Computer System Validation CSV in Data Integrity Implementation Strategies for Pharmaceutical Industry

Author: Alexis Colón Nazario
Advisor: Edgar Torres, Ph D.

Abstract

Computer System Validation CSV in Data Integrity refers to the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA). Due to the rise in cGMP violations involving data integrity during regulatory inspections, there have been issuances of many warning letter, import alerts and consent decrees. Electronic signature and record-keeping requirements as mentioned in 21 CFR Part 11 and apply to certain records, subject to records requirements set forth in Agency regulations, including parts 210, 211 and 212. Further, regulations for Computer System Validation CSV in data integrity issues occur mostly in quality laboratories and production areas and the causes vary due to personnel, equipment and management. The implementation of regulatory guidelines and standard operating procedures for data integrity, regular internal audits or surveillances and training will pave way for pharmaceutical industries to maintain Computer System Validation CSV in data integrity flawlessly.

Introduction

Computer System Validation CSV in Data Integrity is the assurance that data records are accurate, complete, intact, and maintained within their original context, including their relationship to other data records and aims to prevent unintentional changes to information. It refers to maintaining and assuring the accuracy and consistency of data over its entire life-cycle, including the usage of any system which stores, processes, or retrieves data. The definition applies to data recorded in electronic and paper formats or a hybrid of both., which is being followed in certain industries. Ensuring data integrity means protecting original data from accidental or intentional modification, falsification, malicious intent (fraud), or even deletion (data loss). Data integrity and security are closely linked to the 21 CFR part 11 for electronic records and electronic signatures.

Methodology

The methodology to be followed for the Data Integrity Implementation Strategies for Pharmaceuticals Industries. Solving model called complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA). Data integrity – requirements for complete, consistent, and accurate data.

Throughout **cGMP**

ALCOA
Attributable
Legible
Contemporaneous
Original or true copy
Accurate

Remembering: Verifying the integrity of your data means verifying that your data is:

- Reliable
- Consistent
- Accurate

Terms associated with **ALCOA**

Attributable
Who performed an action and when? If a record is changed, who did it and why? Link to the source data.

Legible
Data must be recorded permanently in a readable manner.

Contemporaneous
The data should be recorded at the time the work is performed followed by date & time stamps.

Original
It should be an original record and not a certified true copy.

Accurate
Errors should not be edited without appropriate documentation.

Methodology

Data Security

Within the scope of Computer System Validation CSV, Data Security is best defined as the act of protecting data against unauthorized access or corruption. Typically, not enough controls around computerized system is the root cause of data security issues.

Computerized System:

A computerized system is any combination of hardware, software and associated infrastructure, that collects, creates, modifies, maintains, archives, retrieves, or transmits electronic data.

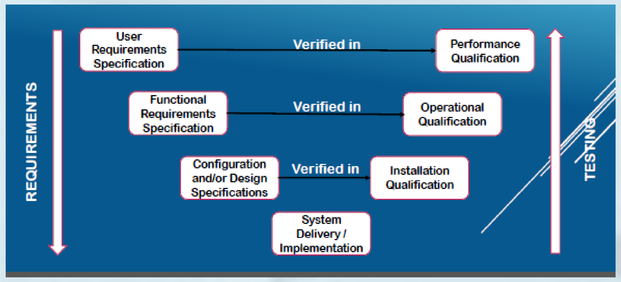

Figure 1 Computer System Validation V-Model

Results and Discussion

Improving Data Integrity in Pharma Industries Training

Awareness about the company's data integrity policy to the employees and new employees is to be made clear through scheduled training programmers conducted by experienced personnel. To make it easier to understand, it is to be oriented in various languages. This is definitely vital since most of the errors or data integrity issues at the workplace are originated due to humans. These human errors can be drastically prevented by appropriate training and by making the employees believe that these changes do make a huge impact on the quality of the medicines manufactured at the facility. They should understand that the impact of carelessness or fraud will ultimately affect the patients' lives. Training should be given to technical and non-technical operating staff. Data Integrity culture should be followed through data integrity policies and Standard Operating Procedure.

Quality Culture

For maintaining data integrity in the company, the management should make personnel aware of the importance of their role in ensuring data integrity and the implication of their activities to assuring product quality and protecting patient safety. The Standard operating procedure for data integrity should be followed efficiently by all personnel working in the company. A code of value and ethics should be followed and it should reflect the management's philosophy on quality, which is achieved through policies. Management should aim to create a quality culture which is open, one in which personnel are encouraged to freely communicate failures and errors, so that corrective and preventive actions can be taken accordingly. The flow of information between all levels of the organization should be permitted. The collection of values, thought processes and behaviors practiced consistently by management and all personnel contribute to creating a quality culture to assure data integrity.

Computerized Systems

Computer systems should have sufficient controls to prevent unauthorized access or changes to data. There should be a record of any change made as to who made the change and when the change was made. Access to folder deletion software installation and user privileges should be controlled. Computer system validation checks should be done in order to discern invalid or altered records. Computerized systems which exchange data electronically with other systems should include appropriate built in checks for the correct and secure entry and processing of data, in order to minimize risks. A secure location should be allotted for backups of all data in order to prevent intentional or unintentional damage. In case of data review, there has to be regular internal and external audits and verification of the attendance, log books and presence of the person. The frequency of data review should be increased.

Results and Discussion

Electronic Systems

Biometric signatures are a method to verify an employee's identity based on measurement of an individual's physical features which are unique and measurable to that individual. For example, voice prints, hand prints and retinal scans. These signatures must consist of two distinctive components and must be used by the genuine owner. Ensuring that no two individuals have the same combination of identification codes and that they're periodically checked, recalled or revised is a necessary step in maintaining data integrity within electronic systems.

Better Communication

Communication is a critical element to reduce data integrity challenges within organizations. Workflow simplification and the adoption of industry best practice pre-defined workflows will reduce complexity. With modern tools such as LIMS, ELN, LES the challenge to the industry is to make pairing a balance with a computer using a laboratory software application. Lowering the barrier to integrate instruments will contribute to lowering data integrity challenges in laboratories significantly.

Conclusion

The objective of this paper was achieved by presenting a strategic and guidance approach to show the importance of maintaining integrity of data parameters in the medical device and pharmaceutical industry throughout the cGMP in a complete manner, consistent and accurate data.

References

[1] Concerns Mount Over Data Integrity and Compliance Issues Abroad Mar 02, 2016

[2] FDA 21 CFR Part 11, Electronic Records; Electronic Signatures, 1997 April 1, 2017

[3] DATA INTEGRITY and DATA MANAGEMENT for GXP REGULATED FIRMS Barbara W. Unger Consulting Inc. March 2015.

[4] US FDA Inspections in China: An Analysis of Form 483s from 2015 10 February 2016

[5] Data Integrity and Compliance with cGMP Guidance for Industry April 2016

[6] Follow-up on PIC/S Data Integrity Guidance August 18, 2016

Figure 2 Data Integrity Model