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Data integrity is an important current issue for regulators around the world. During inspections a multitude of problems being found by the pharmaceutical regulatory agency because poor practices develop the substandard product for patients. Collection of various types of information and results collectively made in the form of data. This data becomes one of the most valuable assets of any organization but without integrity, this data is not much useful. Accuracy and original data increase the chances of stability and performance of an organization.

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Importance of data integrity & its regulation in pharmaceutical industry

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Abstract
Data integrity is an important current issue for regulators around the world. During inspections a multitude of problems being found by the pharmaceutical regulatory agency because poor practices develop the substandard product for patients. Collection of various types of information and results collectively made in the form of data. This data becomes one of the most valuable assets of any organization but without integrity, this data is not much useful. Accuracy and original data increase the chances of stability and performance of an organization.
Data integrity is the extent to which all data are complete, consistent and accurate throughout the life cycle of data. It includes Good Documentation Practice which leads to preventing data from being altered, copied or moved. In data integrity, data means all original records including source data and metadata which may be recorded in paper or electronic form. To assure the data integrity many regulatory bodies such as USFDA, Health Canada, and EMEA recommended the use of ALCOA (Attributable, Legible, Contemporaneous, Original and Accurate).

Keywords: Data integrity, ALCOA, regulatory body, USFDA, 21-CFR

Introduction

The data quality is referred to as "Data Integrity." It is maintaining and assuring the accuracy and consistency of data over its entire life-cycle. Data integrity means that the data is accurate and reliable. Research and processing Information collected and resulting in an increasing amount and varied types of data being collected. This data is very important, but without integrity, this data not have much value. [1]. Data is information that has been translated into a form that is efficient for movement or processing, It has become one of the most valuable assets of any company project or research. The better data integrity a company has, the more ethically successful it is likely to become growth. Poor data integrity practices and vulnerabilities undermine the quality of records and evidence and may ultimately undermine the quality of medicinal products. Data integrity applies to all elements of the Quality Management System and the principles herein apply equally to data generated by electronic and paper-based systems. The responsibility for good practices regarding data management and integrity lies with the manufacturer or distributor undergoing inspection. They have full responsibility and a duty to assess their data management systems for potential vulnerabilities and take steps to design and implement good data governance practices to ensure data integrity is maintained [1].

Data integrity is the issue of maintaining and ensuring the accuracy and consistency of data over its lifecycle. This includes good documentation practice, good data management practices, such as preventing data from being altered each time it is copied or moved. Data integrity applies to both paper records and electronic records. Processes and procedures are put in place for companies to maintain data integrity during normal operation [1].

As per MHRA, GMP data integrity guidance for industry March 2015. Data Integrity is defined as "the extent to which all data are complete, consistent and accurate, throughout the data lifecycle" and is fundamental in a pharmaceutical quality system which ensures that medicines are of the required quality [1].

The word integrity evolved from the Latin adjective integer, meaning whole or complete [2]. Integrity is the qualifications of being honest and having strong moral principles; moral uprightness. It is generally a personal choice to hold oneself to consistent moral and ethical standards [3]. In ethics, integrity is regarded by many as the honesty and truthfulness or accuracy of one's actions. Integrity can stand in opposition to hypocrisy. It's the inner sense of "wholeness" deriving from qualities such as honesty and consistency of character as such, one

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May judge that others "have integrity" to the extent that they act according to the values, beliefs, and principles they claim to hold [2]. So integrity is the "Doing the Right Thing for the Right Reason". It is a personal choice, an uncompromising and predictably consistent commitment to honour moral, ethical spiritual and principles" [3].

Significant attention is given to the subject of integrity in law and the conception of law in 20th century philosophy of law and jurisprudence centering in part on the research of "Ronald Dworkin" as studied in his book Law's Empire. Dworkin's position on integrity in law reinforces the conception of justice viewed as fairness [2].

