

Design Qualification Protocol

(Reference SOP: _____)

Project:	Project No:
Location:	Protocol:

1. Plan

The following table identifies which activities, once completed will be used to support the Design Qualification of any system, equipment and process that has Direct and Indirect impact to any GxP functions.

Area or Items <i>For large projects involving more than one item or component, a single form can be used will the appropriate activities selected for each</i>	Design and Planning		Enhance Design Review							Commissioning and Qualification				Other Activities							
	User Requirement Specification generated.	QA review and approval of URS	Supplier Audit.	Confirm Functional Specification against URS	Confirm other related Project Specifications .	Design Review	HAZOP	Risk Assessment on Product Quality	Impact Assessment for Computerised System. Refer	FMEA	Safety Audit	Commissioning and Qualification Plan	Factory Acceptance testing	Site Acceptance testing	Create Validation Plan						
1																					
2																					
3																					
4																					

Approval to proceed with agreed Plan

Prepared by:	Role	Name	Signature	Date