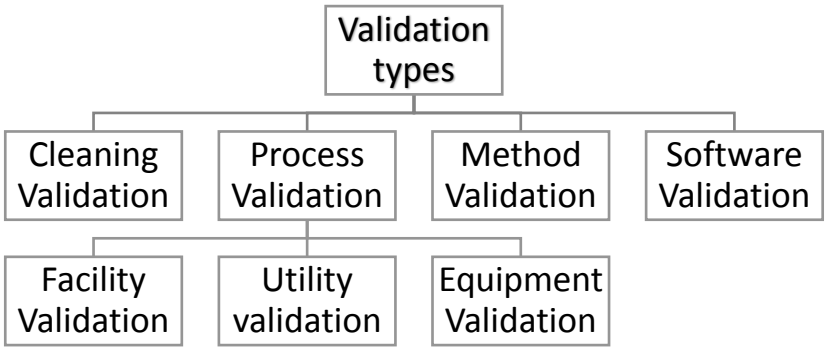
EQUIPMENT VALIDATION IN PHARMACEUTICAL INDUSTRY AS CGMP REQUIREMENT

Quality is imperative for customers whenever they consider a product or service. It is also important as it relates to life-saving products such as pharmaceuticals. In this regard, the Food and Drug Administration introduced good manufacturing practices (GMP) to maintain and improve the quality of pharmaceutical products. cGMP ensures that products are consistently produced and controlled according to the quality standards appropriate to the intended use and as required by the marketing authorization. One of the major cGMP requirements is that all of the critical manufacturing equipment, utilities, and facilities in the pharmaceutical industries must be properly validated before production.

Validations: Validation is a method of quality assurance and an important part of the GMP. Validation is defined by the FDA as "establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specification and quality attributes".

Validation types: Validation activities practiced in the pharmaceutical industry comprise many types as illustrated in Figure bellow[1]:



Equipment validation: According to GMP all equipment must be located, designed, constructed, adapted, and maintained to suit the operations to be carried out. Their layout and design must minimize the risk of errors, allowing effective cleaning and maintenance to avoid cross-contamination, a buildup of dust or dirt, and, in general, any adverse effects on the quality of products.

Equipment validation includes **qualification activities** which It is defined according to EU GMP guideline Part 2 as: "Action of proving and documenting that equipment are properly, installed, work correctly, and lead to the expected results. Qualification is part of validation, but the individual qualification steps alone do not constitute process validation."

According to EU Annex 15: Qualification activities should consider all stages from initial development of the user requirements specification through the end of the use of the equipment, and its consist of:

- **User requirements specification (URS)**

The specification for equipment should be defined in a URS. The URS should be a point of reference throughout the validation life cycle.

- **Design qualification (DQ)**

In is DQ the compliance of the design with GMP should be demonstrated and documented. The requirements of the user requirements specification should be verified during the design qualification.

- **Factory acceptance testing (FAT) /Site acceptance testing (SAT)**

Prior to installation, equipment should be confirmed to comply with the URS/ at the vendor site, if applicable. Where appropriate and justified, documentation review and some tests could be performed at the FAT or other stages without the need to repeat on site if it can be shown that the functionality is not affected by the transport and installation.

FAT may be supplemented by the execution of a SAT following the receipt of equipment at the manufacturing site.

- **Installation qualification (IQ)**

IQ should include, but is not limited to the following:

  - Verification of the correct installation of equipment against the engineering drawings and specifications.
  - Verification of the correct installation against pre-defined criteria.
  - Collection and collation of supplier operating and working instructions and maintenance requirements.
  - Calibration of instrumentation.
  - Verification of the materials of construction.

- **Operational qualification (OQ)**

OQ should include but is not limited to the following:

  - Tests that have been developed from the knowledge of processes, systems and equipment to ensure the system is operating as designed.
  - Tests to confirm upper and lower operating limits conditions.
  - The completion of a successful OQ should allow the finalization of standard operating and cleaning procedures, operator training and preventative

- maintenance requirements.

- **Performance qualification (PQ)**

PQ should include, but is not limited to the following:

- Tests, using production materials, qualified substitutes or simulated product proven to have equivalent behavior under normal operating conditions with worst case batch sizes.
- Tests should cover the operating range of the intended process unless documented evidence from the development phases confirming the operational ranges are available.

According to the previous information, we at AFAQ believe that validation is a critical part of ensuring that cGMP regulations are followed, and the costly consequences of non-compliance are avoided, therefore, we have a special team to prepare the validation protocol document for cGMP compliance and implementation acceptance tests which allow our customers to evaluate practices that support consistent production and quality control.

Our experienced engineers and technicians collaborate with your quality assurance team to successfully complete the testing that validate your production and equipment.

AFAQ provides hard copy and soft copy for all the previous qualifications except the URS and PQ, which are laid on customers duty but, AFAQ could provide significant support to the customers in these two documents.

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