POLICY AND MEDICINE

REPRINTED FROM

LSC Life Science Compliance Update

U.S. EDITION

Volume 3.5 | 2017

Improving Outcomes

Analyzing a Compliance Training Curriculum to Reduce Risk

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Abstract: *Life sciences compliance departments are under constant pressure to roll out updated and comprehensive training that addresses a growing milieu of subject matter, from off-label promotion, HIPAA, and data security, to anti-bribery laws around the globe. The rush to cover all the topics across all the potential audiences can lead to a convoluted curriculum, with gaps or redundancies in terms of which audiences receive what training. Building a curriculum that appropriately addresses the company's unique risks is an important first step, but a regularly-scheduled analysis of all content, and audiences and delivery methods, is critical to ensure on-going effectiveness against risk.*

In response to regulatory changes, compliance departments continually push out training focused on changing rules, regulations, and policies. Redundancies, misalignments, and occasionally, even gaps, emerge. This threatens the effectiveness of the curriculum. Regular, comprehensive analysis, with subsequent reconfiguration and realignment, is necessary to ensure that targeted training is being deployed to the appropriate audiences, at a frequency that maximizes engagement.

An effective, three-phase process begins with a comprehensive documentation of existing training content and components.

Phase 1: Documentation

Understanding the current landscape is critical to improving the overall situation. Therefore, the documentation phase typically begins with a review of existing training assets, including eLearning courses, live training materials, and reference materials. The asset titles need to be documented, along with the major content/topic areas within the assets in which the topics are trained, and the delivery methodology (e.g., eLearning, LIVE, online reference, read & sign, etc.). Once this is accomplished, it is possible to identify:

- The list of topics covered in detail in all training materials
- The primary, secondary, and tertiary audiences for the topics
- The training level at which each topic is treated in the asset, ranging from less detailed to highly detailed
- The length of each topic (time, number of slides, or words, depending on the type of asset)
- The risk each topic represents for each audience
- The frequency with which each audience utilizes the information in each topic in the performance of his or her role

Each of these areas is described in further detail below.

Topics

A simple, high-level list of topics (off-label promotion, anti-bribery, adverse events and product complaints, etc.) does not present a complete enough picture of what is addressed in a curriculum. Topics need to be examined at a granular level. For example, when training that covers off-label promotion is noted, a detailed list of topics within that training should be included. See Table A for an example of sets and subsets of common commercial compliance topics.

Audiences

When documenting audience groups, simply creating large categories such as "commercial," "research," and "corporate,"

Table A: Sets and subsets of common commercial compliance topics

Off-label Promotion	Anti-bribery	Adverse Events
Product label	Bribes	AE defined
Labeling	Foreign officials	Documentation information
Handling unsolicited questions	Third party red flags	Reporting pathways

Table B: Potential audience groups

Commercial Audience Groups	
Field Sales	Marketing Management
Sales Operations	Access – Field
Sales Training	Access – Operations
Field Sales Management	Access Management
Sales Management	Business Development
Marketing – Product Level	Trade Sales
Marketing Operations	Trade Sales Operations
Research	
Clinical/Transitional/Discovery – HCP Contact	R&D Operations (Safety, Reg. Affairs, Compliance etc.)
Clinical/Transitional/Discovery – No Contact w/ HCPs	People Managers
Logistics & Manufacturing	
Non-People Managers	
People Managers	

does not yield the results needed to understand if training is being deployed to the appropriate audience and if risk is being addressed adequately. The granularity of the audience detail is largely dependent on the size and structure of the organization. Table B shows examples of potential audience groups within those three categories.

The level of audience granularity is also dependent on the subject matter the compliance department is responsible for covering. Employees in organizations such as manufacturing and finance, do not typically interact with healthcare professionals or promote products, so the granularity in audience subsets is not needed to the level it is for the commercial organization.

Levels of Detail

The level of detail with which each topic is presented in a course should be assessed and documented. The standard set of descriptors shown in the graphic can be adjusted based on variable client curriculum components.

