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Computer System Validation: A Review

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ABSTRACT

Computer System validation it will be also the equipment those are having their based upon the Control management of Software System. Computer system validation provides recognized proof that the systems will regularly and consistently do what it is deliberate to do, is "fit-for-purpose", and complies with the applicable rules and regulations. The objective of computer systems includes systems used to management of data or support decision making subject to review by regulated authorities whether they are being submitted because its impact on quality or safety on business validation assessment program is a necessity in the pharmaceutical industry to ensure adherence to pharmaceutical current good manufacturing practices guidelines, and to help companies maintain quality of product. Computer system validation to a computer system or an information technology management. It will be essential to maintain quality standards in pharma since non-conformance can have far-reaching consequences. Aims to identify needs of computer system validation of instrument practiced in the perspective of pharmaceutical industry.

KEYWORDS: *Computer System Validation, Good Automated Manufacturing Practices, Validation, cGMP*

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INTRODUCTION

Computer System Validation and provides an overview of CSV methodologies and a road map of the deliverables used in the CSV process on pharmaceutical IT Companies. As computer systems are diverse, depending upon size of management system, novelty, complexibility and business impact, the deliverables may be scaled up or down accordingly. The CSV process discussed in this whitepaper is based on the GAMP 5 framework, as it provides an excellent and rapid approach for CSV which, when followed, they ensure your computerized systems are fit for purpose, will meet the needs of your business, and are compliant with current regulations. The Life Science industry has a strong legacy of Validating Computer Systems thoroughly. However, the traditional 'test everything approach' has become outdated and leaves GMP manufacturing facilities spending more time documenting than testing. Traditional CSV methodologies can see manufacturers spending up to 80% of their time documenting processes, and only 20% of time testing the efficacy of the solutions.

Computer System Validation:

Validations of computer systems that manage processes, organize systems, collect analytical data, and carry out analytical test procedures. Computer system validation includes the qualification of all software & hardware of quality management system, which has impact (Directly/Indirect) on the quality of a product. The purpose of the validation process is to provide a high degree of assurance that a specific process will consistently produce a product (control information or data) which meets predetermined specifications and quality attributes.

