DESIGN TRANSFER REVIEW

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

To ensure device design is translated into product specifications and begin to build-up product inventory for WHO PQ and launch.

Formalize procedures that ensure that the device design is correctly translated into product specifications and implement scale-up activities to build-up product inventory, manufactured at commercial scale, in preparation for WHO PQ and launch.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
▪ Design transfer completed	a) Analytical methods / specifications / acceptance criteria "locked" b) Clear demonstration of specifications that were set / achieved at laboratory scale are applicable at commercial scale c) Confirmation of suppliers being appropriately qualified if the packaging, API + excipients and / or device components will be sourced d) Complete documentation of Design Validation Master File, including protocols for Factory Acceptance Tests / Site Acceptance Tests and Installation Qualification / Operational Qualification e) Updated process risk assessments f) Updated control plans based on risk assessments	▪ Summary report containing key data / information to substantiate conclusions ▪ Illustrative data tables or figures may be reported in an appendix
• Design Transfer Review conducted	a) Conclusions and recommendations from the Design Transfer Review b) Control plans updated based on risk assessment and Design Transfer Review	

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