

# PDA Journal of Pharmaceutical Science and Technology

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**President:** Edmund M. Fry

## COMMENTARY

**Training Commentary****DAVID A. GALLUP and KATHERINE V. BEAUCHEMIN***Training and Communications Group, Inc., Berwyn, Pennsylvania***Qualified or Certified. That is the Question**

Unclear about the difference between qualification and certification?

If so, you aren't alone. Approximately half the people responding to a recent PDA benchmarking survey, *Status of Training in the Healthcare Manufacturing and Researching Markets*, said their companies make a distinction between qualified and certified workers. But when it comes to defining the difference between the two, people are likely to offer a variety of ideas about what the terms mean. Here are some examples.

"Qualification is done for a specific task; certification is done for a series of tasks."

"Qualification equals field; certification equals classroom."

"Qualification is done through internal trainers; certification is done through an outside body."

"Qualification is an ongoing process; certification happens once."

"Qualification equals OJT plus experience and education, which allows individuals to produce desired results consistently. Certification equals documented evidence through pre-established programs that desired results are consistently obtained."

*What's the Answer?*

With such diverse opinions about qualification vs. certification, let's turn to the Merriam-Webster Dictionary for definitions of these two terms.

**Qualification:** "to fit by training, skill or ability for a special purpose. To declare competent or adequate; synonym; certify; meet the required standard."

**Certification:** "to attest authoritatively, to attest as being true or as represented or as meeting a standard. Usually applies to a written statement, especially one carrying a signature."

From these definitions we might say the words are almost identical in meaning, at least according to the dictionary. The only difference is that some type of written document may be associated with certification. So if the definitions are similar, why the concern?

One problem lies in the connotations associated with the terms, especially with regard to the perceived status conferred by the word "certification." Some organizations are reluctant to offer an official-sounding "certification" to employees for a variety of reasons. "If we certify some employees, what about the others?" asked one training

other, "uncertified" workers were somehow less capable than those holding certifications.

"At our organization the word 'qualified' is more acceptable than 'certified,'" said one trainer. "What exactly do we mean by 'certification'? It sounds like it might have some legal status. On the other hand, I've run into a difference of opinion as to what 'qualification' means, too. I'd say the whole area is somewhat nebulous."

Still other organizations seem to be unconcerned about making fine distinctions. "We call all our employees who have been through first-level training 'certified,'" said one training professional. "I don't think anyone's ever questioned it. It's not a problem for us."

*What's Really Important?*

How important are the differences between certification and qualification? In fact, do any real distinctions exist between the two? The answers lie in organizational attitudes toward certification vs. qualification and sometimes in legal considerations about which term to use. But whether employees are considered certified or qualified, healthcare manufacturers share the same underlying need: to establish that their employees are competent to perform their jobs. Regardless of what we call these employees, they all must be capable of helping the organization reach its goals. These include.

- ensuring quality outcomes
- maximizing productivity
- containing costs
- eliminating turnover
- minimizing injuries
- complying with federal regulations

Meeting these goals calls for a workforce competent in performing its assigned tasks. And ensuring that employees are competent—regardless of whether we consider them qualified or certified—relies on providing the kind of training and performance evaluations that will ensure employees possess the skill and knowledge to do their jobs. As most healthcare manufacturers now recognize, this means developing competency-based training for their workforces.

*The Case for Competency-Based Training*

According to John W. Levchuck, formerly of the FDA, "The FDA has not published a guideline establishing acceptable procedures for personnel training, nor is a

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manager. "Are certified employees better than the rest?" A lead operator in a manufacturing organization wondered whether creating a group of "certified" employees would suggest that

guideline being planned.” Neither has FDA specified strict training requirements (“Training for GMPs,” *Journal of Parenteral Science and Technology*, Vol. 45, 1991). In the absence of firm guidelines for training, many in the industry have interpreted FDA commentary and audits to promote a competency-based approach to training, with valid and reliable training programs that produce measurable performance outcomes.

A competency-based approach to training employees begins with identifying the skills and knowledge (competencies) required to do a job by conducting a task analysis. Once job competencies are identified, training is developed around the competencies. This usually involves designing classroom instruction or on-the-job training aimed at conveying knowledge and developing hands-on training to convey

skills. Written tests and performance evaluations are designed to measure the acquisition of skills and knowledge. All evaluations should include evidence that employees are capable of following applicable SOPs and batch records to produce a quality outcome.

Although we may never resolve the issue of certified vs. qualified, most training managers are justifiably more concerned with achieving excellent performance than they are about terminology. If your goal is to encourage excellence— and ensure that the training department plays a key role in contributing to your organization’s bottom line—your focus should be on competency-based training as a means of providing the best-trained workers for your organization.