engineering documents may support these requirements without the need to repeat any work or compromise validation standards.

To support this goal, the Project Manager will need to ensure that:

- All of the documents that are required at the end of the project are prepared, approved and collected throughout the project.
- Document versions and approvals are managed in line with project milestones.
- The relevant departments for review and approval of documentation are identified and included in the project.

2. Procurement Documents

2.1. The documents used for the procurement of equipment should consist:

- User Requirement Specification
- Relevant Standard Demand Specifications, and
- Purchase Agreement.

These documents should form part of the Purchase Order.

2.1.1. The User Requirement Specification covers the specific requirements of the equipment to be procured. It is to be prepared by the procurer.

2.1.2. The Standard Demand Specifications cover the general standards for equipment for manufacturing premises. They are the reference points regarding the principles, requirements and precautions that should be followed to safeguard product quality, EHS objectives, GMP and GEP on site. They are also intended for application to achieve efficient standardisation of equipment, components, hardware and software in the facility.

2.1.3. These Standard Demand Specifications should be reviewed before undertaking any procurement. If they contain any clauses that are pertinent to the equipment procured, they should be included in the demands of the procured item.

2.1.4. For the case of non-conformance with any clause in the Standard Demand Specifications, agreement to the alternatives shall be reached with the Demand Specification Owner before proceeding with the Purchase Order.

2.1.5. The requirements specified in the Demand Specifications should form part of the inspection checklist for the equipment for Factory Acceptance Testing and Site Acceptance Testing. The completed checklists should be attached to the Installation Qualification documentation.

2.2. **User Requirement Specification**

2.2.1. The URS specifies the scope of work and the process requirements for the equipment or system, (i.e. what the equipment or system is supposed to do).

2.2.2. The URS should be checked to ensure it is clear, complete, realistic, definitive and testable. The URS should also be approved by the Engineering Service and, if it has Direct or Indirect GMP impact, a representative from the Quality Assurance department.

2.2.3. Once approved, this document forms part of the Validation documents and is to be archived as per GMP document.

2.2.4. The URS should:

Project Manager, to demonstrate control of the development 'life-cycle'. Electronic copies of final versions should be filed.

3.5. Test documents, generated by the supplier or buyer's project teams, may be used to complement Validation documents and may limit the need for additional Validation testing. Such an approach requires the prior agreement of the Validation Manager and will mean that these test documents must meet the standards for Validation evidence.

4. Design Qualification Documentation

4.1. Design Qualification (DQ) is a process for assuring that the designs of equipment and systems comply with the requirements for use and, most specifically, the code of GMP. The process should commence prior to the construction or manufacture of the item in order to minimise the impact of any omissions, errors or changes. A number of activities may be conducted as part of the Design Qualification, including, but not limited to:

- Verification that design meets relevant URS or standards
- Verification that cGMP requirements are identified and met
- Examination of the material and personnel flow diagram
- Supplier Assessment / Audit
- Design Review (eg against a checklist, or by a team)
- Risk Assessments (eg Product Quality).

4.2. The Project Manager will initially determine the most appropriate review method, based on the system impact, complexity and novelty. The proposed Design Qualification approach should be documented and approved. A Design Qualification Report should record the completion of all the planned activities and the location of any supporting evidence.

5. Installation Qualification Documentation

5.1. To complete Installation Qualification, the Project Manager should ensure that all the relevant Installation Qualification documents have been completed.

The documents should include:

- All Mechanical Demand Specifications.
- Electrical Demand Specification.
- Instrumentation Demand Specification.
- SCADA Demand Specification.
- Control System Demand Specification.
- Technical Documentation Specification.
- EHS requirements in the EHS Verification Report.
- EHS Audit Report.
- Standard Installation Qualification documents relevant to the project should also be completed.
- FAT report, covering the criteria and test results defined in the URS.
- SAT report, covering the criteria and test results defined in the URS.

6. Project Manager's Responsibilities:

