

Installation Qualification Pipework

(Reference SOP: _____)

1. OBJECTIVE

To provide documented verification that all key aspects of the selection, application, construction and installation of *(description name of the process, equipment and system)* adheres to appropriate codes, cGMP s and approved design intentions and that the manufacturers recommendations are suitably considered.

2. ACCEPTANCE CRITERIA

A successful completion of the Installation Qualification process are based on the following:

- All activities listed in Installation Qualification have been executed.
- All entries of data have been signed and dated by the person or persons performing the activity or verification.
- All data has been adequately reviewed and reported.
- Any discrepancies that have occurred have been satisfactorily resolved and are correctly signed and dated as resolved.

3. QUALIFICATION PROCEDURES

The protocol consists of tables containing information that needs verification. The Qualification inspection and verification process are largely depended on visual inspection, comparison to As Built drawings and equipment specification as quoted in the protocol.

Any tables or sections not relating to process or equipment should not be deleted and the word N/A should be used, additional tables or sections can be included.

Other documents that support the Qualification process can be referenced or included as attachments.

All people involved in the Qualification inspection and verification process are required to fill out section 5 of this protocol.

Section 1

Section 1 will require completion for all projects involving pipework that requires validation. The information required will be documented by company staff.

4. GENERAL

The installation and treatment procedure of stainless steel tube for product lines, plant water lines and pure Clean Steam lines (termed pipework) should be prepared as an SOP.

Insert version number of current SOP.

5. SIGNATURE LOG

A signature log is to be signed by every person working on verification activities associated with this project. The signature log/s are to be held as attachments.