

THE RIGHT STUFF:

Compliance Training in Preparation for Your Company's First Product Launch

By Lauren Barnett, Compliance Content Specialist

A first product launch is an exciting and overwhelming time for any life sciences company. So much to do, and what seems like so little time to do it – especially if you are a compliance department of one or two people. As employees are brought on board in support of the launch, planning and implementing an initial compliance training curriculum is a critical task. You need to cover all the essential bases and topics, and direct the training to the appropriate audiences so individuals aren't burdened and distracted by messages and information that may not be applicable to their job duties.

With that in mind, the team has compiled a list of suggested topics and audiences for any company working toward an initial product launch.

Topic 1: Code of Conduct

AUDIENCE: ALL EMPLOYEES

Good code of conduct training introduces employees and external contractors to the behavioral expectations your company has established. It also provides a foundation for understanding the requirements of working in such a heavily-regulated environment. We could fill an entire blog entry with instructional tips for building effective code training, but for now, we'll make this one suggestion – make it more meaningful with scenarios that demonstrate how the concepts are manifested in their daily activities. Learners need to relate to the information being presented in order for it to stick.

If your company has not yet developed a code of conduct, see topic two.

Topic 2: Overview of Healthcare Compliance

AUDIENCE: ALL EMPLOYEES

All employees must be aware of the laws, regulations, and guidance documents related to working for a pharmaceutical or medical device company. If your company doesn't have a code of conduct, or the code doesn't include basic information about the laws affecting the industry, a compliance overview course is especially necessary to communicate the concepts they need



to know. If you do have a code of conduct, consider the idea of narrowing the audience to the commercial, medical affairs, regulatory, and communications groups.

Topic 3: Interactions with Healthcare Professionals

AUDIENCE: SALES, MARKETING, MEDICAL AFFAIRS, AND CUSTOMER-FACING REGULATORY

Employees whose job responsibilities involve interacting with healthcare professionals (HCPs) on some level need training to ensure those interactions are in compliance with laws, regulations, and company policy. The training should include topics such as the rules associated with providing gifts and meals; the use of HCP consultants; proper conduct during speaker programs and advisory boards, and interactions at medical congresses or other scientific meetings.

Topic 4: Good Product Promotion

AUDIENCE: SALES AND MARKETING

Sales and marketing teams need detailed training regarding the regulations that govern prescription drug and device promotion. Focus your promotional training on how the regulations affect both verbal and written promotional statements. It should include topics such as what constitutes promotional statements versus medical information; what is a proper promotional statement (i.e., accurate, balanced, and truthful); FDA guidance on dissemination of reprints; and the use of social media.

... planning and implementing an initial compliance training curriculum is a critical task

Topic 5: PDMA and Drug Sample Management

AUDIENCE: FIELD SALES

If samples are going to be a component of the product program, training regarding the requirements of the Prescription Drug Marketing Act (PDMA) is needed before the sales representatives receive any samples for distribution. The training should be twofold though, and include information about inventory management, and your company's sample documentation processes – a topic just as important for medical device companies.

Topic 6: HIPAA

AUDIENCE: SALES, MEDICAL AFFAIRS, AND ANY GROUP INTERACTING WITH PATIENTS OR HANDLING PATIENT INFORMATION

The protection of patients' personal information is a hot button issue, so you need to ensure those who handle, or who may be exposed to that information, are aware of their responsibilities regarding confidentiality. In addition, credentialing requirements at hospitals and other facilities now require anyone doing business in those facilities to be trained on the requirements of HIPAA and the protection of personal health information. In fact, if your sales representatives are going to be selling in a hospital environment, you will want to add Bloodborne Pathogens and Aseptic Technique training to their curriculum as well, but we will save that for our blog entry on the rise of credentialing and its requirements.



More Information is Available

While the above list of topics constitutes a strong compliance training foundation for any company moving toward its first product launch, the topics and audiences may need to be tweaked based on your company's product and product indication.

Thanks for reading and stay compliant!

