IX ALL-RUSSIA GMP CONFERENCE

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

Data integrity: Implementation in practice & regulatory expectations

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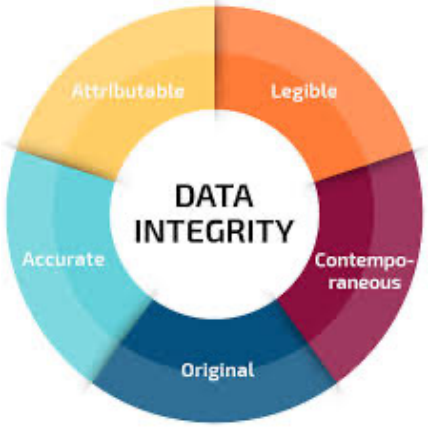
Data integrity

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).



- **Importance of controlling records**
- Records are critical to GMP operations
- Managing and controlling master documents is necessary to ensure that the risk of someone inappropriately using and/or falsifying a record 'by ordinary means' (i.e. not requiring the use of specialist fraud skills) is reduced to an acceptable level.

- **Regulatory expectations**
- All documents should have a unique identifier (including the version number) and should be checked, approved, signed and dated.
- Documents should be stored in a manner which ensures appropriate version control.
- Updated versions should be distributed in a timely manner.
- Obsolete master documents and files should be archived and their access restricted

Specific Data Integrity Considerations for Paper-Based Systems

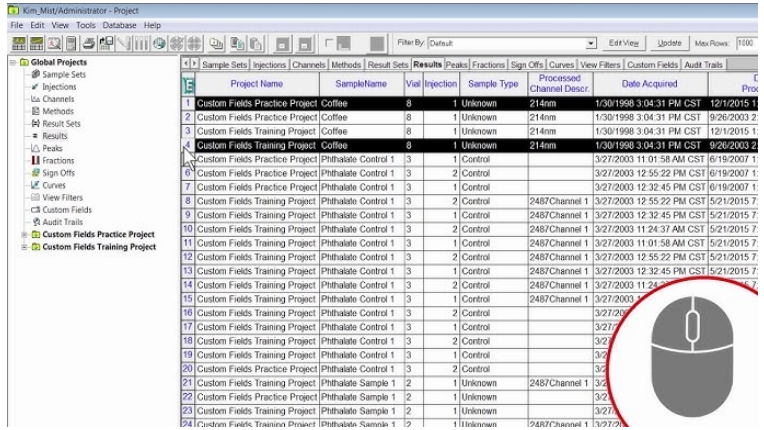
- Document issuance should be controlled by written procedures
- An index of all authorised master documents, (SOP's, forms, templates and records) should be maintained within the Pharmaceutical Quality System
- Records should be available to operators at the point-of-use and appropriate controls should be in place to manage these records.
- The records should be properly filled out, contemporaous, enduring and signed and dated using a unique identifier that is attributable to the author
- Corrections to the records should be made in such way that full traceability is maintained.
- Verification of records should be done by appropriately qualified and independent designated personnel.
- The retention period of each type of records should (at a minimum) meet those periods specified by GMP/GDP requirements.
- All hardcopy quality records should be archived in secure locations to prevent damage or loss.
- A documented process for the disposal of records should be in place to ensure that the correct original records or true copies are disposed of after the defined retention period.

Specific Data Integrity Considerations for Computerised Systems

- The qualification and validation of computerised systems should be performed in accordance with the relevant guidelines
- Validation should be supplemented by appropriate administrative and physical controls, as wells as training of users
- Regulated users should have an inventory of all computerised systems in use
- Computerised systems should be evaluated periodically in order to ensure continued compliance with respect to data integrity controls
- Interfaces should be assessed and addressed during validation to ensure the correct and complete transfer of data
- User access controls shall be configured and enforced to prohibit unauthorised access to, changes to and deletion of data
- Electronic signatures used in the place of handwritten signatures should have appropriate controls to ensure their authenticity and traceability to the specific person who electronically signed the record.
- Audit trail functionality should be verified during validation of the system to ensure that all changes and deletions of critical data associated with each manual activity are recorded and meet ALCOA+ principles

Specific Data Integrity Considerations for Computerised Systems

- Audit trail functionality should be verified during validation of the system to ensure that all changes and deletions of critical data associated with each manual activity are recorded and meet ALCOA+ principles.
- Audit trail functionalities for electronic-based systems should be assessed and configured properly to capture any critical activities relating to the acquisition, deletion, overwriting of and changes to data for audit purposes.
- Systems should be designed for the correct capture of data whether acquired through manual or automated means.
- The company's quality unit should establish a program and schedule to conduct ongoing reviews of audit trails based upon their criticality and the system's complexity in order to verify the effective implementation of current controls and to detect potential non-compliance issues. These reviews should be incorporated into the company's self-inspection programme.



Source: PI 041-1 Good Practices for Data Management and Integrity in regulated GMP/GDP Environments

Data integrity

Thank you!

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