COMPUTER SYSTEM VALIDATION IN PHARMACEUTICAL INDUSTRY

Swarupa Vijay Jadhav1, Swamini Subhash Waghchaure2, Dr. S. Z. Chemate3.

Dr. Vithalrao Vikhe Patil Foundation’s college of Pharmacy, Ahmednagar

Abstract:
Computer Systems Validation (CSV) is a procedure used to secure (and document) that a computer based systems will produce information or data that meet a synchronize defined requirements. If a system match these requirements, it can be accept that it is consistently presenting in the way it was intended. Quality is an critical for customers whenever they consider a product or service. It is also major as it relates to life-saving products such as pharmaceuticals. In this consider, the Food and Drug Administration introduced good manufacturing practice (GMP) to maintain and better the quality of pharmaceutical products. GMP ensures that products are continually produced and controlled according to the quality standards suitable to the intended use and as required by the marketing approval. One of the major GMP requirements is that all of the critical manufacturing equipment, utilities, and facilities in the pharmaceutical industries must be properly certified and validated ultimely to production. Currently, this practice forms the key of the regulations that are strictly followed by pharmaceutical companies worldwide. A validation judgement is a necessity in the pharma industry to ensure attachment to pharmaceutical cGMP guidelines, and to help companies maintain consistent quality. The same principles are applied in computer system validation to a computer system or an information technology system. It’s important to maintain quality standards in pharma since non-conformance can have far-reaching consequences. Computer system validation checks the effectiveness and the efficiency with which the system is meeting the purpose for which it was designed. This study aims to identify needs of computer system validation of instrument/equipment practiced in the perspective of pharmaceutical industry.

Keywords: Computer system validation, Validation, Qualification, GAMP
Introduction

Computer system validation is the documented process assuring that computer based system will produce information or data that meets a set of predefined requirement. Validating computerized systems that help to improve handling complications and system performance in pharmaceutical companies and medical devices.

The main purpose of computer system validation is that to assure accuracy, consistency, reliability and consistency performance of the system in accordance with predetermined specifications. Computer system validation play important role in pharmaceutical industry to improve product quality, to accelerate performance of process, and support for high quality product. The major benefit of validation is computer system is that supporting the quality controls to ensure that the process is followed correctly, to reduce manual error. European Medicines Agency (EMA) and Food and Drug Administration (FDA) both produced guidelines for csv Practices.

In pharmaceutical industry, computer system validation is an unique process that maximize the effectiveness and enhance quality. Computer system validation save cost as well as time.

There are different industries like pharmaceutical, cosmetics, food and beverage that are regulate by Food Drug Administration (FDA). This industries have responsibility to ensure their products are safe and data are secure. Computer system validation in United States comes from the code of Federal Regulations (CFR), most specifically 21CFR Part 11 dealing with electronic record and signatures.

Software validation is part of computer system validation. Any computerized system include software, hardware and other devices which are important for proper functioning of the system.

Computer system is directly affect the quality of pharmaceutical and medical device product and should be checked to GMP and GAMP principles and standards.

If any defect in system that may cause data integrity. Computer system validation find out time to time error Flaws and mistakes (software bugs).

Need of Computer System Validation in pharmaceutical Companies

The need of computer system validation in pharmaceutical industry should be safe for distribution and sale. Computer system validation is one of those observance requirements and it is also part of quality management system in pharmaceutical manufacturing.

Computer system validation deliver accuracy, security, reliability and consistency to pharmaceutical industry.
COMMON COMPUTER SYSTEM VALIDATION PROBLEMS

Computer System Validation (CSV) in the life sciences was focused on software validation and infrastructure and computing platform qualification for systems that supported FDA-regulated activities and records. Today, organizations are increasingly focusing on overall, global IT compliance, to satisfy 21 CFR Part 11 but also equivalent laws in other countries, Sarbanes-Oxley (SOx), HIPAA, export and shipping regulations, and much more. To meet these varied and global needs, pharmaceutical manufacturers must:

**Challenge I. Standards:** Various standards exist across the organization. Policies, plan of action, work instructions, and layout vary by business, department, or site. Remarkable costs result from overlying SOPs and incompatible standards, which make sharing of assets difficult. Industry-wide standard methodologies, guidelines, and tools have been issued by global organizations, such as ISPE and ICH, but in order to make the assets applicable to a wide range of companies, processes, systems, and products, they did not replace the more detailed, localized standards.

**Challenge II. Interpretation:** A significant cost to validation projects is caused by long debates among the various authors and reviewers, rework, and inconsistent interpretation of standards and requirements. Most regulations include very high-level statements that set objectives, but don’t specify how to implement the controls or how much is good enough. For example, 21 CFR Part 11 (11.10 (d)) requires “Limiting system access to authorized individuals.” This one statement can be expanded to varied requirements for technical security controls and procedural controls for managing access.

