IMPORTANCE OF DATA INTEGRITY IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

We attempted to research data integrity and application in the pharmaceutical industry in this essay. Data integrity must be used to maintain all records in the pharmaceutical sector.

The integrity of data is a crucial contemporary concern for authorities all around the world. Numerous issues are discovered by the pharmaceutical regulating body during inspections as a result of inadequate practices that result in subpar products for patients. Data is the result of the compilation of numerous forms of information and outcomes. As one of an organization's most precious resources, this data is of little use if it lacks integrity. The likelihood of an organization's stability and performance is increased by accuracy and original data.

The degree to which all data are comprehensive, consistent, and accurate throughout the life cycle of the data is known as data integrity. Data integrity refers to the accuracy of all original records, including source data and metadata that may be stored electronically or on paper. Many regulatory authorities, including the USFDA, Health Canada, and EMEA, suggested using ALCOA to ensure the data integrity (Attributable, Legible, Contemporaneous, Original and Accurate).

KEYWORDS: - *Data Integrity, USFDA, Health Canada, EMEA, ALCOA.*

I. INTRODUCTION

Digital platforms and technological breakthroughs are transforming how corporate operations are conducted in the current global business climate. Business and the digital platform have become synonymous to increase the productivity and efficiency of organizations thanks to the big data explosion. Business executives should constantly reflect on the economic and commercial potential of big data as well as its larger significance for social and technological advancements. This means that in order for the pharmaceutical sector as a whole to benefit from these technologies, new frameworks of action must be included into daily business operations. Data integrity (DI) is the process of ensuring the accuracy, reliability, and completeness of data generated during corporate operations and medication production. Only when data is trustworthy can business owners make the decisions that are best for their companies, raise the caliber of their output, and boost their overall success.

The subject of data integrity has drawn more and more attention over the past few years. A draught guidance on data integrity for current Good Manufacturing Practices (cGMP) compliance was recently released by the American Food and Drug Administration (FDA). Data integrity is also a goal for other regulatory organizations, like the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency UK (MHRA), particularly in their publications. Despite the fact that these suggestions are "non-binding," we cannot ignore the fact that data integrity is frequently a "hot topic" during audits and inspections in the pharmaceutical sector. Why, therefore, is data integrity so crucial? And how do drug companies make sure that compliance? Let's examine it more closely.

II. PHARMACEUTICAL INDUSTRY

"The Indian Pharmaceutical industry is a success story providing employment for millions and ensuring that essential drugs at affordable prices available to the vast population of this sub-continent". The pharmaceutical industry is developing, producing, and marketing drugs. The pharmaceutical companies are generally dealing in generic or brand medications and medical devices. The pharma products are subject to a variety of laws and regulations in all countries. Because of laws and regulation Pharmaceutical Company has become very large and very complex enterprise.

Since the pharmaceutical industry is driven largely by profits and competition-each company striving to be the first to find cures for specific diseases. It is anticipated that the industry will continue to change and evolve over the time. The Pharmaceutical industry in India is the world's third-largest in terms of volumes and stands 14th in terms of value.Major Segments of Pharmaceutical Industry are Generic drugs, OTC Medicines and API/Bulk Drugs, Vaccines, Contract Research & Manufacturing, Biosimilar & Biologics.

India's pharmaceutical sector forms a major component of the country's foreign trade, with attractive avenues and opportunities for investors. India supplies affordable and low-cost generic drugs to millions of people across the globe and operates a significant number of United States Food and Drug Administration (USFDA) and World Health Organization (WHO) Good Manufacturing Practices (GMP)-compliant plants. India has occupied a premier position among pharmaceutical manufacturing countries of the world.

III. DATA INTEGRITY

As per **USFDA**, 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).

As per **MHRA**, It is the degree to which data are complete, consistent, accurate, trustworthy, reliable and that these characteristics of the data are maintained throughout the data life cycle. The data should be collected and maintained in a secure manner, so that they are attributable, legible, contemporaneously recorded, original (or a true copy) and accurate. Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices.

III. PRINCIPLES OF DATA INTEGRITY

Instead of "ALCOA +," it is advisable to use the term ALCOA. With the "+" standing for complete, Consistent, Enduring, Available, ALCOA stands for Attributable, Legible, Contemporaneous, Original, and Accurate. ALCOA was once thought to be establishing the characteristics of data quality appropriate for regulatory purposes. After that, a "+" was placed to emphasize the criteria. No matter which acronym is used, the requirements are the same since data governance mechanisms should guarantee that data is complete, consistent, enduring, available throughout the data lifetime.

a) **Attributable:** The data generated or collected must be traceable back to the individual who generated the information.

b) **Legible:** The terms legible and permanent refer to the requirements that data are readable and understandable.This is very important in the pharmaceutical industry as a mistaken spelling could result in the administering of a completely different drug.

c) **Contemporaneous:** The data shall be recorded at the time the work is performed. Signature/ initial with date.

d) **Original:** Data should be preserved in its original form or a certified true copy.

e) **Accurate:** The recorded data should be correct, truthful, complete, valid, reliable, free from errors and reflective of the observation.

