Qualification or Validation Concept

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Qualification or Validation

- Action of proving, in accordance with the principles of good practice quality guidelines and regulations (GxP), that any procedure, process, equipment (including the software or hardware used), material, activity or system actually and consistently leads to the expected results.

1. All qualification and validation activities should be planned and take the life cycle of facilities, equipment, utilities, process and product into consideration.
2. Qualification and validation activities should only be performed by suitably trained personnel who follow approved procedures.
3. Qualification/validation personnel should report as defined in the pharmaceutical quality system although this may not necessarily be to a quality management or a quality assurance function. However, there should be appropriate quality oversight over the whole validation life cycle.
4. The key elements of the site qualification and validation programme should be clearly defined and documented in a validation master plan (VMP) or equivalent document.
5. The VMP or equivalent document should define the qualification/validation system and include or reference information on at least the following:
6. i. Qualification and Validation policy;
7. ii. The organisational structure including roles and responsibilities for qualification and validation activities;
8. 3 iii. Summary of the facilities, equipment, systems, processes on site and the qualification and validation status;
9. iv. Change control and deviation management for qualification and validation;
10. v. Guidance on developing acceptance criteria;
11. vi. References to existing documents;
12. vii. The qualification and validation strategy, including requalification, where applicable.
13. For large and complex projects, planning takes on added importance and separate validation plans may enhance clarity
14. A quality risk management approach should be used for qualification and validation activities. In light of increased knowledge and understanding from any changes during the project phase or during commercial production, the risk assessments should be repeated, as required. The way in which risk assessments are used to support qualification and validation activities should be clearly documented.
15. Appropriate checks should be incorporated into qualification and validation work to ensure the integrity of all data obtained.

Qualification Stage

- Qualification activities should consider all stages from initial development of the user requirements specification through to the end of use of the equipment, facility, utility or system.
- The main stages and some suggested criteria (although this depends on individual project circumstances and may be different) which could be included in each stage are indicated below:
- URS (***User requirements specification)***
- DQ (***Design qualification)***
- *FAT* ***(Factory acceptance testing)***
- *SAT* ***(Site acceptance testing)***
- IQ(***Installation qualification)***
- OQ(***Operational qualification)***
- PQ (***Performance qualification)***

URS (*User requirements specification*)

- **URS** is the set of owner, user and engineering requirements necessary and sufficient to create a feasible design meeting the intended purpose of the system**.**
- The specification for equipment, facilities, utilities or systems should be defined in a URS and/or a functional specification. The essential elements of quality need to be built in at this stage and any GMP risks mitigated to an acceptable level.
- The URS should be a point of reference throughout the validation life cycle.

DQ (*Design qualification*)

- **DQ:-**The documented verification that the proposed design of the facilities, systems and equipment is suitable for the intended purpose.
- The next element in the qualification of equipment, facilities, utilities, or systems is DQ where 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.

FAT (Factory acceptance testing) & SAT (Site acceptance testing)

- Equipment, especially if incorporating novel or complex technology, may be evaluated, if applicable, at the vendor prior to delivery.
- Prior to installation, equipment should be confirmed to comply with the URS/ functional specification 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 at IQ/OQ ,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.

IQ(*Installation qualification*)

- **(IQ).** The documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer's recommendations.
- IQ should be performed on equipment, facilities, utilities, or systems.
- IQ should include, but is not limited to the following:

I. Verification of the correct installation of components, instrumentation, equipment, pipe work and services against the engineering drawings and specifications;
II. Verification of the correct installation against pre-defined criteria;
III. Collection and collation of supplier operating and working instructions and maintenance requirements;
IV. Calibration of instrumentation;
V. Verification of the materials of construction.

OQ(*Operational qualification*)

- **OQ:-**The documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges.
- OQ normally follows IQ but depending on the complexity of the equipment, it may be performed as a combined Installation/Operation Qualification (IOQ).
- OQ should include but is not limited to the following:

A. Tests that have been developed from the knowledge of processes, systems and equipment to ensure the system is operating as designed;

B. Tests to confirm upper and lower operating limits, and /or “worst case” conditions.

- The completion of a successful OQ should allow the finalization of standard operating and cleaning procedures, operator training and preventative maintenance requirements.

PQ (*Performance qualification*)

- PQ:- The documented verification that systems and equipment can perform effectively and reproducibly based on the approved process method and product specification.
- PQ should normally follow the successful completion of IQ and OQ. However, it may in some cases be appropriate to perform it in conjunction with OQ or Process Validation.
- **PQ should include, but is not limited to the following:**

A. Tests, using production materials, qualified substitutes or simulated product proven to have equivalent behavior under normal operating conditions with worst case batch sizes.

B. The frequency of sampling used to confirm process control should be justified;

C. Tests should cover the operating range of the intended process, unless documented evidence from the development phases confirming the operational ranges is available.

To be continue……..

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