

Compliance Basics 4 - Conducting Effective Education and Training

Introduction

This article looks at the purpose of, and the differences between, training and education, discusses who should be trained in what, when and how that training should be delivered. It also looks at keeping training records in a simple way, according to the needs of your organisation.

Before discussing training and education, we need to look at whether or not there are any differences between the two, and if so, does it really matter.

A dictionary definition of education is:

“a form of learning in which general knowledge, powers of reasoning, and habits are transferred through teaching or training.”,

and training is:

“the acquisition of a particular skill or type of behaviour with the specific goals of improving one's capability, capacity, and performance.”

This fits with my own view that training is more specific, for example training staff in a particular standard operating procedure so that they all work in a particular way that is proven to give the right results, whereas education is more general, for example, educating staff about the values that underpin a company's Code of Conduct (or equivalent document). This matters because the objectives of training and education are different, and when designing education and training programmes, it is vital to design them with the objectives in mind.

The guidance issued by the Office of Inspector General (OIG)¹, entitled “OIG Compliance Program Guidance for Pharmaceutical Manufacturers”² states that “[t]he proper education and training of officers, directors, employees, contractors, and agents, and periodic retraining of personnel at all levels are critical elements of an effective compliance program”. The guidance goes on to say “[t]he specific training should be tailored to make it as meaningful as possible for each group of participants.” From this we can see that the US authorities are keen to ensure that companies train and educate the right people in everything that they need to know to enable them to conduct their roles effectively. This is mainly common sense in that we would not expect anyone to drive a car without first being shown how all the parts operate to propel the vehicle forwards, backwards and round corners, and to stop in a safe manner, and without first having the opportunity to practice their technique in a reasonably safe environment with a qualified instructor on public roads. In most countries, we also would not expect people to drive alone on public highways without having first passed a test to demonstrate their competence and safety behind the wheel. We therefore should not expect staff to undertake key roles within a company such as medical representative, production line operative, clinical research specialist, etc. without first receiving both general education of the company's aims, and specific training in the tasks that they will undertake for the company.

¹ The Office of Inspector General is part of the US Department of Health and Human Services

² Federal Register Vol.68, No. 86, 5th May 2003, is available to download under “05-05-2003” at <http://www.oig.hhs.gov/compliance/compliance-guidance/index.asp>

Needs Assessment

The first step in developing an effective education and training programme is to assess needs according to role, level of experience, and prior knowledge of the individual in the role. The education and training needs assessment should include general education that all employees and directors need, such as knowledge of the company's Code of Conduct (or equivalent), including its values and mission or vision statement. There may be specific training needs identified with a particular site, such as a manufacturing facility where everyone who regularly works on the site needs a basic level of health and safety training, or there may be a specific hazard associated with working on that site that all staff will need to be aware of, including what to do in an emergency. People operating heavy machinery are likely to require additional training above the basic health and safety training. There will definitely be specific training needs for particular teams, such as those operating production lines who will have specific standard operating procedures to follow.

Many companies now develop a general training needs matrix that covers the basics for all staff with individual business units adding the requirements based on general roles, and departments adding the specific training needs for each member of the team based on their existing knowledge, experience and competence. An illustration of such a training needs matrix can be seen in diagram 1 where "awareness" needs are highlighted in lilac and detailed needs are highlighted in green.

Diagram 1 - A basic, illustrative training needs matrix

Item	All Staff	Senior Mgt	Third Party Staff	Medical Reps	Admin Staff	W'house Staff	Production Staff	Laboratory Technician	Clinical Research
Code of Conduct	Lilac	Lilac	Lilac	Lilac	Lilac	Lilac	Lilac	Lilac	Lilac
Anti-Bribery / Anti-Corruption		Green		Green					Lilac
Acceptable Use of IT		Lilac		Lilac	Lilac			Lilac	Lilac
Local Sales & Marketing Code		Lilac		Green					
Safe Lifting Procedures		Lilac		Lilac	Lilac	Green	Green	Lilac	Lilac
Local Warehouse SOPs						Green			
Local Production SOPs							Green		
GMP (Manufacturing)						Green	Green		
GDP (Distribution)				(only for samples)		Green			
GLP (Laboratory)								Green	
GCP (Clinical)									Green

Objectives

According to Herbert Spencer,³ “The great aim of education is not knowledge, but action”, so how can companies develop education and training programmes that will lead their employees to take the right actions? The next step is to develop the right objectives for the education and training programme.

When training a medical representative in the local industry code of practice, the objective is to ensure that the rep knows what behaviour is permitted in all their interactions with healthcare professionals, and what is not, so that they will only act in a manner likely to bring positive results for the company. A suitable objective for this type of training might be to “ensure that medical representatives behave in a compliant manner in their interactions with healthcare professionals”. However, the objective of their education in the company’s Code of Conduct and the underpinning values might be to “ensure that employees are able to act as ambassadors for the company, modelling our values in their internal and external interactions”. The two objectives are subtly different in that the first is specific to healthcare professional interactions and ensuring compliance with local laws and codes of practice, whereas the second is more values-based and includes all interactions, both internal and external.

