

Validation Plan (Ref.VAL-005)

Performance Qualification Phase

Fill in details

The Performance Qualification will consist of plus any additional tests determined to be necessary during the Operational Qualification phase.

Change Control

The Change Control Procedure according to SOP QMS-030 will be enacted after the commencement of the Operational Qualification phase of this project.

Responsibilities

List of personnel who have been allocated as resources for the validation project and their individual responsibilities.

NB the understanding and acceptance of the personnel listed must be obtained in advance.

	Activity	Position
1.	Validation Plan Prepared by: Authorised by:	Project Co-ordinator Validation Manager Quality Assurance Manager Operations Manager
2.	Training needs assessment	
3.	Modifying current SOP's Writing required SOP's,	
4.	Preparation of Installation Qualification Reports for approval to execute. Prepared by: Checked by: Authorised by:	QA or Validation Manager
5.	Review of completed IQ Report Prepared by: Checked by: Authorised by:	Electrical Mechanical Project Co-ordinator Validation Manager Quality Assurance Manager Operations Manager
6.	Writing Operational Qualification Test Protocols Prepared by: Checked by: Authorised by:	QA or Validation Manager
7.	Conducting OQ tests	
8.	Completed OQ Test Protocols Documented by: Checked by: Approved by:	QA or Validation Manager