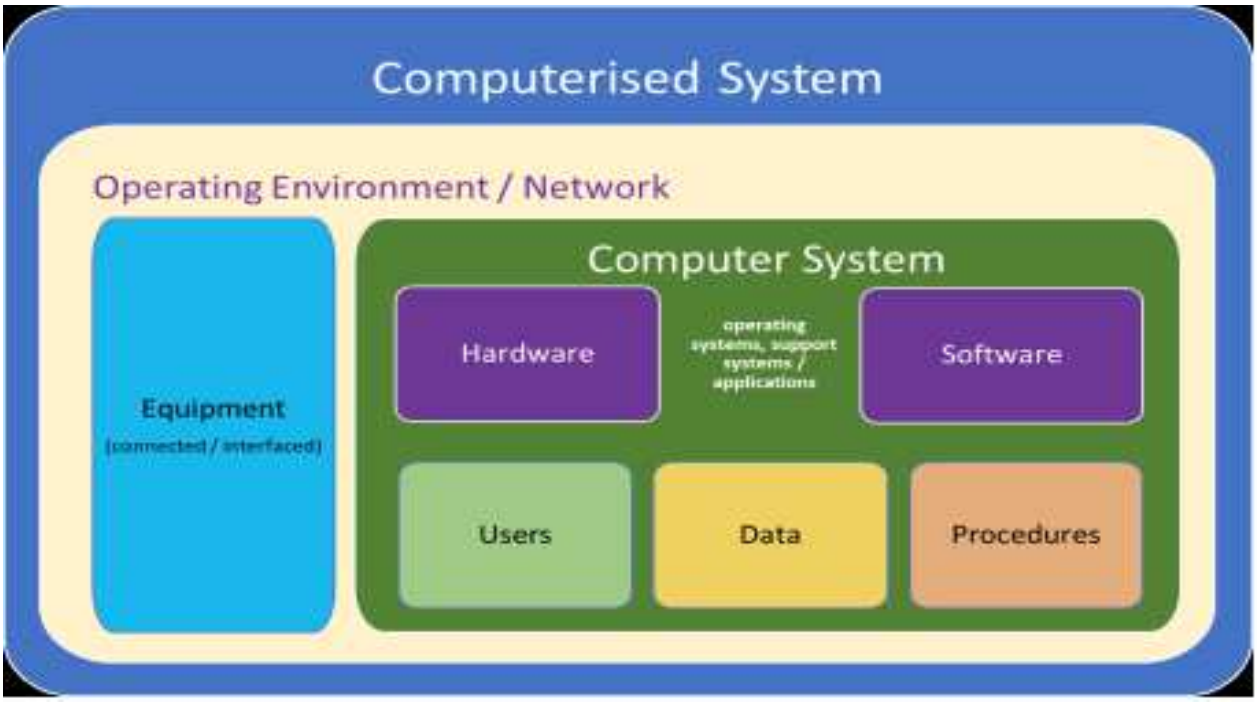

Fig: Life Cycle of Computer System Validation

1. Concept Phase:

In the concept phase also include in the Software and Hardware of management system Categorization to establish the validation approaches and determination of the deliverables:

- Cat 1 – Infrastructure modeling Software
- Cat 2 – Non-Configuration system
- Cat 3 – Configuration System
- Cat 4 – Customization of applied branches
- Hardware Cat 1 – Excellent Hardware objectives
- Hardware Cat 2 – Customization of Build Hardware objectives.

2. Project Phase:

The system supplier must be assessed to determination of their suitability to provide a quality system that me Risk Management. it will be should performed at various key stages of the validation process by multidisciplinary team so that a full understanding of all processes and requirements are covered and considered.

3. Operation Phase:

The CSV Is in coming in operation. It's Maintain the validation status, all aspects of the system and operating environment must be kept in a documented state of control.

4. Retirement Phase:

Retired from operational service so that the process is documented and controlled.

What is Validation?

"Validation is the documented evidence which provides a high degree of assurance that specific process will consistently produce a product meeting its predetermined specifications & quality characteristics". Validation is a very vital part of quality assurance which gives confirmation of the quality in the equipment, manufacturing process, software & testing. Validation assures that products with specific quality characteristics & attributes can be produced constantly within given limits of manufacturing process. Validation is bridge to move the product from development to commercial production.

Types of Validation:

- Process validation
- Equipment validation
- Facilities validation
- HVAC system validation
- Cleaning validation
- Analytical method validation
- Computer system validation

Computer System Validation Process:

