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Computer Software Validation in Pharmaceuticals

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ABSTRACT

When consumers are considering a product or service, quality is crucial. It is also significant in terms of life-saving goods like medications. To preserve and improve the quality of pharmaceutical products, the Food and Drug Administration implemented good manufacturing practices (GMP). GMP guarantees that goods are consistently manufactured and managed in accordance with quality standards appropriate for their intended use and as mandated by marketing approval. All of the vital facilities, utilities, and manufacturing equipment in the pharmaceutical sectors must be appropriately certified and validated prior to production, which is one of the main GMP criteria. Currently, this approach constitutes the key of the laws that are closely observed by pharmaceutical businesses worldwide. A validation judgement is a necessary in the pharma sector to verify attachment to pharmaceutical cGMP guidelines, and to help companies maintain consistent quality. When validating a computer system or an information technology system, the same principles are used. It's crucial to maintain quality standards in pharma since non-conformance might have far-reaching effects.

Keywords: Pharmaceutical Validation, Good Manufacturing Practices, Pharmaceutical cGMP Guidelines.

INTRODUCTION:

Validation is "establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes." (FDA 1987) [1] A properly designed system will provide a high degree of assurance that every step, process, and change has been properly evaluated before its implementation. Testing a sample of a final product is not considered sufficient evidence that every product within a batch meets the required specification. Regulations and laws affect how pharmaceutical products are manufactured, ordered and received, handled in warehouses, distributed, processed and tested in laboratories, and also affect a multitude of other manufacturing, quality assurance, marketing and research and development activities. In essence, regulations control many aspects of how a pharmaceutical business is run. It is essential that all Computer systems involved in these and other processes are validated, and are supported and controlled by procedures and documentation that keep them in compliance.[2] It is the technical discipline that life science companies use to ensure that each information technology application fulfils its intended purpose. Stringent quality requirements in FDA regulated industries impose the need for specific controls and procedures throughout the Software Development Life Cycle (SDLC). Evidence that these controls and procedures have been followed and that they have resulted in quality software (software that satisfies its requirements) must be documented correctly and completely. These documents must be capable of standing up to close scrutiny by trained inspectors since the financial penalty for failing an audit can be extremely high. More importantly, a problem in a life science software application that affects the production environment could result in serious adverse consequences, including possible loss of life.[2] The activities involved in applying the appropriate controls/procedures throughout the SDLC and for creating the necessary trail of documented evidence are all part of the technical discipline of computer system validation. As we will discuss in this article, software testing is a key component in this discipline. However, computer system validation, involves more than what many it people consider to be software testing. [3,4] The concept of validation was first proposed by Ted Byers and Bud Loftus in the mid-1970s to improve the quality of

pharmaceutical products [5]. Currently, in the pharmaceutical manufacturing industry, validation plays a vital role in producing high-quality pharmaceutical products that meet good manufacturing practice (GMP) guidelines. Validation is an important requirement imposed by authorities worldwide to regulate the production of pharmaceutical and medical devices. An equipment, utility, or facility that is not validated may produce inferior outputs [6].Thus, the Food and Drug Administration (FDA) requires validation, which is defined as the process of collecting and evaluating data to draw scientific evidence that an equipment, utility, or facility is capable of consistently delivering quality products. On the one hand, validation involves confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled [7].The concept of validation was developed in the 1970s and is widely credited to Ted Byers who was then Associate Director of Compliance at the U.S. FDA. The concept was focused on: ―Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.[8]

IMPORTANCE OF COMPUTER SYSTEM VALIDATION

The FDA states that process validation is "establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes" [9]. It is the process by which all aspects of a process (including buildings, equipment, and computer systems) are shown to meet all quality requirements, and comply with applicable rules and regulations regarding product quality, safety and traceability. For a process supported by a computer system, we can say that computer system validation provides documented proof that the system (e.g. Hardware, software, peripherals and network) will repeatedly and reliably do what it is designed to do, is "fit-for-purpose", and complies with the applicable rules and regulations. Computer software validation must show that the system operates predictably according to its specifications, and that conclusion is supported by formal, documentary evidence because regulators will not take your word for it. The ultimate goal of any computer system validation project is to realize and sustain compliance, while ensuring the peak performance and functionality of those systems. Computer software validation what to validate, when and is a sound business practice that supports quality assurance, and promotes responsible and profitable operations. Computer software to validate, when and provides the evidence that a computer system does what it is intended to do according to the system specifications and operating procedures.