Before a pharmaceutical product available for a patient, the manufacturing company has to present evidence of efficacy and safety. For this, they have to run trial studies and lab testing. ALCOA in pharmaceuticals is used to ensure that the quality of the evidence collected is maintained as per regulatory guidelines. Many regulatory bodies as the FDA, Health Canada and the EMEA recommend the use of ALCOA to ensure good documentation practices in pharmaceuticals [4].

ALCOA: ALCOA is defined by US FDA guidance as Attributable, Legible, Contemporaneous, Original and Accurate. It relates to data, whether paper or electronic and these simple principles should be part of your data lifecycle, GDP, and data integrity initiatives [4]. It helps in developing strategies so that the integrity of the evidence is maintained both in research and manufacturing. The aspects of ALCOA in pharmaceuticals have been discussed below:

Attributable: Attributable means that the evidence or every piece of data entered into the record must be capable of being traced back to the person collecting it. This ensures accountability. This contains a record of who performed an action and when. This could be a paper or electronic record [4]. It requires the use of secure and unique user logins and electronic signatures. Using generic login IDs or sharing credentials must always be avoided. Unique user logons allow for individuals to be linked to the creation, modification, or deletion of data within the record [6]. It should be possible to demonstrate that the function was performed by trained and qualified personnel. This applies to changes made to records as well: corrections, deletions, changes, etc [1].

Legible: The record created, especially the paper-based records should be legible. The records should be permanent and not erasable so that they are reliable throughout the data lifecycle [4]. The terms legible and traceable and permanent refer to the requirements that data are readable, understandable, and allow a clear picture of the sequencing of steps or events in the record [8]. This is very important in the pharmaceutical industry as a mistaken spelling could result in the administering of a completely different drug [4]. For an electronic record to be considered legible, traceable and permanent. Prohibit the creation of data in temporary memory as well as immediately committing data to a permanent memory before moving on [6].

Contemporaneous: Contemporaneous is the evidence of actions, events or decisions should be recorded as they take place or generated [8]. This documentation should serve as an accurate attestation of what was done, or what was decided and why i.e. what influenced the decision at that time [5]. If executing a validation protocol, tests should be performed and their results recorded as they happen on the approved protocol [8].

Original: The original data sometimes referred to as source data or primary data whether recorded on paper (static) or electronically. Information that is originally captured in a dynamic state should remain available in that state [1]. This could be a database, an approved protocol or form, or a dedicated notebook. It is important where your original data will be generated so that its content and meaning are preserved. For example: Ensure validation test results are recorded in the approved protocol. Recording results in a notebook for transcription later can introduce errors and if your original data is handwritten and needs to be stored electronically, ensure a "true copy" is generated, the copy is verified for completeness and then migrated into the electronic system. [3]

Accurate: The recorded data should be correct, truthful, complete, valid, reliable, free from errors and reflective of the observation [7]. Editing should not be performed without documenting and annotating the amendments. For example, if witness checks are used for critical data collection. Videos of the record making process are also gaining acceptability in this regard. These standards make sure that the data is collected and processed with integrity [4]. ALCOA in pharmaceuticals helps both the companies and the users making it sure that there are no record-keeping errors due to which some sub-standard product is released onto the market. Therefore, ALCOA is a necessity for maintaining quality in the pharmaceutical field [4].

ALCOA-plus: It is an implicit basic ALCOA principle commonly used an acronym for "attributable, legible, contemporaneous, original and accurate", which puts additional emphasis on the attributes of being complete, consistent, enduring and available [4].

Data: Data is the original records and true copies of original records, including source data and metadata and all subsequent transformations and reports of these data, which are generated or recorded at the time of the GXP activity and allow full and complete reconstruction and evaluation of the GXP activity. Data should be accurately recorded by permanent means at the time of the activity. Data may be contained in paper records (such as worksheets and logbooks), electronic records and audit trails, photographs, microfilm or microfiche, audio- or video files or any other media whereby information related to GXP activities is recorded [9]. The data on which these decisions are based should, therefore, be complete as well as be being attributable, legible, contemporaneous, original and accurate, commonly referred to as "ALCOA" [8]. Data retention may be classified as archive or backup.

