance Program

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Executive Summary

The mobile workforce demands a new learning paradigm, and this is especially true for regulated companies that are striving toward more proactive compliance programs.

Sales representatives who regularly interact with Health Care Professionals (HCPs) can use mobile devices to share product usage and research more conveniently and with greater impact.

However, there is risk in not documenting these interactions within the corporate or compliance learning management system (LMS), as it exposes the company to greater risks during an inquiry or audit. Compliance teams can mitigate this risk by having mobile-ready training events stored with electronic signatures.

Based on our relationship with global life science compliance teams, we provide four strategies for embedding mobile content into an existing compliance learning program to improve learning retention and track events within the corporate LMS, to ensure accurate audit record keeping.

White Paper

White Paper

Mobile Compliance Training: Beyond a Check Box

Today's compliance programs are focused on dozens of business conduct and compliance topics that include:

- Anti-bribery
- Conflicts of interest
- Fraud and anti-kickback
- Good Promotional Practices, including off-label use
- Privacy

The U.S. Department of Justice (DOJ) has made it clear that a company's compliance program, when set up properly, can help mitigate fines and penalties associated with criminal wrongdoing. Additionally, recommendations to the U.S. Sentencing Guidelines in 2010 noted that an organization facing a criminal inquiry could receive reduced penalties if the individual running the compliance program reports directly to the organization's governing authority (rather than to the General Counsel).

Compliance teams can seize these opportunities to make their compliance training more effective by using mobile devices to go beyond traditional "check the box" content:

- **More Training "Touches" in Less Time**
- **Improve Retention though Targeted Scenarios**
- **More Learning "In the Moment"**

Electronic Signatures and the Audit Trail

Since the mid to late 1990's, when some training shifted to e-learning and computerized systems, the U.S. Federal government enacted laws that have given electronic signatures and records the same validity as paper records and signatures. E-signatures have also eased the burden of compliance teams when preparing for audits, making it easy to identify and produce a full audit trail of training events. Compliance teams were also able to better demonstrate compliance to boards and senior management.

What's critical for compliance teams is that training and HCP interactions completed through a mobile device should be captured as part of the employee's profile within the corporate learning management system, alongside classes, traditional e-learning, and other compliance training events. Further, an auditor will consider an electronic record based on the integrity of the system in which it is stored. As anyone in the FDA-regulated community knows, 21 CFR Part 11 represents perhaps the strictest law for managing electronic records.

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The FDA expects an electronic record to be authentic, reliable, trustworthy, and accessible, and any change to the record must include time and date stamped audit trails.

Embedding Mobile Learning into the Compliance Program

Theoretically, mobile content involves more "touches" with learners than traditional online learning. This may be particularly beneficial to compliance teams, who are challenged to keep training fresh and relevant. Based on our clients' desire to make compliance training more relevant and efficient, we have identified four mobile content strategies that can improve the overall effectiveness of a compliance program.

Strategy #1: Keeping Annual Training "Top of Mind"

Many organizations conduct annual Code of Conduct training, along with key ethics and compliance content related to the industry codes (PhRMA, AdvaMed) and other topics (FCPA, UK Anti-Bribery, etc). Mobile content can ensure these issues resonate with employees throughout the year. As an example, consider the company that delivers its annual Code of Conduct training as a mobile-ready course so that completions are stored as part of the employee's training profile.

But what if employees need to recall guidelines during a business interaction months after they have completed the course? What if a company has implemented a Corporate Integrity Agreement (CIA) that requires the compliance program to deliver ethical "lessons learned" to sales teams to keep Code principles relevant? What if additional scenarios are raised during calls to the ethics hotline that are relevant to the entire salesforce?

Mobile devices can fulfill these issues by providing critical compliance facts in an engaging way that keep this content "top of mind" for employees and sales agents. Such training reinforces the Code and the company's ethical culture. When the learner completes these modules, they can electronically sign and make this training event part of their personal history file.

Strategy #2: Delivering Policies & Procedures Anywhere

Policies and procedures are integral to any training program. The most effective and automated way to capture a "read and understand" from a mobile workforce is to deliver the material via their mobile devices.