A key source document providing FDA guidance on the general topic of validation is "general principles of validation, food and drug administration" from the centre for drug evaluation and research. [10] Validation, as described in this document, is aimed at manufacturers of pharmaceuticals and medical devices who must demonstrate that their processes produce consistent product quality. It applies to all processes that fall under FDA regulation, including, but not limited to, computer systems. For example, validation applies to pharmaceutical manufacturing processes which include checking, cleaning, and documenting that all equipment used in manufacturing operates according to predetermined specifications. Computer system validation (or computerized system validation as it sometimes called in the literature) is the result of applying the above definition to a computer system: "Establishing documented evidence which provides a high degree of assurance that a computer system will consistently produce results that meet its predetermined specification and quality attributes." [11] Note that a "computer system" in the life sciences sector is more than computer hardware and software. It also includes the equipment and instruments linked to the system as well as the trained staff that operate the system and/or equipment using Standard Operating Procedures (SOPs) and manuals. As applied to computer systems, the FDA definition of validation is an umbrella term that is broader than the way the term validation is commonly used in the industry. In the industry, validation usually refers to performing tests of software against its requirements. A related term in the it world is verification, which usually refers to inspections, walkthroughs, and other reviews and activities aimed at ensuring that the results of successive steps in the software development cycle correctly embrace the intentions of the previous step [12,13]. As we will see below, FDA validation of computer systems includes all of these activities with a key focus on producing documented evidence that will be readily available for inspection by the FDA. So testing in the sense of executing the software is only one of multiple techniques used in computer system validation.[14]

There are two key reasons why computer system validation is extremely important in Pharma-sector:

1. Systematic computer system validation helps prevent software problems from reaching production environments.
2. FDA regulations mandate the need to perform computer system validation and these regulations have the impact of law. Failing an FDA audit can result in FDA inspectional observations ("483s") and warning letters.
3. A key point to be gleaned from 1 and 2 above is that not only do FDA regulated companies need to do computer system validation, but they need to do it right. Cutting corners on doing a validation might save a little money in the short term but these savings will look minute and inconsequential when compared to the potential costs and impacts of not doing the validation correctly.[15]

ANALYTICAL INSTRUMENT QUALIFICATION & IMPORTANT OF CALIBRATION

Before you conduct validation, you must complete the process of qualification. It is a systematic process that starts by the project phases of the installations, equipment and utilities. Analytical Instrumentation Qualification, also known as AIQ,

is the documented process where a complex and sophisticated measurement device is demonstrated to be accurate, precise and selective enough for the intended analytical measurement. This is carried out to determine the sustainability and qualification of any instrument for the intended purpose. Qualification is not limited to a validation process, but it is a part of it. It can be further divided into installation qualification (IQ), operation qualification (OQ) or performance qualification (PQ). Based on the operation and function of equipment, system or utility, you must make installation qualification and operation necessary. They should be monitored and calibrated periodically and they must be submitted to preventive maintenance. If you want to fulfil the GMP requirements for quality assurance of products, you must consider several factors such as infrastructure, equipment's and raw materials. Make sure that the whole production process is controlled until the final product is released. Since all the three processes, validation, calibration and qualification, are extremely critical in pharmaceutical processes, you must ensure that you have the right outsourcing partner to conduct them. When you have the correct partner by your side, you get vital assistance in maintaining GMP standards, while keeping the costs down. Look for important traits while choosing a partner, such as their quality management system, their ability meet all your requirements while containing the costs, response to fluctuating workloads, etc. Make sure you tie up with the partner who is right for your company, and there will be one less thing that you have to worry about. To make sure that validation of processes is legitimate, you have to do calibration. It is a process which demonstrates that an instrument is producing results within the specified limits as compared to those produced by a traceable standard over an appropriate range of measurements. Using uncalibrated instruments can lead to safety risks, which is an absolute no-no for any pharmaceutical company. Further, equipment of poor quality will cost you a lot of money too, putting a financial burden on your company. Calibrate your equipment periodically to ensure that the measurements and outputs achieved are accurate at all times without affecting the quality of the final product. [16-18]