IV. HOW REGULATORY BODY ADDRESS THE ISSUE?

Regulatory agencies carry out data integrity assessments and are dedicated to following fraud instances all around the world. Regulatory authorities exchange nonconformity cases among themselves to gain an overall understanding of how the industry has handled the problem.

In order to ensure that workers feel accountable for the integrity of the data generated in their department, stage of production, or analysis, it is crucial for industries to invest in employee training for handling pertinent Gx P data and to establish an on-site culture of attention to procedures that involve the integrity of critical data.

Technology has become the transparency's strongest ally and a crucial tool for boosting data reliability and integrity.

The Digital Compliance Platform (DCP) now makes it feasible to coordinate and carry out validation/qualification projects, with the specialist's efforts focusing on evaluating vulnerable risk situations, including mitigations and, where appropriate, data integrity issues.

Pre-ready validations and data integrity evaluations are included in the DCP, along with raw data and metadata that are thought to be Gx P relevant.

It is simple to import risk scenarios, requirements, and test scripts from the library for computerized systems validation projects, bringing items like data integrity, access control, audit trail, and electronic signature, among others, to evaluate the process and data pertaining to systems and/or processes.

V. IMPORTANCE OF DATA INTEGRITY IN PHARMACEUTICAL INDUSTRY

Pharmaceutical and biotech companies gather and store data at all times. However, the quality of this data must not be compromised. Here, we shall examine why these companies must maintain data integrity.

- **Safety & Effectiveness**
  Data integrity provides assurance that pharmaceuticals can be used safely. Additionally, it demonstrates that using medications will make them work. This is due to the protection of all manufacturing-related information.

  Data integrity is crucial for therapeutic efficacy. It accomplishes this by fusing three factors: gathering, analysing, and evaluating. It enables predictive analysis, ensuring that newly made medications are successful on the market.

  For instance, merely classifying Chloroquine as an anti-malarial is insufficient. The three parameters discussed before will be used by data integrity to decide dose. As a result, toxicity, overdose, ineffectiveness, and drug intolerance will be reduced. Data integrity is therefore crucial for the pharmaceutical industry as well as other regulated industries.

- **Accuracy**
  Data integrity has accuracy to it. The accuracy and relevancy of data are ensured by thorough cleaning. Additionally, it makes data tracing simple when necessary. Pharmacies benefit from the removal of incomprehensible data since it improves clarity. Making final quality assurance checks is also beneficial.

- **Effective Production and Distribution**
  Observing data integrity procedures helps with medicine distribution and production. Pharmaceutical companies use data integrity to create the best possible medications. In a similar line, it aids them in providing such drugs to the proper clients.

  Let's imagine that a pharmaceutical corporation notices a rise in the COVID-19 rate in a certain region of the nation. This might motivate it to develop COVID-19 therapies. Producing consistently high-quality treatments is vital for data integrity in all production and manufacturing processes.

- **Trust Building**
  Consumers find it challenging to trust pharmaceutical companies when their data is exposed. Additionally, other businesses would shun all types of affiliation. When data integrity is upheld, trust is created and maintained.

The biotechnology and pharmaceutical businesses must maintain secure documentation procedures. As a result, regulatory bodies will have more confidence in the

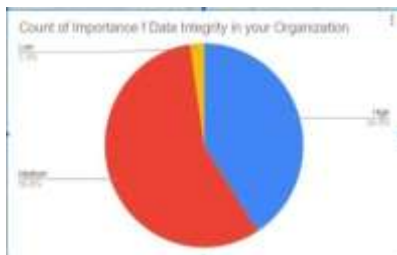## VI. DATA ANALYSIS AND INTERPRETATION

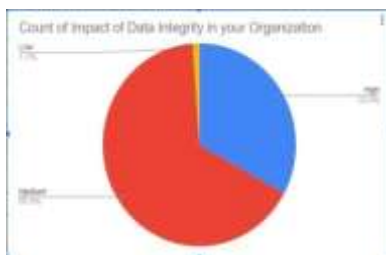Q.1 How often you are aware about the Data Integrity?
A. High
B. Medium
C. Low
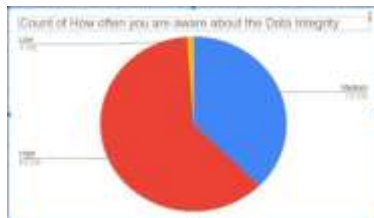
Q.2 Importance of Data Integrity in your Organization?
A. High
B. Medium
C. Low