White Paper

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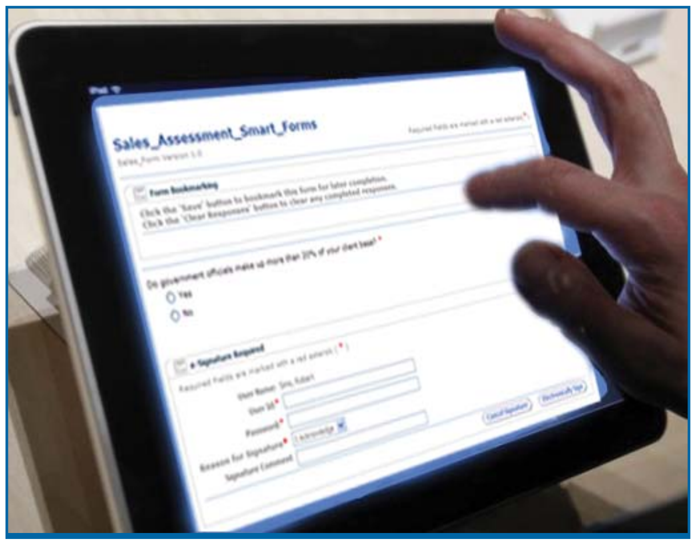
Using their web browsers, mobile device learners can open the PDF file, read the document, then complete a quiz that challenges their understanding of the material. Both the policy and the quiz are combined into an assignment that requires an electronic signature. As noted in the first strategy, the document is now easily accessible for reference by employees and sales agents in the same secure fashion.

Strategy #3: Performing Risk Assessments that Target Training

Compliance teams that perform ongoing assessments are able to monitor activities in the field, and identify high-risk relationships that trigger appropriate risk mitigation steps. Compliance risk areas could include anti-bribery, conflicts of interest, and fraud (misleading customers, switching contract terms, etc.).

This process can be automated so that the sales person can complete a risk assessment via the mobile device, providing a sense of immediacy to the risk monitoring process. For example, an anti-bribery assessment might ask: “Did you interact with a government official?” The answer could trigger a specific training module that focuses on anti-bribery policies, or even send an e-mail to a member of the compliance team to follow up on the matter. Similarly, a “ride along” assessment can also be captured via the device, in which both the monitor and salesperson are required to electronically sign.



Strategy #4: Tracking Interactions with Health Care Professionals

In addition to capturing records for sales representative training, compliance teams face the burden of monitoring the interactions between the sales rep and their clients. They also need to ensure that only vetted sales presentations, product information and other content is available via the mobile device.

In the life science industry, the ability to monitor all types of client communication has become a necessary procedure. When a sales representative visits the physician’s office, the rep needs to document which content was shared with the client. Without an audit trail, the organization could face regulatory, civil, and criminal consequences.

For compliance teams that have a program for monitoring field based personnel to ensure that they are not engaging in off-label promotion, specific electronic checklists can be completed via mobile devices. With the right LMS, sales reps and "ride along" monitors can "electronically sign" via their tablets immediately following a product-related presentation given to a healthcare professional. The form can require the e-signature of both the monitor and the salesperson, and be stored within the salesperson's training profile, along with other compliance-related activities.

The result is an electronic audit trail for each visit, which can be especially critical should the compliance team receive an inquiry from a regulatory or local government agency.

Conclusion

As more companies rely on mobile sales teams and third-party agents to conduct their business worldwide, they will need to embed mobile-ready content into their compliance programs. How they blend mobile content with more traditional training methods will determine the quality of their audit readiness, and the overall effectiveness of the programs.

Use of mobile devices throughout a sales and service workforce provides an opportunity for compliance teams to shift compliance learning from a reactive to a proactive process, so that training is a more continual process that occurs throughout the year. With the right strategy in place, compliance teams can streamline delivery of policy and procedure training to the mobile workforce. In addition, mobile-ready forms can automatically generate targeted training or even an e-mail sent to the Compliance Officer or Sales Manager.

The end result is a full audit trail of these additional proactive compliance activities, without any additional administrative burden. In this way, compliance teams should embrace mobile devices as a new channel for reducing risks and improving compliance.

About Kaplan EduNeering

Kaplan EduNeering (www.kaplaneduneering.com) is part of Kaplan, Inc., a worldwide education services leader and a subsidiary of The Washington Post Company (NYSE: WPO). Kaplan EduNeering develops technology-enabled knowledge solutions for improving business performance and assuring regulatory compliance.

Kaplan EduNeering recently launched EduM, our mobile learning solution, which is an optimized user experience for the Kaplan EduNeering Platform, that is used by nearly one million learners around the world. EduM enables our clients to deliver mobile device-ready, graphic-rich content and assessments to tablet and smartphone learners. Our Learning Services team can develop courses that are optimized for the mobile device experience (touch screen, sliders, etc.), delivered via the browser-based Kaplan EduNeering Platform for 24/7 availability. EduM is available for Apple iOS, Android, and Blackberry operating systems.

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