NEED OF VALIDATION, QUALIFICATION AND IT SYSTEM VALIDATION

Computers and automated equipment are used extensively throughout all aspects of research and development, laboratory testing and analysis, product inspection and acceptance, production and process control, environmental controls, packaging, labeling, traceability, document control, complaint management, and many other aspects of a pharmaceutical company's operations. Increasingly, automated plant floor operations can involve extensive use of embedded systems such as programmable logic and digital function controllers, statistical process control, SCADA, and robotics. In addition, software tools are frequently used to design, build, and test the software of computer systems. Other commercial software applications, such as word processors, spreadsheets, databases, and flowcharting software may be used to implement systems. All computerized equipment, systems, applications, tools and embedded systems that affect, monitor, or control product safety, quality, efficacy, or purity are subject to one or more of good manufacturing, laboratory, or clinical practice (GxP) and other applicable regulations and hence computer software validation.[19]

Pharmaceutical facilities consist of various processes, each of which must be accurate to ensure that the end product is of high quality. While validation is concerned mainly with processes, it is referred to as a qualification when the same approach is applied to a machine or equipment instead of a process [20]. Validation is a systematic approach where it is confirmed that any process in a pharmaceutical facility will operate within the specified parameters whenever required. This is achieved by collecting and analyzing data. Validation is done to assure that the processes will produce consistent and repeatable results within the predetermined specifications. Validation is needed as it verifies whether the quality standards and compliance are being met by the product in real time, which is really important in every pharmaceutical facility. Further, it also establishes that the facility is meeting current good manufacturing practice (cGMP) guidelines that are set for the industry by concerned regulatory bodies. Validation can be considered as documented evidence of the process meeting the predetermined specifications. No pharmaceutical plant is complete without an IT system, which is responsible for controlling, supporting and documenting various processes. It is extremely important to validate the computer and IT systems as it makes sure that all the concerned IT applications are fulfilling their intended purposes. Validation helps in controlling different phases of development, design, testing and routine of the software that is being used by the IT system during its life cycle. As long as the computer system is running accurately, you can be assured that all the information and reports that they store remain safe. You must implement stringent quality requirements in GMP-regulated industries to control the procedures throughout the Software Development Life Cycle (SDLC). Focus the validation efforts on crucial aspects such as risk analysis and in-depth validation approach. Make sure that you apply the documentation to the computerized system as it manages crucial data that has an impact on the quality of the products. The components of computer system validation include all the activities that are involved in applying the appropriate controls throughout the SDLC and for procedures that are necessary for creating the documentation [21-23].

VALIDATION CONDUCTED IN PHARMACEUTICLES INDUSTRY

A. Process Validation

In the manufacturing process, the used methods and systems which may have an impact on the quality of the products should be defined and validated. Process validation is a function of quality assurance that helps to receive a high degree of assurance, that a specific process will consistently deliver a product, which meets its predetermined specifications and quality characteristics through documented evidence. Production process validation assures that process performance is

constantly monitored and evaluated. To maintain the validated status of a process inadequate state, steps must be taken to recognize and address if any significant process changes made. Such measures can apply to equipment, standard operating procedures, manufacturing instructions, environmental conditions or any other aspect of the processing system.

