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The right training, the right people, the right time

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Presentation Summary: Regulatory expectations for GMP/Quality System training programs state that companies must have a robust process for determining organizational training needs and for providing employees with the necessary training in order to perform their responsibilities. Organizations continually struggle with this seemingly simple process as evidenced by an increasing number of FDA warning letters around training issues.

The traditional method of SOP “Read and Understand” is no longer acceptable to inspectors at many agencies governing our industry. Training groups must be able to identify the competencies (skills, knowledge and abilities) involved in any position or role in the organization and provide the most appropriate training opportunities for employees to be proficient in those competencies. In addition, we must be able to provide objective evidence of employee competency through training effectiveness/evaluation methods.

This presentation will outline how an organization can manage a transformation to a competency and role-based training model. A purposeful shift to a new model will bring our organizations into compliance, reduce the amount of unnecessary training and increase the quality and effectiveness of the core training that all individuals need in order to perform their responsibilities.

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