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Computer System Validation in the Perspective of the Medical Field

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ABSTRACT

It is the process by which to validate the computer system and software in the pharmaceutical field. Which meet all quality requirements and comply with applicable rules and regulations regarding product quality, safety, and traceability, which is used for improving quality and also GMP compliance. It helps to reduce validation costs and time. 21 CFR part 11 regulation impact on production quality, safety, identity, or efficacy.

It is likely that the future will see the convergence of computer system validation terminology and techniques as a common technical discipline across other industry sectors as well.

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INTRODUCTION:

According to FDA, validation is the process of establishing the "high degree of assurance" that a specific process will consistently produce a product that meets its predetermined specification and quality attributes[1]. Computer software validation must show that the software operates predictably according to its specification. It promotes responsible and profitable operations. It is the process by which all aspects of the process are shown to meet all quality requirements[2].

Computer system validation provides documented proof that the system such as Hardware, Software, peripherals, and network will repeatedly and reliably do what it is designed to do, is "fit-for-purpose", and complies with applicable rules and regulation SOP must comply with the Computer Systems Validation Policy and any Business Unit policies that may be approved by the appropriate management for that site or departments[3].

It is the technical discipline that life science companies use to ensure that each information fulfills 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) [4]. The activities which are 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.

Legal requirements:

Computerized systems used in the manufacture of API's should be properly developed, validated, and maintained to assure data and product integrity[5]. The newly developed guidelines for the manufacture of APIs (ICH Q7a) cover these requirements. It should be noted that according to the current understanding, 21CFR part 11is not legally binding for API manufacturers; however, it is advisable to consider the principles and recommendations contained in this document prior to validating computerized systems as required by ICH Q7a[6].

Regulatory Requirements for Software Validation:

The FDA's analysis of 3140 medical device recalls conducted between 1992 and 1998 reveals that 242 of them (7.7%) are attributable to software failures of that software-related recalls, 192 (or 79%) because of software defects that were introduced when changes were

made to the software after its initial production and distribution[7]. Software validation and other related good software engineering practices discussed in this guidance are principal means of avoiding such defects and resultant recalls. Software validation is a requirement of the quality system regulation, which was published in the Federal Register on October 7, 1996, and took effect on June 1, 1997[8]. Validation requirements are important for the software which is used in medical devices, such software is medical devices themselves, and this software is used for production, implementation of devices, and quality systems.

Need of 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, and robotics[9].

Fit for purpose:

The meaning is the activities defined in the validation plan have been completed and the necessary actions to maintain the system in its validated state are taken, the system is validated. This is predicated on the validation plan being "fit for purpose"[10]. Completion of the activities defined in the validation plan will often require that: the purpose of the validation plan has been completed and the action which is necessary to maintain the system in its validated state system is validated. This is predicated on the validation plan being "fit for purpose"[10]. Completion of the activities of

- Validation plan/quality plan has been followed without major non-compliances;
- The system specifications provide for all Gape requirements to be met through
- Automated processes and sops - Gape requirements may be implicit;
- The system is shown to comply with 21 CFR part 11 (e-records and e-signatures);
- The system is shown to perform consistently and correctly as specified;

- Data at start-up is validated;
- All documents have been written reviewed and approved by demonstrably.

Principles of computer software system:

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

Requirements:

The requirements of the computer software system specifications provide both validation and verification. Without an established software requirement, specification the software process cannot be completed.

Defect Prevention:

Defect prevention in the software development process is an important parameter in quality assurance and not on trying to "test quality into" the software code after it is written[11].

Time and Efforts:

For the validation of software time and effort are required. The process of software validation begins during design and development planning and design input. At the last, the result shows that the software is validated should be based on evidence collected from planned efforts conducted throughout the software lifecycle.

Software Life Cycle:

The establishment of the software life cycle takes place by using software validation. software engineering tasks and documentation which contain software life cycle which is important to support the software validation effort. Specific verification and validation task are the important parameters of the software life cycle which are appropriated for the intended use of the software[12].

Plans: The software validation plan defines "what" is to be accomplished through the software validation effort. Quality system tool is the most important parameter for software validation plan. Software validation plans. The software validation plans are used in specific 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:

When there is any change is made in software even change is small and then need to revalidate the software[13]. 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 is enough to show that all software validation plans and procedures have been completed.

successfully[14].