Types of Process Validation: Different types of pharmaceutical process validation include:

a) Prospective Validation

This type of validation usually performed during the product development stage on a minimum of three consecutive production-size batches. Before the process is put into commercial use, the validation protocol is executed. In the product development stage, the production process is divided into individual steps. Each & every step is evaluated on the basis of actual or theoretical considerations to determine the critical parameters that may affect the quality of the finished product. A series of trials are designed to discover the criticality of these factors. Each trial is planned and documented fully in an authorized protocol. All equipment, production facilities and the analytical testing methods used should be fully validated. To sell or supply validation batches, the conditions under which they are produced should comply fully with the requirements of Good Manufacturing Practice, along with the satisfactory outcome of the validation exercise and the marketing authorization.

b) Concurrent Validation:

In this type of validation process, the company will sell the product during the qualification runs, to the public at its market price, similar to prospective & retrospective validation. This validation constitutes in-process monitoring of critical processing steps and product testing. This helps to generate and documented evidence to show that the manufacturing process is in a control state. In unusual situations, it may be allowable not to complete a validation programme before routine commercial batches start. Reasons to carry out concurrent validation must be explained in brief, documented and approved by authorized personnel. The need for documentation for concurrent validation is the same as specified for prospective validation.

c) Retrospective Validation:

This validation generally dedicated to a product that is already in distribution. Process validation is based upon the already established production, testing and control data. It also proves that the process always remained in a control state & does what it is assigned to do. Retrospective validation is mainly allowable for well-established processes and will be inadequate if any recent changes in the composition of the product or operating procedures or equipment have done. Validation of such processes is usually based on past historical data.

d) Revalidation:

Revalidation usually performed in the system when some changes introduced in the process environment or facility or equipment or in an existing product or due to incorporating a new product. It ensures that these changes do not unfavourably affect the process characteristics and product quality. Documentation requirements for this type of validation shall be the same as for the initial validation of the process. Periodically evaluation conducted to assure that manufacturing facility, systems, equipment and processes, including cleaning, remain in an invalid state.

Following some of the changes that require validation are as follows:

- Changes in raw materials
- Changes in the supplier of active raw material.
- Changes in packaging material or its supplier (primary /secondary)
- Changes in the process or methods (e.g., mixing time, drying temperatures and batch size)
- Changes in the equipment (e.g., the addition of an automatic detection system).
- Changes in the plant site/facility. A decision not to perform the revalidation studies must be fully justified and documented.

B) Validation of Analytical methods

Validation of analytics is related to methods used for in-process, stability testing, and final control. For pharmaceutical product or for the specific ingredient of the product the analytical monitoring, is necessary to ensure that its safety and efficacy is maintained throughout all phases of its shelf life, including storage, distribution, and use. Monitoring should be carried out according to the specifications mentioned and validated during product development. The primary purpose of analytical validation is to ensure that the adopted analytical procedure will give consistent, reproducible and reliable results adequate with the intended purpose.

C) Cleaning Validation

Validation of cleaning processes ensures that specified facility, production sites, equipment, quality control premises etc. are cleaned as per specified standards. This validation for production equipment should demonstrate that contamination from the previous product; detergent or microbial sources have been reduced to a pre-determined level. A documentation system, which clearly identifies the previous batch and shows that the equipment was properly cleaned, must be established.

D) Computer System Validation

In this validation, a system that includes the input data, electronic processing, and the output information to be used for automatic control or for reporting are validated. Suitable installation qualification and operational qualification has illustrated the suitability of computer hardware and software to perform the specified task. The functions where computerized systems are used to control a GMP-related processor to store and retrieve data that have GMP implications, they are validated. Computerized system validation ensures adequate control to prevent unauthorized access or changes to data. In case computerized systems breakdown or failure may result in a permanent loss of critical record, then a backup system and a recovery plan are provided. If changes to computerized systems are required then it supposed made according to the "change control" system, & have to be formally authorized, documented, tested and subjected to the re-validation process.

Departments Responsible for Validation:

The primary departments those are responsible for validation are: A Validation team is mainly responsible for conducting and supervising validation studies. Trained & experienced personnel in a relevant discipline may conduct such studies. Following are some responsibilities of the validation team are:

- Creates updates and reviews/approves validation master plan, individual project validation plans and validation deliverables.
- Make sure validation compliance with the company validation master plan and project validation plan.
- Harmonize, apply & verify elements of VMP.
- Consults evaluates and approves changes in validation scope within the system. Reviews and approves IQ/OQ/PQ process validation procedures and plans.
- Reviews test results and give comments related to release.
- Assess risks and develops contingency plan.[24]

PRINCIPLES OF SOFTWARE VALIDATION

This section lists the general principles that should be considered for the validation of software.