Design and Develop Specific Education and Training Interventions

Once you have clear objectives for your training or education intervention, you should then be able to design and develop an intervention that best meets those objectives. The design phase includes not only the key messages, but also the delivery method. As a result of recent advances in technology, a much wider set of possibilities has become available to companies in terms of delivery methods. Previously, there were only two possible ways to train people:

- face to face, either in a classroom situation, or “on the job”, and
- via the printed word.

Face to face training has many advantages, including the ability to tailor the approach in each session to fit the audience (although there is also a disadvantage in the loss of consistency), to know whether or not each participant has fully engaged in the topic, to emphasise particular points that the current audience finds difficult, and to spot those people who need more in-depth training in specific areas.

The printed word has the advantage of consistency, and usually uses more precise language, thus reducing the possibility of misinterpretation. The main disadvantage is that just because someone has bought or borrowed a book, it does not mean that they have opened it, or that they have read and understood every page.

In the 1980s and 1990s, the affordable training video was born, and many companies invested in generic videos on a wide range of topics from time management to conducting effective appraisals. Some of these videos used humour to spread their serious messages whilst others took a more scholarly approach. The great advantage of the training video over face to face training is that the same “performance” is guaranteed in every playing of the video. Another advantage is that these videos are often cheaper to buy than the time of expert trainers and they can be made available to anyone with access to a video player (or, more recently, a DVD or Blu-ray player) regardless of where

³ Herbert Spencer, British social philosopher, 1820-1903

they are based, in the same way that books can be borrowed from corporate libraries. Disadvantages of video training materials include the inability of the viewer to ask questions and explore topics in more depth, difficulty in translating the materials into other languages, and also not knowing whether or not the viewer has watched the whole performance, or has skipped through the parts that they find less interesting.

The humble training video has recently morphed into a vast library of online, often interactive, training materials that are instantly available at any time of the day or night from anywhere in the world that has an internet connection. Companies now invest large sums of money each year to develop company-specific eLearning materials on their Code of Conduct and relevant values, plus other more specific topics. It is now more important than ever for companies in our industry to ensure that all employees fully understand the corporate values and act on them every day of their working lives. eLearning modules can provide companies with a cost-effective way to get the key messages out to the largest possible audience in a very short time. Different languages can be catered for in eLearning modules, both in the on-screen text, and in the spoken delivery, although the latter is more expensive and care must be taken in choosing those doing the speaking to avoid any heavy accents. It is also possible to “push” this type of training to those staff identified as requiring the training, to track who has undertaken the eLearning modules, and to follow up with those who have not (see the section on training records below). However, the disadvantage of not really knowing who has properly completed these modules makes them generally unsuitable for job-specific training with compliance elements.

Given the advantages and disadvantages of each delivery method, many companies have, for some time, adopted a blended approach to training where perhaps some basic information is transferred via compulsory eLearning modules including a test of their understanding, which is then followed up with their line manager, both individually and in groups, to discuss the key issues arising from the training. Another advantage of using line managers to reinforce training is that the discussion can take place in the local language, thus ensuring that none of the core message is “lost in translation”. In this way, the key messages are consistently and cheaply (assuming the audience is large enough) delivered to the maximum audience and managers take responsibility for ensuring that their team members fully understand the key messages and will act on them.

My favourite saying on this topic is the Chinese proverb “tell me and I will forget, show me and I may remember, involve me and I will understand”. For this reason, I am a great fan of case studies, both in printed and interactive forms. They are an especially powerful tool for both training and education when conducted with a group of peers who will have very different ways of looking at a particular situation. I have run in-house and external case study sessions for many years and I find that the participants often think of at least one different possible solution to at least one of the cases discussed during these sessions. This shows the power of discussing cases to enable all aspects of the topic to be appreciated by the participants.

Delivery

Once the programme has been developed, it must be delivered. The participants will already have been identified from the needs assessment matrix, and the development phase will have identified the delivery method. It is now critical to ensure that the delivery itself is as good as it can be, whether that means that the trainer had a good sleep the night before, or the technology all works together, regardless of what type of computer and operating system the participants use, and wherever in the world they are based. To ensure that the key messages are received and understood as intended, it is important to run a small pilot of any large-scale training programme so

that lessons can be learned, and materials or delivery modified to ensure that the objectives are met.

One delivery method that works well with people in separate geographical locations is a “webinar”, or internet based seminar. The simplest way to do this is for all participants to dial in to a telephone conference, and to have already been sent the presentation materials by email. The person delivering the training needs to tell participants which page of the materials they should be on so that they can keep up and advance the pages or slides at the appropriate point. There are more complex forms of webinar available, including those using specialist software where participants dial in to the webinar using their computers to get the interactive presentation, with the presenter in control of advancing the pages at the appropriate pace. Participants may also need to dial in to a telephone conference to get the sound, or this may be provided via the software on their computers. Some software also allows participants to ask questions of the presenter or to have a private text-based discussion with each other during the presentation. Whether participants dial in to a separate telephone conference, or this is provided via the computer, it is important that the presenter has the option to mute all the lines except for their own when they are speaking so that the background noise does not become overwhelming. The lines can be taken off mute at the end of each key point to enable the participants to ask questions. I have found that this delivery method works well, including with people for whom English is not their first language. It is far more cost-effective than physically bringing together groups of people that work in separate geographic locations. It is also better than eLearning modules because the presenter can check for key learning points along the way. However, it is not as good as face to face training, as people can (and do) respond to emails whilst “attending” these sessions, which is not ideal for maximum learning.