At the Awareness level, a basic understanding of knowledge is required. The General level requires a thorough explanation, but not as much detail as a policy or SOP. Detailed means the topic is fully described, and is typically reserved for policies or explanation of an SOP. Finally, Knowledge Application is used when learners need to apply a previously established base of knowledge. The level of detail is documented in terms of what exists and what should exist for each topic. This allows for easy identification of gaps during the analysis phase.

Length

Noting the length of each training component is necessary to evaluate whether the volume is sufficient when compared to the risk level of the topic. For example, if a topic is designated

high risk, one or two screens in an eLearning module is not enough to address that topic at a level that appropriately mitigates the risk.

Risk

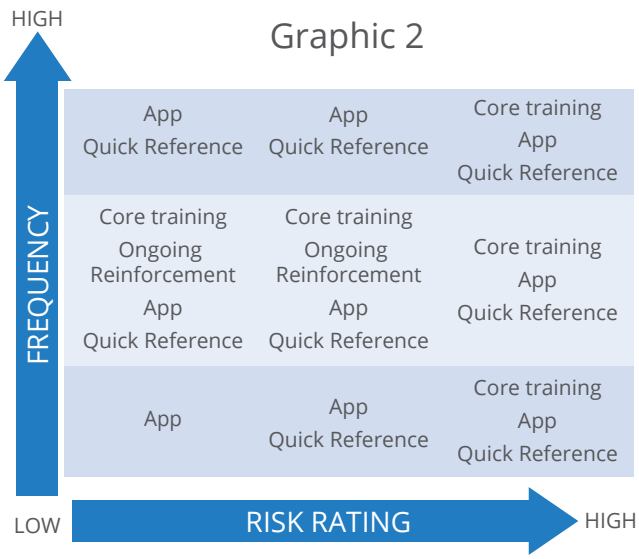
Once all topics and audience groups are listed, the level of risk (critical, high, medium, or low) each topic represents for each audience can be assigned. Assess risk from the perspective of the risk the topic represents for the industry in general.

This is a time to "gut check" those risk assessments. Depending on the nature of a company's business, or business processes, the level of risk may vary from what is the norm in the industry. A good example is "venue selection for a speaker program" for the field sales audience, which is addressed in the PhRMA Code, and has been a point of focus in industry settlements with the Department of Justice. It's clearly a high-risk area. However, if your company does not allow field sales representative autonomy in selecting a venue, the topic represents a lower risk.

Frequency

Frequency at which an audience utilizes the information in performance of their job is critical when considered in conjunction with the risk level of each topic. Too often, compliance training is rolled out on a yearly basis, no matter the risk and frequency, and without consideration of the Ebbinghaus Forgetting Curve, which demonstrates that what humans remember after a single learning event decreases rapidly after that event is completed.

Graphic 2



Areas at a higher risk and higher frequency require more support, which might include core training; performance reinforcement through tools like micro-learning modules; and reference apps. By contrast, areas of lower risk may only require a reference app, and perhaps an infographic at the low frequency levels, to support and reinforce the learner's basic understanding of the content.

The rubric in Graphic 2 shows some of the tools and training approaches that can be utilized to address varying risk and frequency levels.

Phase 2: Analysis

Once the documentation phase is completed, the analysis to identify redundancies and gaps and determine whether the level of training versus the risk for the audiences is sufficient, begins in earnest. Redundancies are simply topics that are repeated for an audience group. Some redundancies are to be expected. For example, those trained at an awareness level in a code of conduct course are sometimes trained in greater depth in other courses. However, redundancies need to exist for a good reason. Those that bring no value to the learner are obviously concerning, and if your curriculum has been in place for years, you're likely to find them.

Capturing any company-specific processes or information is also important. For example, if your curriculum includes training on the use of the compliance intranet site, that would not normally be included on a standard compliance topic list but analyzing the frequency at which it is trained is important.

