

# ANALYTIC METHOD DEVELOPMENT PROCESS

	Early Development	GLP	GMP (Phase I & II)	GMP (Phase III+)
<b>Method Goal</b>	Solid, well-understood method	Scientifically sound method	Minimally validated method	Fully validated method
<b>Analytic Goals</b>	Build robustness into the method	Establish results for appropriate validation elements	Limited precision and robustness studies	Extensive evaluation of precision and robustness
<b>Validation Requirements</b>	Not a requirement, unless requested by a client	Not a requirement, unless requested by a study director	Required by Phase II	Required
<b>Documentation Requirements</b>	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

**Jin-Ying Zhang**



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