Archival: It is the process of protecting records from the possibility of further alteration or deletion, and storing these records under the control of dedicated data management personnel throughout the required records retention period. [10] Archived records should include, for example, associated metadata and electronic signatures [4].

Raw Data: Raw data was described in 21 CFR 58.3 a "Raw data means any laboratory worksheets, records, memoranda,

notes, or exact copies thereof, that are the result of original observations and activities of a nonclinical laboratory study and are necessary for the reconstruction and evaluation of the report of that study" [11]. Means it is an original record and documentation, retained in the format in which they were originally generated (i.e. paper or electronic), or as a 'true copy'.

Raw data must be contemporaneously and accurately recorded by permanent bases. In the case of basic electronic equipment which does not store electronic data, or provides only a printed data output (e.g. balance or pH meter), the printout constitutes as the raw data [5].

Meta Data: Metadata is the data that describes the attributes of other data, and provides context and meaning [1]. Metadata describe the structure, data elements, inter-relationships and other characteristics of data. It is structured information that describes, explains, or otherwise makes it easier to retrieve, use, or manage data [10]. They also permit data to be attributable to an individual. For example, in weighing the number 8 is meaningless without metadata, i.e. the unit, mg. Other examples of metadata may include the time/date stamp of the activity, the operator ID of the person who performed the activity, the instrument ID used, processing parameters, sequence files, audit trails and other data required to understand data and reconstruct activities [9]

Static Data: A static record format is a fixed data document (e.g., paper record or an electronic image) [12], It is one that is fixed and allows no or very limited interaction between the user and the record content. For example, once printed or converted to static pdf, chromatography records lose the capabilities of being reprocessed or enabling more detailed viewing of baselines or any hidden fields [9].

Dynamic Data: Many electronic records are important to retain in their dynamic format, such as electronic records, to enable interaction with the data. Data must be retained in a dynamic form where this is critical to its integrity or later verification. This should be justified based on risk [5]. Dynamic record format allows an interactive relationship between the user and the record content [12]. For example, electronic records in database formats allow the ability to track, trend and query data; chromatography records maintained as electronic records allow the user to reprocess the data, view hidden fields with proper access permissions and expand the baseline to view the integration more clearly [9].

Electronic Data: This includes data from ERP software used for controlling quality systems, laboratory electronic data and records, etc [10].

Quality Risk Management (QRM): This refers to a systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product life cycle [10]

Data Life Cycle: Data lifecycle is a planned approach to assessing and managing risks to data in a manner commensurate with potential impact on patient safety, product quality and/or the reliability of the decisions made throughout all phases of the process [9] include the life of the data (including raw data) from initial generation and recording through processing (including transformation or migration), use, data retention, archive / retrieval and destruction [5, 1]

True Copy: True copy is an exact verified copy of an original record (e.g. analytical summary reports, validation reports etc.) of data [1, 5]. That has been certified to confirm it is an exact and complete copy that preserves the entire content and meaning of the original record, including in the case of electronic data, all metadata and the original record format as appropriate [10]. These records must be controlled during their life cycle to ensure that the data received from another site (sister company, contractor etc.) are maintained as "true copies" [1].

Data Governance System: The data governance system should be integral to the pharmaceutical quality system described in EU GMP [5]. The rationale for this is based on MHRA's interpretation of ICH Q10 on Pharmaceutical Quality Systems (PQS) [13]. as per MHRA guidance, the data governance system is "The sum total of arrangements to ensure that data, irrespective of the format in which it is generated, is recorded, processed, retained and used to ensure a complete, consistent and accurate record throughout the data lifecycle" [9, 13]. The totality of arrangements to ensure that data, irrespective of the format in which they are generated, is recorded, processed, retained and used to ensure a complete, consistent and accurate record throughout the data life cycle [1].