Requirements: A documented software requirements specification provides a baseline for both validation and verification. The software validation process cannot be completed without an established software requirements specification.

Defect Prevention: Software quality assurance needs to focus on preventing the introduction of defects into the software development process and not on trying to "test quality into" the software code after it is written.

Time and Effort: To build a case that the software is validated requires time and effort. Preparation for software validation should begin early, i.e., during design and development planning and design input. The final conclusion that the software is validated should be based on evidence collected from planned efforts conducted throughout the software lifecycle.

Software Life Cycle: Software validation takes place within the environment of an established software life cycle. The software life cycle contains software engineering tasks and documentation necessary to support the software validation effort. In addition, the software life cycle contains specific verification and validation tasks that are appropriate for the intended use of the software. This guidance does not recommend any particular life cycle models – only that they should be selected and used for a software development project.

Plans: The software validation process is defined and controlled through the use of a plan. The software validation plan defines "what" is to be accomplished through the software validation effort. Software validation plans are a significant quality system tool. Software validation plans specify areas such as scope, approach, resources, schedules and the types and extent of activities, tasks, and work items.

Procedures: The software validation process is executed through the use of procedures. These procedures establish "how" to conduct the software validation effort. The procedures should identify the specific actions or sequence of actions that must be taken to complete individual validation activities, tasks, and work items.

Software Validation after a Change: Due to the complexity of software, a seemingly small local change may have a significant global system impact. When any change (even a small change) is made to the software, the validation status of the software needs to be re-established. Design controls and appropriate regression testing provide the confidence that the software is validated after a software change.

Validation Coverage: Validation coverage should be based on the software's complexity and safety risk – not on firm size or resource constraints. Validation documentation should be sufficient to demonstrate that all software validation plans and procedures have been completed successfully.

Independence of Review: Validation activities should be conducted using the basic quality assurance precept of "independence of review." Self-validation is extremely difficult. When possible, an independent evaluation is always better, especially for higher risk applications.

Flexibility and Responsibility: Specific implementation of these software validation principles may be quite different from one application to another. Software is designed, developed, validated, and regulated in a wide spectrum of environments, and for a wide variety of devices with varying levels of risk. [25,26]

CONCLUSION

Systematic computer system validation helps to prevent software problems from production environment. A problem in a pharmaceutical software application which affect the production environment can result in serious adverse consequence and also affect the product quality and business firm like lawsuits, financial penalties which ultimately results the company suffering from economic instabilities, staff downsizing and possibly eventual bankruptcy. FDA regulation mandate the need to perform computer software validation and these regulations has the impact of law. Failing in FDA audit can result in FDA inspectional observation and warning letters. And failure to take corrective action in a particular timing can results in shutting down manufacturing facilities, consent decrees, and stiff financial penalties. So computer software validation is very important for pharmaceutical companies and laboratories. A computer system must be validated at the time of installation, before and during any project is running, any change in the software or computer system. A validation must be done by a qualified person who has completely information regarding the system and project to be done. Good computer system validations have many advantages like improve quality assurance, reduce other validation cost and time, improve GMP compliance and 21 CFR part 11 regulation which impact on product quality, safety, identity or efficacy that subject to GxP rules. Pharmaceutical manufacturers can definitely improve their validation projects by performing several measures to minimize or eliminate the deficiencies in the computer system validation problems discussed above. Collaboration, prioritization, planning, oversight, and clarity of purpose can also substantially promote the success of validation projects. Research study on the existing validation frameworks should be carried out to identify possible positive elements which may help to eliminate most of the pitfalls discussed in this paper. These elements can be incorporated in a framework which fulfills the basic framework design requirements. It must be simple, systematic, can easily be understood by the future implementers and flexible enough to adapt itself to different contexts. This framework must be validated by applying it in case studies which must be carried out in pharmaceutical companies to confirm its flexibility, robustness and validity.

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