
Method Validation Studies—How GLP Interacts With Guidance Documents



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This discussion addresses the need for analytical method validation in good laboratory practice (GLP) studies including stability studies. Regulations clearly state that stability studies must be done and completed no later than the end of the GLP study. Responsibility for appropriateness of testing and completion of stability studies rests with test facility management. Stability of test mixtures containing active drugs with carriers is specifically addressed. Stability of the active drug alone does not answer this concern. GLPs apply to chemical procedures used to characterize the...

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