

ANALYTIC METHOD DEVELOPMENT PROCESS

	Early Development	GLP	GMP (Phase I & II)	GMP (Phase III+)
Method Goal	Solid, well-understood method	Scientifically sound method	Minimally validated method	Fully validated method
Analytic Goals	Build robustness into the method	Establish results for appropriate validation elements	Limited precision and robustness studies	Extensive evaluation of precision and robustness
Validation Requirements	Not a requirement, unless requested by a client	Not a requirement, unless requested by a study director	Required by Phase II	Required
Documentation Requirements	Good documentation practices	Good documentation practices, usually no written protocol or report	Written protocol and report with acceptance criteria by Phase II	Full validation protocol and report



Analytical Method Development And Validation

ML Morrison



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