**Challenge III. Organization and Governance:** Many companies still have decentralized governance and uncontrolled execution. The ownership and management of validation activities vary from project to project and from one department to another. Projects are not handled consistently with clear roles and responsibilities. Some are led by IT, other by users or quality.

**Challenge IV. Efficiency Across Sites and Departments:** Site-to-site efficiencies have not been achieved due to site- and department-specific procedures, templates, and interpretation. We’ve seen many cases where multiple sites develop complete validation packages for the same system that they use the same way, because there is no sharing of inventory and project information.

**Challenge V. Execution:** As stated earlier, we see excessive rework being done by validation teams. Most often, the rework is a result of different opinions and styles of project team members and inconsistent quality of work that is done by unqualified individuals. A common scenario is that individuals perform work that doesn’t align with their level and skills. Junior quality reviewers, who are qualified to review documents and identify incomplete or inaccurate information and deviations from standards, end up determining the course of action to remediate the problems. The solution is often redoing the work. On the other hand, we see highly-
qualified, expensive resources performing low-level mechanical tasks, because a fixed team is assigned to the project and must share the workload.

**Challenge VI. Tools:** System life cycle assets, such as templates, outlines, forms, and guidance documents are often inconsistent across departments and are not targeted to drive value. They are put in place to minimize the risk of project team members taking shortcuts and skipping sections, but are not flexible and drive unnecessary efforts with minimal value to quality or compliance. We’ve seen cases where an extensive validation package was prepared for a new CD writer, or complete detailed Installation Qualification protocol, scripts, and report were produced for the installation of utilities such as WinZip and virus scan.

**Challenge VII. Training:** Training is usually conducted within each business on standards and processes; however, there is minimal coaching and guidance. The short training that is usually provided is rarely enough to qualify individuals without coaching and support until they gain hands-on experience. Often multiple training sessions have to be taken in a very short period of time, where the individual’s ability to absorb, understand and retain the materials is in question.

**Challenge VIII. Personnel:** Working with many life science companies shows that usually there are capable, knowledgeable central validation groups, but weaker decentralized execution groups. CSV standards are often deployed without the appropriate training and coaching and without assurance of consistent interpretation. Organizations believe that simply reading standard operating procedures (SOPs) and receiving a few hours of training enable individuals to follow a consistent approach
Process of computer system validation

There are five steps involved in computer system validation:

1. Validation Master plan
2. Project plan
3. Installation Qualification (IQ)
4. Operational Qualification (OQ)
5. Performance Qualification (PQ)
1. **Validation master plan:** Master plan is the process of preparing blueprint for entire Computer system validation. This process is the main process of validation hence it covers complete setup such as hardware, software and also validate processes such as reduction of risk.

2. **Project plan:** For evaluation of validation program each step require Standard Operating Procedure (SOP) and also require validation master plan.

3. **Installation qualification:** This stage delves deeper into installation process and creates checks and balance for any new component that may have been purchased or any new hardware or software that may have been installed

4. **Operational qualification:** Operational qualification check the security process like software security, physical security) and OQ also check the accuracy of operational function.

5. **Performance Qualification:** Performance qualification test specific applications and enterprising engage in maintenance and conduct performance test.

All the processes give to effectively meeting pharmaceutical cGMP and all these technical processes are help to require product quality standard.

**Aspects of healthcare**

- Services
- Equipment
- Computer system
- Processes

**FDA compliance software**

Every computer based control system being used in medical devices should comply to following requirements

- Information security
- Information backup
- Information restore
- Information recovery capabilities in cases as “disaster”
- Periodic Maintenance

**Basic requirement of CSV**

- To develop validation plan.
- Usage of standard operating procedure.
- Documented training on SOPs.
- Development of detailed specification.
- Development of test plan
Validation HPLC-

Validation is a demanding tool to assure the quality of computer system performance. Computer system software system validation increases the accuracy of system, and causes less risk to process and data integrity. Major benefits of computer system validation are decrease long term system and cost of project by minimizing the cost of maintenance and rework.

Validation of HPLC system is most demanding and important because all regulatory authorities focusing on this instrument and data integrity problems are found during FDA inspections; therefore, validation of HPLC is an important example in computer system validation.

This system updates all requirements which are used in HPLC like injection volume, flow rate, column temperature, wavelength etc.

Benefits of Computer system validation

1. Legal observance with FDA
2. Reduces risk associated with pharmaceutical industries
3. Find out fault before a system build goes live.
4. Continuous improvement of pharma industries
5. Reduces operating as well as labour cost.
6. To maintain consistency in final product.

Conclusion of computer system validation

The main conclusion of computer system validation is it maintain consistency and accuracy in final product. It also prevent from data integrity due to the fault in computer system. It finds out time to time error in software that’s why it prevent data integrity issues which are happens during FDA inspection.

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