The effort and resource assigned to data governance should be commensurate with the risk of product quality and should also be balanced with other quality assurance resource demands. As such, manufacturers and analytical laboratories are not expected to implement a forensic approach to data checking on a routine basis, but instead design and operate a system which provides an acceptable state of control based on the data integrity risk, and which is fully documented with supporting rationale [5]. The organization shall appoint a task force to govern the overall data reliability process. A robust data governance approach will ensure that the data is complete, consistent and accurate, irrespective of the format in which data is generated, used or retained [10].

GxP: GxP is an acronym for the group of Good Practice Guides governing the preclinical, clinical, manufacturing and post-market activities for regulated pharmaceuticals, biologics, medical devices, such as good laboratory practices, good clinical practices good manufacturing practices and good distribution practices [9].

Importance of Data Integrity: Regulators increased attention to data integrity for several years, the FDA and other global regulatory bodies have emphasized the importance of accurate and reliable data in assuring drug safety and quality [14]

World Regulatory Guidance on Data Integrity
USFDA: 21-CFR: 21-CFR (Code of Federal Regulation) is a codification of the general and permanent rules published in the federal register by the executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration. Each title/volume of the CFR is revised once each calendar year on approximately April 1st of each year [15].

MHRA: MHRA guidance on GMP data integrity expectations for the pharmaceutical industry the guidance is intended to complement existing EU GMP relating to active substances and dosage forms. Data integrity is fundamental in the pharmaceutical quality system which ensures that medicines are of the required quality [5].

TGA: Australian regulatory body Therapeutic Goods Administration (TGA) give the requirement of data integrity in the form of deficiency. A deficiency in a practice or process that has produced, or may result in, a significant risk of producing a product that is harmful to the user. Also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data [16].

cGMP: As a reflection of the importance of this issue FDA released guidance on Data Integrity and Compliance with cGMP within the guidance itself the FDA notes the trend of increasing data integrity violations. [14]. cGMP compliant record-keeping practices prevent data from being lost or obscured. FDA's authority for cGMP comes from FD&C Act section 501 a drug shall be deemed adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirement of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess" [12].

Good Documentation Practices. In the context of these guidelines, good practices are those measures that collectively and individually ensure documentation, whether paper or electronic, is attributable, legible, traceable, permanent, contemporaneously recorded, original and accurate [10].

WHO: Essential medicines and health products, WHO launches data integrity guidelines to protect patients all over the world. WHO proposed a guideline on international good practice for regulatory authorities and inspectors that can help reduce incidents of incomplete presentation of data by manufacturers or deliberate data falsification? While us developing a medicine and bringing it to market. It involves a multitude of actors and activities, a fundamental step is linked to the robustness and accuracy of the data submitted by manufacturers to national regulatory authorities. That data must be comprehensive, complete, and accurate and true to assure the quality of studies supporting applications for medicines to be put on the market. It also must comply with a number of standards, namely: good manufacturing practices (GMP), good clinical practice (GCP) and good laboratory practices (GLP) [17].

EME: The European Medicines Agency (EMA) has released new Good Manufacturing Practice (GMP) guidance to ensure the integrity of data that are generated in the process of testing, manufacturing, packaging, distribution, and monitoring of medicines. Regulators rely on these data to evaluate the quality, safety, and efficacy of medicines and to monitor their benefit-risk profile throughout their life cycle.

Good controlling of data records helps to ensure that the data generated are accurate and consistent and help to take good decision making by pharmaceutical manufacturers and regulatory authorities [18].

Management Responsibility: It is common observation management using 'Rule by Fear' method with employees (for example- employee do what employer are told him). This leads to a culture of fear and blame and an inability of employees to challenge and not follow regulatory guidelines.

- Poor education could lead to bad decisions or inappropriate behaviour based on knowing 'How' but not 'Why Complex systems and systems with inappropriate design can encourage and, at times, even force bad practices.
- An employee should be encouraged to take advantage of an open-door route to organization top management when it comes to raising compliance issues and discussing potential compliance concerns pertaining to data reliability [10].