Independence of Review: The quality assurance precept of "independence of review" is a key parameter in validation[15]. Self-validation is not easy when possible, an independent evaluation is always better, especially for higher-risk applications.

Flexibility and Responsibility: Software validation principles may differ from one application to another. Software is designed, developed validated, and regulated in a wide spectrum of environments, and risk may vary with the variety of devices[16].

FDA regulated medical device applications include software:

Software is used in the form of medical devices, sometimes itself medical device or the software is used to designing, develop and manufacture or other parts of the medical devices. In every field, the software is used for different purposes including in-house developed software, off-the-shelf software, and contract software shareware. The systems, devices, and processes are the important parameters of software validation. For the design development and manufacture of the devices, there is a need to validate the software for all the processes.

Role of a life science company to determining the needs of specific computer system Validation:

Software validation is based on the FDA regulations and FDA guidelines as well as their efforts to adopt industry best practices. Best practices include life science industry group

guidelines[20]. Some of the FDA regulations provide rules on the quality system under which life sciences companies must operate known as the "regulated Gape environments". The gape is an umbrella term that covers: **GMP (**good manufacturing practice), **GLP** (good laboratory practice), and **GCP** (good clinical practice). These codes/quality systems are sometimes referred to collectively as the predicate rules. Depending on the software application, different predicate rules may apply. For example, there are specific regulations that cover medical device software (21 CFR 820.30 (g)). Guidance on validation of medical device software is provided in an FDA paper called general principles of software validation: final guidance for industry and FDA staff [21].

In addition to the government agency rules, government agency steerage documents, and best practices that apply, there are other factors that have an effect on what must be necessary to be done in the specific computer system.

Validation:

- The type of software that is being validated.
- Whether the software is off-the-shelf, configurable, or custom-developed impacts the Validation.
- Business and compliance risks associated with the specific computer system should be used to determine validation priorities.

A typical computer system validation (actual process):

Computer system validation is definitely not a "one size fits all" procedure; the approach that an individual company may take to a specific validation depends on the rules, guidance, best practices, and characteristics of the system being validated[22]. On the other hand, there are some strong similarities between the activities in most automatic data processing system validations and therefore the variety of documentation. In fact, one way to get a good understanding of computer system validation is to take a look at the type of documents that would be accumulated[23]. The following is a list of the documents that might result from the validation of a computer system application to be used in a Gape sensitive environment[24.]

CONCLUSION:

At the time of installation, the computer system must be validated. To run any project or to change in the computer system a validation must be done by a qualified person who has complete information regarding the system and project to be done. For effective validation, a well-experienced person is needed who has complete information Good computer system validations have several benefits like improving quality assurance, lowering the other validation cost and time, improving GMP compliance, and 21 CFR part 11 regulation which affects product quality, safety, identity or efficacy that subject to Gape rules FDA regulation mandate the need to perform computer software validation and these regulations has the impact of the law. Failing in FDA audit can result in FDA inspectional observation and warning letters. And failure to take corrective action at a particular time can result in shutting down manufacturing facilities, consent decrees, and stiff financial penalties. Hence computer software validation is a necessary parameter for pharmaceutical companies and laboratories.

SUMMARY:

The objective of these activities is to document evidence that each computer system will fulfill its intended purpose in a Gape production, laboratory, or research operation. The intention is to avoid software problems that could have a serious impact now a day, the term computer system validation refers specifically to the technical discipline used in the life sciences sector to help ensure that software systems meet their intended requirements. Through its regulations/guidance on computer system validation, the FDA has shaped its testing and analysis processes to match the needs and requirements of the industries it governs. As a result, computer system validation has become an integral part of doing business in FDA regulated environments.

Computer system validation requires a comprehensive set of equally important static testing activities that need to be conducted throughout the SDLC. This includes a variety of analyses, audits, walkthroughs, reviews, and traceability exercises. Documentation must be accumulated that demonstrates that these activities have been performed effectively. It is likely that the future will see the convergence of computer system validation terminology and techniques as a common technical discipline across other industry sectors as well.

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