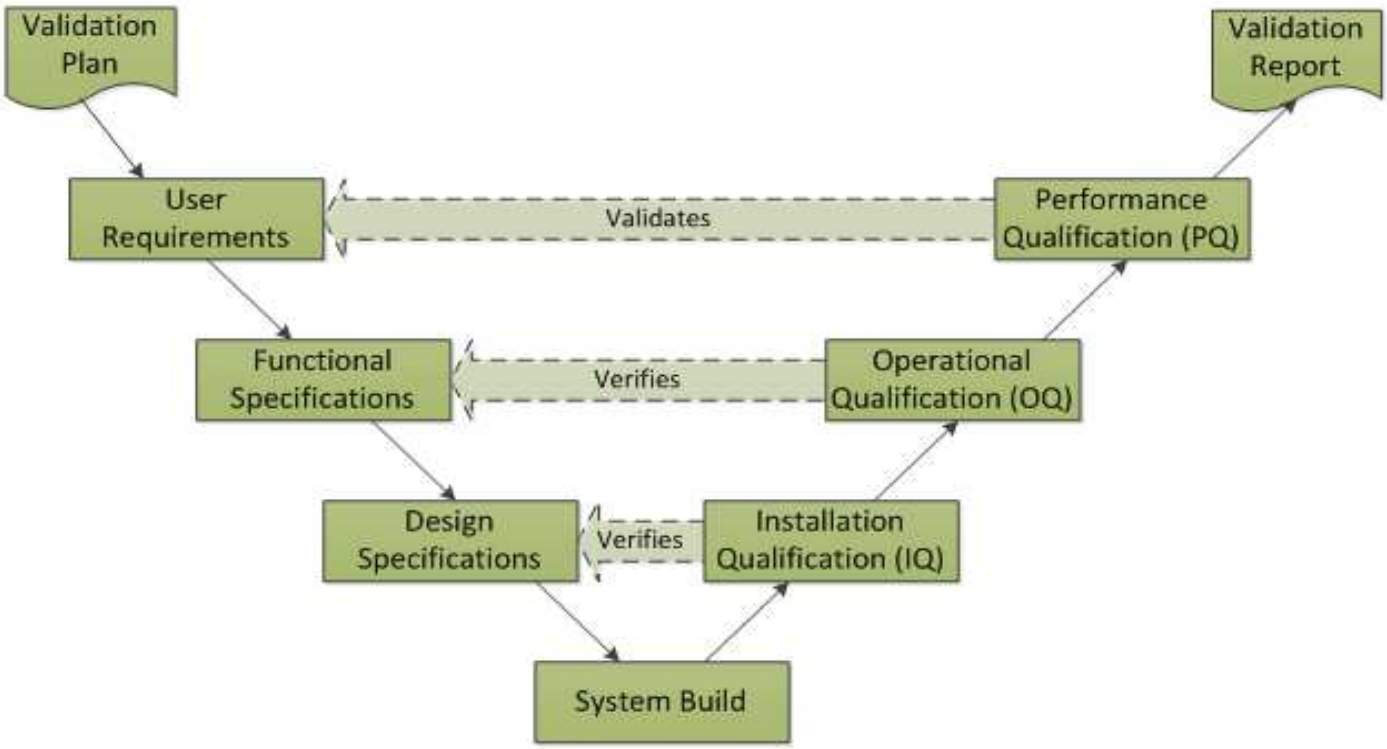

Figure 2: Model of Computer System Validation

1. **Infrastructure Qualification** – documentation showing that the network and infrastructure hardware/software supporting the application system being validated has been installed correctly and is functioning as intended.
2. **Installation Qualification (IQ)** – test cases for checking that system has been installed correctly in user environment.
3. **Operational Qualification (OQ)**–test cases for checking that system does what it is intended to do in user environment.
4. **Performance Qualification (PQ)**–test cases for checking that System does what it is intended to do with trained people following SOPs in the production environment even under worst case conditions

Objective of Computer System Validation:

1. Accuracy
2. Reliability
3. Consistency
4. Regularity
5. The integrity of the e-records

Project Plan:

The project plan outlines what is to be done in order to get a specific system into compliance. For inspectors, it is a first indication of the control a laboratory has over a specific instrument or system and it also gives a first impression of the qualification quality. Documentation and training on the standard operating procedures (SOPs) is carried out.

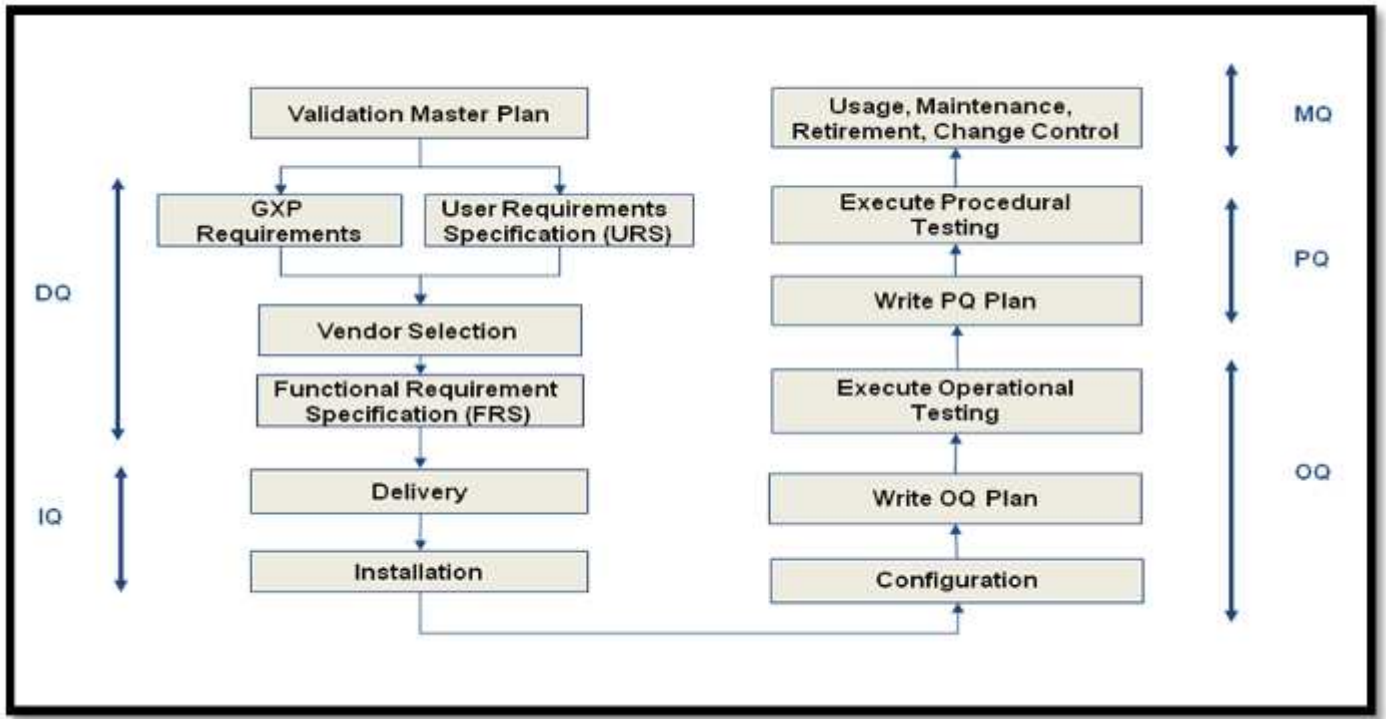

Figure 3: Project Plan

A detailed documentation and training on the standard operating procedures (SOPs) is carried out during this process.

