DESIGN VERIFICATION AND VALIDATION REVIEWS

GLOBAL DRUG DEVELOPMENT

Goals / Definition

To confirm that the design output meets the design input requirements.

Objective evidence, in the form of validation testing, to ensure that product design meets specifications, government/ industry requirement, and user needs.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Design verification executed	a) Execute design verification based on in-process controls and monitoring plan b) Validate analytical tests and methods c) Conduct transportation and stability testing studies d) Initiate documentation of Design Validation Master File, including protocols for Factory Acceptance Tests / Site Acceptance Tests and Installation Qualification / Operational Qualification	e) Summary report containing key data / information to substantiate conclusions f) Illustrative data tables or figures may be reported in an appendix
▪ Design Verification Review conducted	g) Conclusions and recommendations from the Design Verification Review h) Control plans updated based on risk assessment and Design Verification Review	
▪ Design validation executed	i) Execute design validation based on in-process controls and monitoring plan j) Validate analytical tests and methods k) Conduct transportation and stability testing studies l) Validate molding and assembly process by demonstration of full functionality against design input requirement	
▪ Design Validation Review conducted	m) Conclusions and recommendations from the Design Validation Review n) Control plans updated based on risk assessment and Design Validation Review	

*Candidate progression is discussed at standing grantee update meetings with the investment team