

Application of Validation Principles to the Training Quality System Part 1 - Overview



By [Paul L. Pluta](#) Nov 20, 2018 10:42 am PST

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ABSTRACT

This discussion initiates a multipart series in which well-accepted concepts in manufacturing and validation are proposed for application to the training quality system. Applicable concepts include the lifecycle approach to process validation, qualification principles, and the validation master plan. These concepts are applied to training module design and development; trainer qualification, trainee screening and training, training quality system function, and training documentation. Applying well-accepted guidances, principles, and approaches used in pharmaceutical manufacturing and validation to the training quality system processes provides a structured approach to training that may help identify omissions and deficiencies in the site program.

INTRODUCTION

The training quality system is a critical component of the site quality program in pharmaceutical, medical device, and other regulated industries. Personnel in these industries must be trained as required by global regulations and guidelines. The site training program is reviewed in essentially every regulatory audit. Training is supportive to all functions – technical and non-technical -- in a manufacturing plant. Re-training is a part of essentially every CAPA investigation. Training is complex with multiple individual considerations. The training quality system must function in an organized way to provide effective training.

Methods to provide the training by trainers and trainees who receive training through the site training function under the active support of site senior management are key components of an effective training program. Beyond these, however, are many supportive considerations associated with training. Quality managers comment that regulatory auditors are now asking more questions – and more difficult questions -- about specific training considerations. For example:

- What are the qualifications of the trainers who present interactive training sessions? How are required trainer competencies determined and evaluated?

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