Equipment's and Computer Validation Master Plan Include:

1. Validation Plan
2. Change Control
3. Risk Assessment
4. Design Qualification
5. Installation Qualification
6. Operational Qualification
7. Performance Qualification
8. Traceability Matrix and Report.

Good Manufacturing Practices of Validation:

1. Primary Materials and Products

Primary materials are the raw ingredients used to create a product, which is the end result that is sold to consumers. If the primary materials are not of the utmost quality, flaws can occur in the end result.

2. Premises

Laboratories are the backbone of pharmaceutical manufacturing and must be properly maintained.

3. People

People are the backbone of any business, and that's no different in pharmaceutical manufacturing. Having trained people operating each facility is required in order to remain cGMP compliant.

4. Procedures

A manufacturer's procedures will be scrutinized when audited. All procedures must be regularly revisited to ensure that they are making use of the latest technology and science involved in pharmaceutical manufacturing.

5. Processes

Processes involved in GMP refer to the documentation that is used to prove that procedures are being followed.

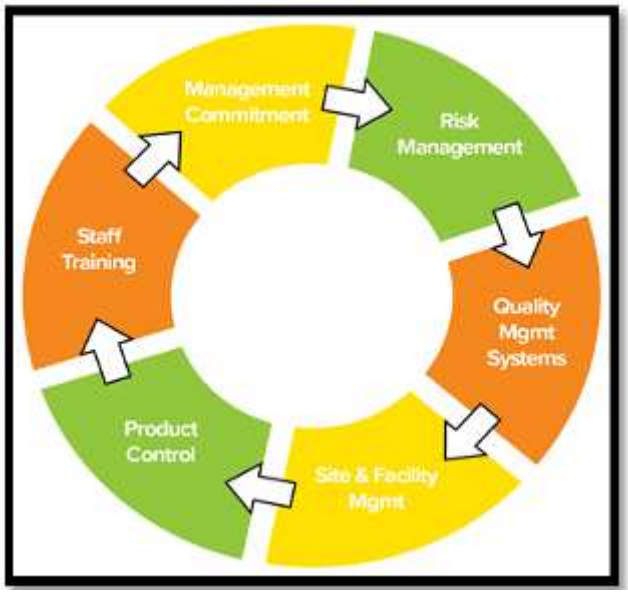

Figure 4: Component of Good Manufacturing Practices Validation

Need of Computer System Validation:

1. It minimizes the risk of preventing problems & thus assures the smooth running of the process.
2. Validated process is more efficient & produces less reworks, rejects & wastage.
3. Validated process may require less in-process controls & end product testing.
4. It minimizes risk of defect cost & risk of regulatory noncompliance.

Cares About Computer System Validation:

- Resources involved in any way with IT, computer or automated systems is affected:
- Developers
- Maintainers
- Users
- Regulatory Authorities
- QA

Future of Computer System Validation:

These regulatory agencies require CSV processes to confirm the accuracy and integrity of data in computerized systems in order to ensure product safety and effectiveness.

1. **Develop Clear and Precise Functional and User Requirements -** One of the biggest mistakes companies make when starting an informatics project is to not do the strategic planning necessary to ensure success.
2. **Perform risk-based CSV -** CSV takes a lot of time and IT resources to accomplish, so it is wise to follow a flexible approach that utilizes a risk-based assessment on the system to determine required test cases and the optimal level of testing for each.
3. **Good Validation Plan -** Like any technical endeavor, CSV processes should be guided by a good plan that is created before the project starts.

CONCLUSION

Computer system validation is an important part of confirming the accuracy and integrity of your data, along with ensuring product safety and effectiveness. Effective, risk-based validation of computerized systems is also an important part of maintaining regulatory compliance. Inefficient or ineffective CSV processes prevents projects from being delivered on time and within budget and may also result in regulatory action that can be legally and financially devastating to an organization. Validation Master Plan defines computerized system validation strategy. System Assessment represents the actual documentation quality status of the system.

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