PDA
Parenteral Drug Association

Connecting People, Science and Regulation

What is Data Integrity?
Focus on Laboratory and Manufacturing Systems

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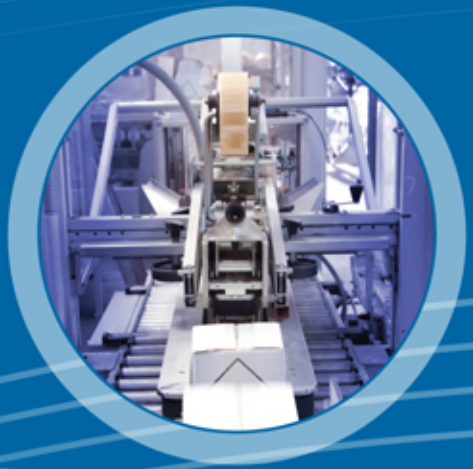

Learning Objectives

- What is Data Integrity?
- What is a Data Integrity Breach?
- Examples of Laboratory and Manufacturing System Data Integrity Gaps
- Managing Data Integrity Issues
- Data Integrity Warning Signs
- Summary

What is Data Integrity?

- What is Data?
  - Collection of facts
  - Recorded evidence of an activity
  - Numbers/Measurements/Observations
  - Calculations
- What is Meta Data?
  - Data about the data
    - What (Type of data / test / activity)
    - Who performed activity
    - When (date/time of data generation)
    - Units of measure

Data Integrity

Data integrity refers to the quality and accuracy of data over the entire data lifecyle

Key attributes of Data Integrity:

- **A Attributable**
- **L Legible**
- **C Contemporaneous**
- **O Original**
- **A Accurate**

Data Integrity Breach

- Not recording data accurately
- Manipulating data
  - Misrepresenting facts
  - Copying (Recreating) existing data as new data
  - Backdating/adding or modifying data after the fact
- Fabricating data
- Discarding data
- Omission of material facts

Laboratory System Examples

- Inadequate system controls and security
  - Sharing passwords
  - Privileges given to users or reviews that allows them to manipulate/overwrite/delete data
  - Abuse of administrative access and/or granting administrative access to users and reviewers
- Raw data not recorded or maintained
    - Not maintaining printouts for sample weights
- Data generated but not reported
  - Use of test/trial injections
  - Saving Data to other file folders or projects
- Test results for one batch used to release multiple batches

Laboratory System Examples

- Lack or inadequate traceability of samples and/or test results to samples
- Use of lab system features that allow for data to be overwritten/"saved as"
- Stand alone systems where data is stored on PC allowing data to be deleted, renamed or changed date/time stamp
- Manual integration
  - Changes to processing parameters impacting peak areas
  - Changes to sample weights/standard weights/concentrations

Manufacturing System Examples

- Data not recorded by personnel performing task
  - Activity started by one person and finished by second person
    - Batch record does not list both individuals
- Data recorded after the fact
  - Time and attendance records or area access records conflicting with date/time of activities

Manufacturing System Examples

- Product manufactured on a filling line but not recorded in the filling log and no batch record on file
  - Mechanisms for Detection:
    - Observation
    - Material reconciliation from point of receipt to destruction
    - System files and audit trails on filling line showing runs that cannot be reconciled against batch records
    - Discrepancies in production metrics (Manpower or material usage/ costs vs. volume/output)
    - Lack or reconciliation of batch number issuance

Managing Data Integrity

- Use your Quality System to manage and mitigate risks identified
- Create a safe culture of transparency
- Conduct thorough investigations
  - Include product/application impact assessments
  - Extend investigations where appropriate
  - Be cautious of making any assumptions
    - Investigate to “find” vs. writing to “prove”
- Create clear procedures and utilize Risk Management
  - All risks are not created equal; establish rationale/justification
  - GMP good documentation error would not be treated the same as a more severe intentional/fraudulent act

Data Integrity Warning Signs

What Risk factors can be monitored to predict data integrity gaps?

- Discrepancies between Workload and Capacity
  - Equipment
  - Facility
  - Personnel
- Lack of documented deviations/incidents/OOS reports
- Lack of documented data integrity issues
  - Not reported and/or documented in your quality system
    - Use of “audit” reports vs. investigations or deviations
- Separate quality system or laboratories for “other” markets
- Lack of knowledge and procedures governing computerized systems including audit trails

Data Integrity Warning Signs

What Risk factors can be monitored to predict data integrity gaps?

- Gaps in Data Governance Programs
  - Are there established mechanisms for routine monitoring of Data Integrity Gaps
  - Are there built-in deterrents?
  - Do process controls provide for easy detection of authentic records and/or Data Integrity gaps?
  - Are these programs in place, adequate and followed?
  - How is transparency promoted?
    - Rewards and recognition to promote transparency

Summary

- Create a culture and environment fostering the detection, reporting and management of Data Integrity issues.
- If you are aware of, discover or witness a practice that is a breach of Data Integrity regulations or policy, follow your quality system.
- Awareness of the issues is key and prompt action will reduce your risk of regulatory sanctions and consequences.