In contrast to the identification and evaluation of redundancies, gap analysis is more involved. An effective analysis searches for gaps in the audience and topic; level of detail a topic is covered for the audience; and the risk associated with a topic by the audience.

Topic gaps for an audience are easily identified. Remember to document the topics being trained, and those that should be trained. Then, to identify the gaps, sort the topics that have no level of training assigned. The level of training as it currently exists against the desired states should also be documented.

Identification of gaps based on the level of risk, in relation to level of detail, needs to be determined by audience. Topics not presented in enough detail for the risk they represent are a concern. Note the topics of low risk that are trained in high detail. Addressing those topics differently, perhaps through an infographic or micro-learning, could be a more efficient approach.

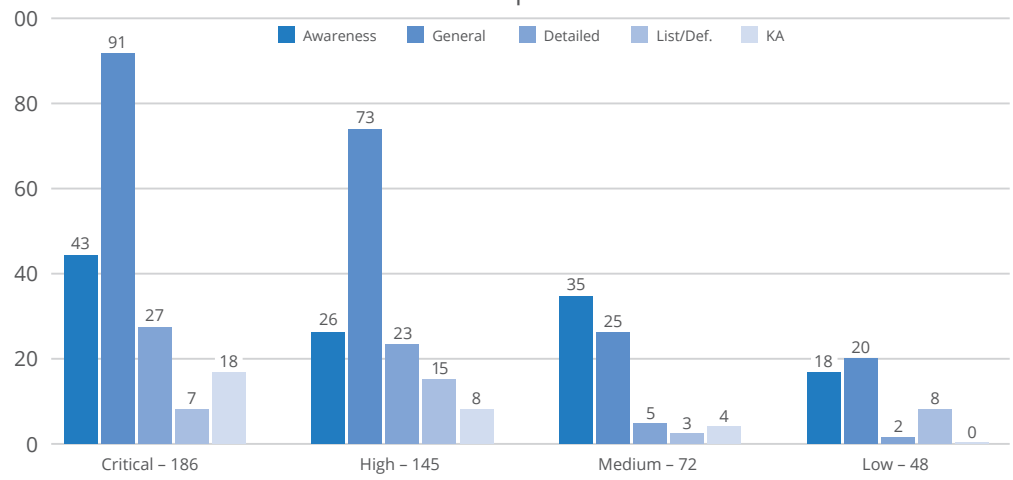
Phase 3: Evaluation and Planning

In the Evaluation and Planning phase, begin by producing and evaluating the results of Phase 2: Analysis. It's important to provide a snapshot of the "as is" state of the training curriculum as documented in the curriculum analysis spreadsheet. Table C lists the basic metrics recommend for that report.

Table C: CCAT

Total Training Instances	Redundant Training by Audience
Percentage Each Delivery Method Represents	Risk Exposure by Audience
Training Time by Audience	Topics with Risk Gaps

Graphic 3



The even more critical information for review includes cross-referenced information, such as risk rating as compared to training level, as presented in Graphic 3.

In the case illustrated in the chart, 70% of topics deemed high or critical risk are treated at the less-detailed training levels of awareness and general. This is an area of concern. The higher the risk, the greater the need for detailed training.

At this stage, solutions to address the gaps and redundancies need to be planned. That could include new courses, the removal of some courses, the modification of audience groups assigned to specific courses, or the implementation of alternative training components such as infographics, micro-learning, and gaming. Instructional design concerns need to be documented as well, and addressed appropriately during redevelopment of individual components in the curriculum.

With a thorough evaluation of the current curriculum complete, a training map and long-term development plan can be established to guide the curriculum improvement effort moving forward. At this point, any recommendations need to be addressed in context of the other departmental priorities that may affect what updated or new training components can realistically be implemented, in what timeframe.

Compliance training curriculums are changing fast – sometimes too fast. A regularly-scheduled, comprehensive compliance curriculum analysis helps ensure that on-going training is being delivered to the right audiences, at the right level of detail, and at the right frequency. That is one significant step toward reducing your company's risk and building a stronger compliance culture in the long term.