Fig 1: Role of employee and management in Data integrity

Warning Letter and Compliance Issue: The risks of non-compliance increase with the number of NDAs/ANDAs and facilities, as increased scrutiny comes with scale and regulatory authorities are willing to send warnings to multiple sites based on the review of one site. A pharmaceutical manufacturer's lever to pull to reduce the risk of regulatory action is in improving Data Integrity. Doing so may provide a sustainable advantage in a highly competitive market [2].
As Jan 2018 analysis by GMP (good manufacturing practices) intelligence expert, Barbara Unger, approximately 65 percent of all US Food and Drug Administration (USFDA) warning letters issued in FY2017 (October 1, 2016, until September 30, 2017) included a data integrity component. [19]. In 2017, FDA released 476 warning letters. Top FDA warning letter violations were (1) adulterated products, (2) misbranded products, (3) unsanitary conditions and (4) unapproved new drugs [20]. Out of which 32% issued to China and 28% to India. China and India, taken together, account for 80 percent of the import alerts associated with warning letters. They are prevented from selling product from these sites in the U.S [21].
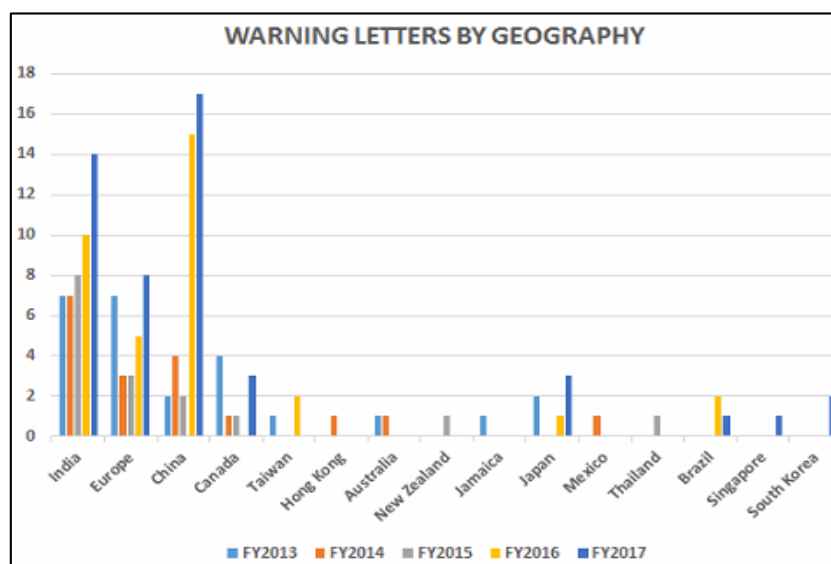
Fig 2: Drug GMP warning letters issued from FY2013 to 2017 regarding Sites

From the stating days of discovery of issues relating to data validity and reliability, it is important that their potential impact on patient safety and product quality and on the reliability of the information used for decision-making and applications are examined as matters of top priority.

Respective health authorities shall be notified if the investigation identifies the material impact on patients, products and reported information or on application dossiers [10]. Data Reliability Auditors are responsible for performing scheduled and unscheduled data reliability assessments (DRAs) and inspections at sites as per authorized data reliability checklists with the help of trained data reliability auditors

Auditors are responsible for ensuring compliance related to the discrepancies identified during the inspection

Common Data Integrity Issues
- **User privileges:** The system configuration for the software does not adequately define or segregate user levels and users have access to inappropriate software privileges such as modification of methods and integration.
- **Common passwords**: Where analysts share passwords, it is not possible to identify who creates or changes records, thus the A in ALCOA is not clear.
- **Computer system control:** Laboratories have failed to implement adequate controls over data, and unauthorized access to modify, delete, or not save electronic files is not prevented; the file, therefore, may not be original, accurate, or complete. [1]
- **Audit Trail capture:** FDA recommends that audit trails capturing changes to critical data be reviewed with each record and before final approval of the record.
- Audit trails subject to regular review should include, for example, changes to finished product test results, sample run sequences, sample identification, critical process parameters [12].
- Overwriting
- Runs that have been aborted
- Testing into compliance
- Deleting data
- Backdating
- Altering data

Expected Approach: Expectations have been communicated by the regulatory agencies in a variety of forms, including regulations and guidance documents from the USFDA, MHRA, EMA, and WHO [23].

