COMPLIANCE TRAINING CASE STUDY

One Emerging Company's Approach

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Introduction

While small to mid-size life sciences companies face the same compliance challenges and risks as their larger counterparts, their ability to address those challenges is typically hampered by a shortage of resources and personnel. Over the last ten years, the compliance training SMEs at NXLevel Compliance have worked with a number of those smaller companies to deploy and maintain an effective compliance training curriculum, even when faced with the time and budget constraints associated with being a department of one or two.

Here is how one company faced the challenges.

Company Description

Due to client confidentiality reasons, we cannot disclose the name of the company being discussed, but we can tell you that it has under $100 million a year in revenue, with a focus on niche markets, including pain management and gastroenterology. The company currently has a small number of products commercialized and more in clinical trials. There is a need to train approximately 250 people, in total, across the company. Our direct client contact (we'll call him Robert) is actually in the sales training function, but he teams with the Chief Compliance Officer to manage the rollout of the compliance training.

Challenges and Pain Point

When we first met with Robert, his most important issue was the need to launch effective compliance training that addressed the risks associated with the company's product focus and the industry in general. Beyond the initial rollout, Robert was looking for a method by which training could be launched on a yearly basis, and in a manner of speaking, he could "certify" that the learners completed the training every year. His primary pain point was similar to that of any life sciences company, small or large – reduce the risk of compliance violations and be able to demonstrate that employees are being trained on compliance topics affecting the industry and the business. And of course, he needed to accomplish all of this with the limited resources that typically come along with being a smaller company.

The Options

When Robert first approached us about his needs, he graciously shared the various options he was considering:

OPTION 1: Comprehensive System with Learning Management System (LMS) Capabilities and Courses

Advantages

- All-in-one system
- Industry-focused courseware

Disadvantages

- Expensive
- Limited courseware offerings

OPTION 2: Off-the-shelf Ethics Training Launched on an LMS with Minimum Functionality

Advantages

- Cost-effective
- Comprehensive set of courses

Disadvantages

- Courseware not industry-specific
- Client locked into three-year contract

OPTION 3: Compliance Foundations eLearning modules on our Access LMS

Robert and his colleagues chose to deploy six modules from the Compliance Foundations™ curriculum on a client-customized version of our Access LMS:

- *Commercial Compliance Overview*
- *Good Promotional Practices*
- *The PDMA and Drug Sample Management*
- *On-label Promotion*
- *HIPAA for Pharmaceutical Sales*
- *The Sunshine Act and Open Payments*

Implementation

The team of compliance SMEs worked with Robert and his colleagues to identify the company's key compliance risks and select the courses. After minor customization to add information like the company's compliance hotline and their logo, the modules were posted to the company-branded instance of the Access LMS. We then worked with Robert to delineate which groups of learners should receive each module. For example, the *Compliance Overview* module was launched company-wide because it presents a high-level view of the regulations and concepts all employees should understand, whether they are customer-facing or not. On the contrary, courses like *Good Promotional Practices and HIPAA for Pharmaceutical Sales Representatives* are targeted to those who do interact with HCPs, particularly field-based staff.

Once the appropriate rosters were created in Excel for each module and the LMS instance was established, the training was launched across the company. We worked with Robert to craft an email that introduced the LMS and the courses, emphasized the importance and reasoning behind the training, and provided clear directions on how to access the system and begin the training. From start to finish, the course customization and LMS implementation process took 6 weeks to complete.

During the customization and LMS setup process, Robert realized he also had a need to roll out product-based assessments that were based on clinical content and were built in-house, using a popular rapid development tool. He asked if hosting assessments on the Access LMS would be possible. Since the end-products were SCORM-based, that wasn't a problem. After a brief testing period, the assessments were also loaded to the LMS and assigned the designated rosters. Robert was assigned administrative rights for the LMS, which gives him on-going access to completions reports for each of the modules as well as the assessments.

Year-Over-Year Training

In our discussions with Robert about the need for compliance training to be more than a one-time event, we worked with him to create a strategy by which the core modules would be relaunched every year to existing learners and any new hires. That process is a cost-effective one, since the licensing for the courses are on a per-learner, perpetual basis. So the budget is based solely on any updated customization and the time needed to "repackage" the courses and upload to the LMS – which is minimum.

Results

Over the last four years, Robert and his colleagues in the Compliance department have utilized the Compliance Foundations™ modules to train over 250 field staff and back-office support staff on the key concepts and best practices related to the promotion of products in the pharmaceutical industry. In addition to the compliance modules, the company continues to use our Access LMS to roll out multiple online assessments covering content delivered in live training sessions. As new hires join the company, Robert provides us with new roster sheets for the modules and assessments, and through his administrative access, he regularly tracks the completion status for each of those learners.

The bottom line – through the use of off-the-shelf, customizable, and industry-focused eLearning modules deployed on a flexible and cost-effective LMS, Robert knows he is doing what he can to integrate good and up-to-date compliance practices into his company's daily business activities. That's quite a comforting return on investment for the compliance or sales training manager of any small or mid-size life sciences company.

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