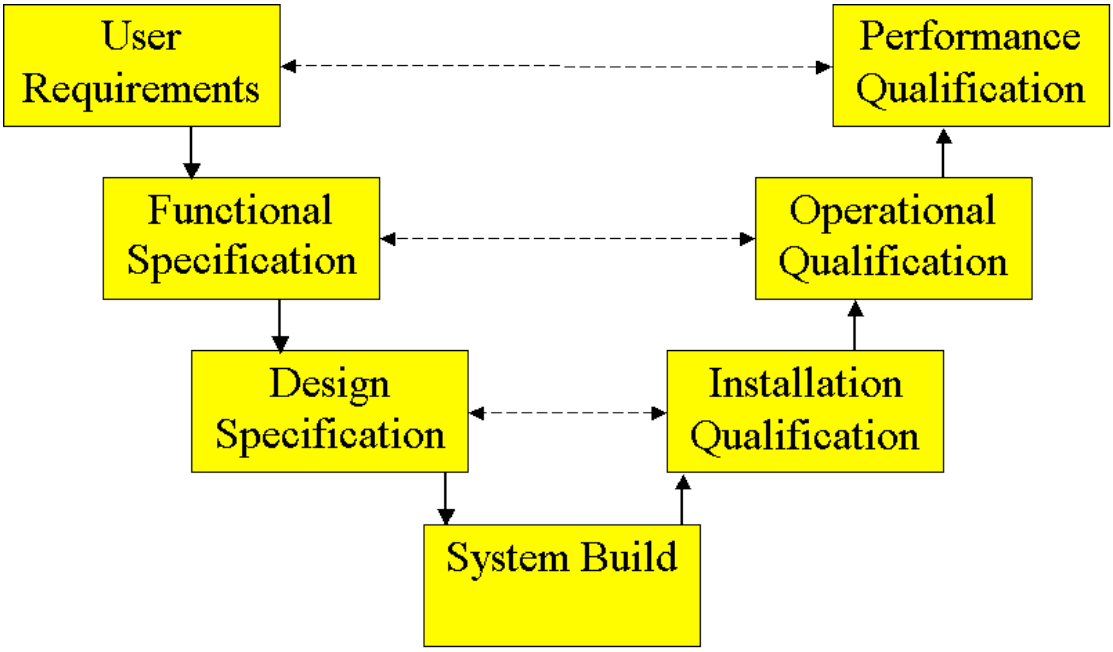

All new utilities classified as critical will require validation. Where utilities are being modified or relocated limited validation might be performed based on a GMP risk assessment.

7.2 Acceptance criteria

7.2.1 DQ –general acceptance criteria

Design Qualification should demonstrate that the design conforms to cGMP requirements and increases the safety to reach the target of a project.

The following must be verified:

- The design ensures the separation of different activities to prevent any cross contamination
- The design corresponds to the user requirements
- Practical aspects of cleaning, maintenance and sampling have been considered
- The design is consistent with the material flow and methods of work by personnel
- The proposed instrumentation is in accordance with the user requirements

DQ will reference all the technical Documents created as part of the project e.g.:

- P&ID's (Pipe & Instrument Diagrams)