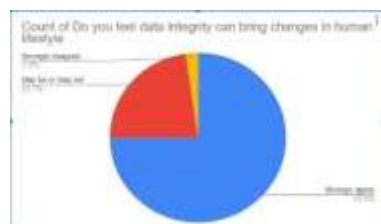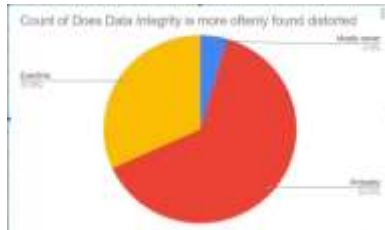Q.3 Impact of Data Integrity in your Organization?
A. High
B. Medium
C. Low

Q.4 Do you feel data Integrity can bring changes in human lifestyle?
A. Strongly agrees
B. Strongly disagrees
C. May be or May not

Q.5 Does Data Integrity is more often found distorted?
A. Every time
B. Mostly never
C. Probably

Q.6 Does your company have the procedure to review data integrity?
A. Yes
B. No
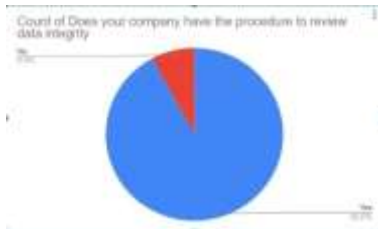
Q.7 Issue on privacy of Data Integrity should be considered?
A. Yes
B. No
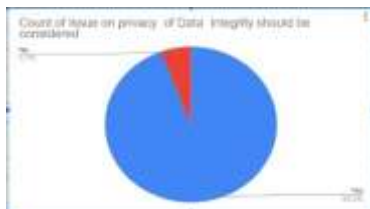
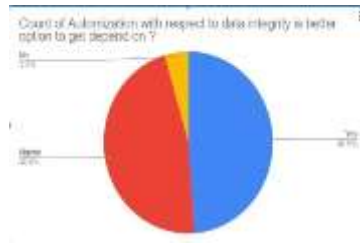Q.8 If Data Integrity was not the concept would you trust the source or company?
A. Yes
B. No
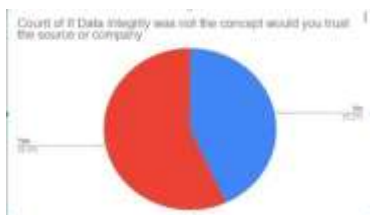
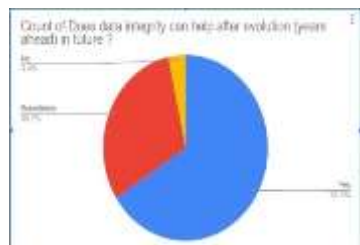Q.9 Data integrity is directly proportional to quality of product?
A. True
B. False
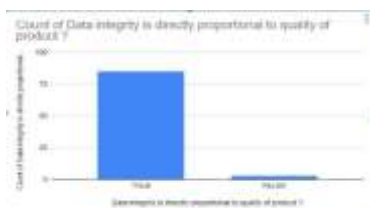
Q.10 Automization with respect to data integrity is better option to get depend on?
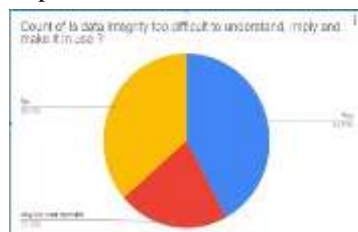A. Yes
B. No
C. Maybe

Q.11 Does data integrity can help after evolution (years ahead) in future?
A. Yes
B. No
C. Sometimes

Q.12 Is data integrity too difficult to understand, imply and make it in use ?*
A. Yes
B. No
C. anyone can operate

VII. CONCLUSION

Because faulty practises can let a sub-par product reach patient, data integrity plays a crucial function in the pharmaceutical sector in maintaining the quality of a final product. As a result, it's essential for an existing system to guarantee the data integrity, data traceability, and reliability. Data integrity is a crucial part of a Quality System from a quality perspective. The foundation for the company's confidence in using accurate data to operate in compliance with regulatory standards is quality data. For a variety of reasons, including patient safety, business procedure, and product quality, authorities place a high priority on data integrity. The reliability and accuracy of the data serve as a foundation for the regulators' assessment of the company.

The manufacturer is also accountable for preventing and identifying bad data integrity practises that arise from ineffective quality control measures. When data is collected and utilised to make decisions about manufacturing and quality, the Quality Risk Management (QRM) strategy may prevent, detect, and control any risks and ensure that the data is trustworthy and dependable.

VIII. ACKNOWLEDGEMENT

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