RESEARCH PAPER

Data Integrity In Pharma Industry Safeguarding Trust And Compliance

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ABSTRACT
Data integrity is crucial in every industry. If any sector fails to maintain data integrity, it compromises the quality of its products. A decline in quality can ultimately lead to concerns about safety and efficacy. For this reason, pharmaceutical regulatory agencies emphasize the importance of data integrity for pharmaceutical products. Non-compliance with these standards has resulted in the termination of many employees within the industry. This review article discusses data integrity's significance in the pharmaceutical industry.

Key words: Data Integrity, USFDA, CDSCO, GMP, and ALCOA+
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INTRODUCTION

The pharmaceutical industry is highly regulated, with oversight from various governing bodies depending on the market. Companies in this sector are expected to adhere to Current Good Manufacturing Practices (cGMP) and established processes. Effective data management[1] is crucial in the pharmaceutical industry, as it ensures that the entire manufacturing and testing process is documented in compliance with regulations. This documentation is essential for understanding how processes are executed from start to finish. Data recording and storage can be managed manually, electronically, or through combinationof both methods. However, inappropriate documentation practices and data falsification are significant concerns for both the pharmaceutical industry and regulatory authorities worldwide [2]. To maintain data integrity in line with current guidelines, several key elements must be considered:

ALCOA +: Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available

A - Attributable: who performed the activity, who is documented or recorded and when

L - Legible: documented or recorded data is Clearly visible and permanently available

C - Contemporaneous: documented or recorded data is at the time of action without any delay

O - Original: documented or recorded data is true or from an authentic source

A - Accurate: documented or recorded data is without any medication [3]

+ Complete: documented or recorded data is giving whole action background

+ Consistent: documented or recorded data is always on time with applicable time stamps

+ Enduring: documented or recorded data is long lasting for intended duration

+ Available: documented or recorded data is available for review during its life cycle [4]

SIGNIFICANCE OF DATA INTEGRITY

Data integrity (DI) ensures that the information recorded during the manufacturing, testing, and other operations of drug production is accurate, complete, and reliable[5]. Data integrity is essential for assuring the safety, integrity, strength, purity, and quality of the manufactured drug. In simpler terms, the quality of a company's data directly influences the quality of its products in the market [6].

REASONS FOR DATA INTEGRITY ISSUES

Data Integrity (DI) issues arise for various reasons and are not always intentional, despite widespread misconceptions. One significant source of DI issues in the pharmaceutical industry is insufficient and unqualified staff [7]. When a small number of employees are required to handle excessive workloads, the risk of entering incorrect data during the manufacturing or testing of drug products increases. Some DI problems stem from organizational practices that either encourage overworking a limited staff or fail to intervene when these practices occur [8]. Additionally, ineffective training is another major contributor to DI issues. Often, improper trainers provide training that is not relevant to the actual job, and some organizations view training merely as a regulatory requirement rather than a crucial aspect of ensuring the quality and importance of the testing and manufacturing processes related to current Good Manufacturing Practices (cGMP) [9]. Organizational culture also plays a vital role in compliance with DI

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standards. If employees fear reporting mistakes due to potential job repercussions, this can lead to data falsification instead of investigation and corrective actions to identify and address the root causes. The absence of robust quality systems and regulatory-standard equipment can result in DI non-conformance [10]. Organizations must prioritize continuous improvement of existing systems in alignment with cGMP requirements, and these improvements should be identified as part of internal audits as well as corrective and preventive actions during regular deviations. Before purchasing equipment and instruments, organizations must evaluate whether they comply with cGMP standards [11]. Once substandard systems, instruments, and equipment are operational, it becomes challenging to remediate any DI issues that may arise during inspections or commercialization of drug products. Therefore, initial evaluation and validation are critical to selecting appropriate systems to avoid DI problems [12].

MISCONCEPTIONS OF DATA INTEGRITY

Warning letters give impression that DIs are always intentional, however some of the cased in which DIs are unintentional too. For example, systems purchased are mentioned as 21 CFR complaint, however during audits they will not be able to meet the regulatory requirements [13]. These types of unintentional DIs are due to inadequate systems, software's, incompetent suppliers and may be combination of incompetent suppliers along with poor validation and verification practices.

Most often DI occurrence is considered due to manipulation of data in testing results or at manufacturing steps, however along with that validation and investigation reports does not support the conclusions upon reviewing the provided data [14]. It is evident that team or organization wanted to hide the root cause by taking wrong decision and these practices also fall under DI [15].