Data integrity requirements equal to paper (manual) and electronic data. Manufacturers and analytical laboratories should be aware of reverting from automated/computerized to manual/paper-based systems will not in itself remove the need for data integrity controls. This may also constitute a failure to comply with Article 23 of Directive 2001/83/EC, which requires an authorization holder to take account of scientific and technical progress and enable the medicinal product to be manufactured and checked by means of generally accepted scientific methods. Designing systems to assure data quality and integrity systems should be designed in a way that encourages compliance with the principles of data integrity. For examples: Attribution of actions in paper records should occur, as appropriate, through the use of Initials, full handwritten signature or personal seal [5]

Expectations for Electronic: Designing and configuring computer systems and writing standard operating procedures (SOPs), as required, that enforce the saving of electronic data at the time of the activity and prior to proceeding to the next step of the sequence of events (e.g. controls that prohibit generation and processing and deletion of data in temporary memory and that instead enforce the committing of the data at the time of the activity to durable memory prior to the next step in the sequence),
- Use of secure, time-stamped audit trails that independently record operator actions,
- Unique user logons that link the user to actions that create modify or delete data or electronic signatures, (either biometric or non-biometric).
- Electronic signature and record-keeping requirements in 21 CFR part 11 apply to certain records subject to record requirements set forth in the regulations (i.e., 210, 211, and 212) [12].
- Outline back-up copies of original electronic records stored in other location as a safeguard in case of a disaster that causes loss of the original electronic records,
- controlled and secure storage areas, including archives, for electronic records;

- Access to clocks for recording timed events
- Accessibility of batch records at locations where activities take place so that ad hoc data recording and later transcription to official records is not necessary
- Control over blank paper templates for data recording
- User access rights which prevent (or audit trail) data amendments
- Automated data capture or printers attached to equipment such as balances
- Proximity of printers to relevant activities
- Access to sampling points (e.g. for water systems)
- Access to raw data for staff performing data checking activities.

Sharing login ID: Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand. [22]

Electronic signature: Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks. Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following:
a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.
b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.
c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.
d) Limiting system access to authorized individuals. [22]

Expectations for Paper: Paper record should be legible, traceable and permanent controls it includes.
- Use of permanent, indelible ink, use of single-line cross-outs to record changes with name, date, and reason recorded and
- No use of pencil or erasures,
- No use of opaque correction fluid or otherwise obscuring the record;
- Controlled the issuance of bound, paginated notebooks with sequentially numbered pages (e.g. that allow persons to detect missing or skipped pages)
- Controls for retention of original paper records or certified true copies of original paper records include, but are not limited to:
- Expectations for paper controlled and secure storage areas, including archives, for paper records;
- Designated paper archivist(s) who is independent of GxP operations as is already required by GLP guidelines;

Back up of data: A backup means a copy of one or more electronic files created as an alternative in case the original data or system are lost or become unusable (for example, in the event of a system crash or corruption of a disk). It is important to note that backup differs from archival in that backup copies of electronic records are typically only temporarily stored for the purposes of disaster recovery and may be periodically over-written. Backup copies should not be relied upon as an archival mechanism [9]
It is a true copy of the original data that is maintained securely throughout the records retention period. For example, the backup file shall contain data (including associated metadata) and shall be in the original format or in a format compatible with the original format and shall be maintained for the purpose of disaster recovery. The backup and recovery processes must be validated disposal of original record [10]

Audit trial reviewed: An audit trail is a process that captures details such as additions, deletions, or alterations of information in a record, either paper or electronic, without obscuring or over-writing the original record. An audit trail facilitates the reconstruction of events relating to the creation, modification, or deletion of an electronic record, Chronology: who, what, when, and why of a record. Track actions at the record or system level [12]. For example, in a paper record, an audit trail of a change would be documented via a single-line cross-out that allows the original entry to be legible and documents the initials of the person making the change, the date of the change and the reason for the change, as required to substantiate and justify the change. Whereas, in electronic records, secure, computer-generated, time-stamped audit trails at both the system and record level should allow for reconstruction of the course of events relating to the creation, modification and deletion of electronic data. Computer-generated audit trails shall retain the original entry and document the user ID, time/date stamp of the action, as well as a reason for the action, as required to substantiate and justify the action. Computer-generated audit trails may include discrete event logs, history files, database queries or reports or other mechanisms that display events related to the computerized system, specific electronic records or specific data contained within the record [9].

