



DATA INTEGRITY

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DATA INTEGRITY (from PDA'S Code of Conduct)

3.5 Auditing of Quality System for Data Integrity

3.5.1 The company shall establish and execute as part of its internal audit program provisions to periodically evaluate the elements of the quality system used for collecting, analyzing, reporting and retaining information and data.

3.5.2 The audit program will include periodic audits to confirm adherence to established requirements for data integrity. Such shall utilize independent auditors who are qualified by education, experience and training to evaluate data integrity.

3.5.3 Employees who conduct data integrity audits will maintain a current awareness of applicable laws, regulations and legislative directives that pertain to documentation and record keeping requirements.

Data Integrity: A L C O A



Attributable. uniquely identified as executed by the originator; traceable; who/when

Legible, traceable and permanent data are readable, understandable, and allow a clear picture of the sequencing of steps or events in the record so that all GXP activities conducted can be fully reconstructed by the people reviewing these records. Record design (e.g., enough space to fill out needed information).

Contemporaneous data are data recorded at the time they are generated or observed.

Original data: the first or source capture of data; reviewed, raw data.

“accurate” means data are correct, truthful, complete, valid, complete and reliable

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