Regulatory agency inspection or audit findings sometimes mention as poorly executed investigations or employees not doing job properly, in such cased companies fail to identify the gaps in system to arrest DI practices, instead focus on training and actions to employees [16]. Companies should focus on robust systems in place not to allow personal to do modifications in data whether it is a manual system or e-system[17].

Some cased it is considered that a system or computer or software is substandard, however it is identified, qualified, accepted, configured, and tested by the human [18]. Hence DI vulnerabilities not resulted due to substandard system, and it is mainly due to improper human or man controls which fails to identify substandard system [19].

When DI identified, it is mostly considered as a mistake of Human, however company culture and policies are to be considered for its openness to accept the mistakes of employees and substandard materials acceptance (due cost implications) because company culture plays a major role on setting up no non-conformances with respect to DI [20].

CONSEQUENCES OF DATA INTEGRITY

As a result of data integrity (DI) issues during regulatory inspections or audits, pharmaceutical companies may fail to obtain approval for the manufacturing and distribution of drugs to the market [21]. When regulatory agencies identify non-compliance with DI standards, they issue warning letters, non-compliance statements, and consent decrees to the organizations [22]. This non-compliance prevents companies from manufacturing and distributing drugs, ultimately hindering their mission to save lives and damaging consumer trust and business viability [23]. DI is a critical aspect that must be consistently monitored, not just during audits and inspections. If DI issues are identified during re-inspections in commercial stages, it can lead to import alerts, product recalls, and the seizure of products [24]. The distribution of adulterated drugs poses a significant threat to patient safety and will not be tolerated by regulatory agencies once DI issues are detected [25]. When DI issues arise, the trust of regulatory agencies is compromised [26]. Regaining that trust can be challenging; agencies may conduct more frequent or surprise inspections and request additional data and evidence to assess compliance. In some cases, regulatory agencies recommend appointing third-party consultants to review and release data on behalf of company employees [27]. This process can be expensive and reflects poorly on the pharmaceutical company [28]. If DI issues are caused by the intentional falsification of data by a group of employees, without management's involvement, it can result in job losses and guilty pleas. This may also hinder their future employment prospects in other pharmaceutical companies [29]. In summary, non-compliance with DI requirements can be costly for pharmaceutical companies, their employees, and patients, particularly if it leads to the distribution of falsified or adulterated drug products intended for treating illnesses [30].

RECOMMENDATIONS

Pharmaceutical organizationsand regulatory bodies rely heavily on data, which necessitates that documents and systems are in a qualified or validated state [31]. This ensures that no modifications, deletions, or adulterations of data occur, thus allowing organizations to avoid data integrity (DI) issues [32]. Effective procedures and comprehensive training programs must be implemented for all employees to help them identify, report, correct, and prevent DI issues within the pharmaceutical industry [33]. Continuous monitoring of documents and systems should be conducted through internal reviews, audits, and third-party assessments to identify potential areas where DI issues may arise [34]. Once such issues are identified, objective-based corrective and preventive actions should be implemented[35].

It is essential to periodically review and disseminate knowledge about various DI issues across the

pharmaceutical industry to all employees [36]. This empowers them to identify and report internal DI concerns to management [37]. Organizations must also ensure the availability of sufficiently educated resources to carry out the required tasks effectively, enabling employees to perform their jobs appropriately [38].

Additionally, pharmaceutical organizations should consistently focus on regulatory updates, current Good Manufacturing Practices (cGMP), and sustainable long-term strategies to maintain compliance with data integrity standards [39]. The pharmaceutical organizations always need focus on regulatory updates, cGMP aspects and long terms sustainable ways to keep up the operations in compliance to DI [40].

CONCLUSION

Each step of Data collection, management and storage needs to be handled precisely to avoid DI issues, and to achieve the same organizations need focus on educated staff and qualified or validated equipment, instruments, and process to be in place. Highly regulated pharmaceutical industry always relays on data, if it is not documented it is not executed, if data is altered it is considered that manufactured drug is adulterated. DI finding poses big concern to regulators that how many other DIs exist in organization and that creates untrustworthy impression of all the existing data which is not the expectation from any pharmaceutical organization.

Data integrity is always very critical aspect to have confidence on Safety, integrity, strength, purity, and quality of manufactured drug product. Poor DI practices are big area of concern to pharmaceutical organizations as a result of that regulatory agencies and consumer market loss trust, business and ultimately it will stop the companies to live their purpose of saving lives by producing effective pharmaceutical drugs.

ABBREVIATIONS

current Good Manufacturing Practices (cGMP),Data integrity (DI).

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