

Determining Training Effectiveness

Training effectiveness is an important element in an operational quality management system. In this case we look at the requirements from ISO 13485:2016, but the issue applies to FDA QSR and other management systems.

ISO 13485:2016 Clause 6.2 requires that people performing work that affects product quality are competent based on education, training, skills, and experience. The manufacturer defines the process for establishing competence and provides the needed training.

In addition, the manufacturer needs to perform three activities:

- Determine the necessary competence for personnel performing work affecting product quality
- Provide training or take other actions to achieve or maintain the necessary competence
- Evaluate the effectiveness of the actions taken

A common approach to establishing competence a job description that includes the four elements. A gap analysis between the required training and a given person's actual training (based on the training records), identifies needed training.

It is usually easy to provide the training, but this leaves open the training effectiveness question.

The newly published ISO 13485:2016 Handbook offers some methods to evaluate training effectiveness based on the risks associated with the work for which the training or other action is being provided:

- Surveying the trained personnel to assess whether he or she feels they have learned the required information
- Testing or questioning the trained personnel to assess their competence using objective criteria
- Evaluating the work performance of the trained personnel
- Reviewing the trainer assessment of training effectiveness

In addition, ISO 10015:1999 *Quality Management – Guidelines for Training* provides a comprehensive system. Clause 4.5.1 says, “The purpose of the evaluation is to confirm that both organizational and training objectives have been met, *i.e.*, training has been effective.” It recommends evaluation on both a short-term and a long-term basis. In the short-term, use trainee feedback information on the training methods, resources used, and knowledge and skills gained as a result of the training. In the long-term, assess trainee job performance and productivity improvement. In addition, Table A.4 provides suggestions on the inputs, process, outputs, and records for evaluating training outcomes.