Process flow mapping in data integrity: To balance the focus on electronic data that data integrity tends to drive, a useful approach is to map the workflow within the laboratory, to identify and list all the steps performed for each analytical technique (from sample receipt to approval of results) and each laboratory operation. For each step [1], the mapping should identify:
- What actions are performed
- How those actions are performed
- How they are recorded
- Any decisions made
- The extent to which the process is manual or automated
- The possible risks associated with the step (e.g., how could fraud be prevented or detected).

Types of Error: Overwriting of electronic raw data and paper document is common error until acceptable results not found [16]. Human errors may be a data entered by mistake ignorance (not being aware of regulatory requirements or poor training) willfully (falsification or fraud with the intent to deceive). Selection of good or passing results to the exclusion or poor

or failing results, unauthorised changes to data post-acquisition, errors during transmission from one computer to another, changes due to software bugs or malware of which the user is unaware, Hardware malfunctions, technology changes making an older item useless, old records may become unreadable or difficult to understand [16].

The reason of issue: There is various reason for data integrity issue some of them write the following:
1. No raw data to support records or loss of data during changes to the system
2. Creating inaccurate and incomplete records
3. Test results for one batch used to release other batches
4. Backdating
5. Discarding data repeated tests, trial runs, sample runs (testing into compliance)
6. Changing integration parameters of chromatography data to obtain passing results
7. Deletion/manipulation of electronic records or fabricating of data
8. Turning off audit trail
9. Sharing password
10. Inadequate controls for access privileges
11. Inadequate/incomplete computer validation.
12. Activities not recorded contemporaneously
13. Employees that sign that they completed manufacturing steps when the employees were not on premises at the time the steps were completed

Conclusion
In the pharmaceutical industry, data integrity play an important role to maintain the quality of a final product because the poor practice can allow the substandard product to reach patients, so it's necessary for an existing system to ensure the data integrity, data traceability, and reliability. On quality bases, data integrity is a critical component of a Quality System. Quality data provides the base for the confidence of the company to utilize correct data to operate in accordance with regulatory requirements.

Data integrity is critically important to regulators for various reasons, including patient safety, process, and product quality. The integrity and trustworthiness of the data provide a baseline for the regulators' opinion about the company.

It's also the responsibility of the manufacturer to prevent and detect poor data integrity practices which occur due to the lack of quality system effectiveness. Quality Risk Management (QRM) approach can prevent, detect and control potential risks where data is generated and used to make manufacturing and quality decisions, ensure it is trustworthy and reliable.

Abbreviations
- FDA: Food and Drug Administration
- MHRA: Medicines and Healthcare Product Regulatory Agency
- PQS: Pharmaceutical Quality System
- GMP: Good Manufacturing Practice
- SISPQ: Strength, Identity, Safety, Purity, and Quality
- SME: Subject Matter Expert
- DRA: Data Reliability Assessment
- ICH: International Conference on Harmonization
- GLP: Good Laboratory Practice
- GCP: Good Clinical Practice
- GXP: Good Practice Guides

- cGMP: Current Good Manufacturing Practice
- IT: Information Technology
- LIMS: Laboratory Information Management System
- SAP: Systems, Applications, and Products
- WHO-NOC: World health Organization – Notice of Concern
- BMR: Batch Manufacturing Record
- BPR: Batch Packaging Record
- SOP: Standard Operating Procedure
- COTS: Computer Off-The-Shelf
- CFR: Code of Federal Regulations
- RPN: Risk Priority Number
- CAPA: Corrective Action and Preventive Action

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