Evaluation

An important stage in an effective training and education programme is the evaluation of both individual delivery, and the programme as a whole. How do you know whether or not your training and education programme really is effective? Donald L Kirkpatrick⁴ split the evaluation into four steps:

1. Reaction – to what degree the learners react favourably to the training undertaken; best measured quite soon after the initial delivery;
2. Learning – To what degree participants acquire the intended knowledge, skills, attitudes, confidence, and commitment; this should be measured over a period of time, e.g. immediately after, three months later, and a year later, to understand lasting as well as initial improvement;
3. Behaviour – To what degree participants apply what they learned during training when they are back on the job, or the impact on the learner’s behaviour and performance; again this is best measured over time;
4. Results – To what degree targeted outcomes occur as a result of the training event and subsequent reinforcement, or the impact on business performance; this has to be related back to the original objectives and should be as specific as possible, and should also be measured over time.

⁴ Donald L Kirkpatrick, American author, speaker and Professor Emeritus at Wisconsin University (USA), from his PhD dissertation. For more information, see www.kirkpatrickpartners.com

However you choose to measure the effectiveness of your programme, it will be made easier by having more specific objectives, and targeted outcomes. However, if your objective is to change how people think, and what their values are, their behaviour can be a good proxy, especially if one of your objectives was to have an impact on behaviour.

Most companies are under pressure in the current environment to demonstrate a positive impact on turnover from their training and education programmes. In the life science industry, the situation is much more complex and must take into account such factors as the need to comply with the various laws, regulations and codes of practice.

Training Records

For many roles in life science companies, it is a regulatory requirement to keep accurate training records that enable companies to demonstrate to external inspectors who has been trained in what, and therefore who is qualified to carry out certain roles. For this reason, companies have often integrated training records with their electronic personnel records. This type of integration can be very useful, for individuals and managers alike, although it can sometimes prove difficult to extract information in a meaningful format for an auditor or inspector. For example, typical audit or inspection questions might be “show me a list of all people in role abc”, or “show me a list of all people who have been trained in xyz”. Whilst the former might be easy to answer from a training record integrated with personnel records, the latter may prove more difficult. These questions are likely to lead on to other questions, such as a name being selected at random from either list followed by “what else has this person been trained in”, and possibly “how do you know that this person is qualified to carry out their role”. This last question links the training record back to the training needs assessment for each individual in their role depending on their experience, knowledge, skills and training record to date.

Another question to ask yourself is how easy it needs to be to gain access to original training records and certificates of attendance. For example, some years ago, I worked on a project to implement new software and new ways of working in manufacturing sites around the world. The company stored all original training records from the project in an off-site, commercial archive location in the UK alongside the original documentation for the project. A service level agreement was signed with the archive company guaranteeing that individual records would be located within a certain timeframe following receipt of a request, and also sent by courier to a nearby company location within a certain time limit after that if required. Every individual who worked on this project also kept a certified copy of the original certificates in their personal training folders. This meant that an inspection at any of the global locations where the project had been implemented had immediate access to certified copies, could receive faxed copies of the original documents within a limited time following the request by an inspector, and could receive the original documents by courier as soon as physically possible after that, depending on geography. At the time, this was thought to be a best practice solution, especially as it kept all the original documents in one place. It was backed up by a very simple spreadsheet at each implemented location that showed who had been trained in what, so the typical inspection questions could be readily answered. Only on rare occasions was it necessary to retrieve the original documents from storage.

During development of the above solution, one of the suggested solutions was to give all the original certificates to individuals to hold. There were many reasons for not choosing this solution, including what would happen to the original documents when people left the company or moved on internally, and what would happen if someone chose to throw away or destroy an original certificate that was later needed for an inspection.

For business units that are not likely to undergo regulatory inspections, and for day-to-day training records, rather than project-based training records, it is usually less burdensome for individuals to hold the original training records. Alternatively, these could be kept centrally within the department where the individual works to relieve the individual of the burden of holding their own training records. If there is any chance that access to a training record for an individual who has left the department or company may be needed in the future, then it would be wise to implement a department, or site, or global training records mechanism.

It is, therefore, vital to understand all the purposes for which training records are being kept, and to ensure that the mechanism chosen is able to fulfil all of those purposes, including retrieval of the records at the appropriate moment, with the lowest possible administrative overhead.

The next article in this series will look at the fourth element of an effective compliance programme: “developing effective lines of communication”, including normal lines of communication via line managers, HR, legal, and local or global reporting lines.

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In January 2010, Sue established the management consultancy, Sue Egan Associates Limited, specialising in Corporate Governance, Compliance, Risk Management and Change Management. Sue works with clients in various sectors (life sciences companies, charities, a government agency, and other industries) to help them find innovative ways to conduct business ethically and sustainably.