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8.2 Making Corrections

- 8.2.8 Significant error that is due to a deviation shall be reported as a deviation per SOP QA-041, *Deviations*. Documentation errors that have no actual impact on testing, production, storage, etc. do not require deviation, but require timely correction with appropriate reference and/or explanation (example: when batch record is issued by QA and lot or part number was corrected prior to providing the document to manufacturing, deviation is not required; error must be corrected as outlined in this procedure and all related logs and records must be reviewed/verified for accurate information. When error was found and corrected after the document was provided to manufacturing for use, deviation is required).
- 8.2.9 Sign/initial and date the correction.
- 8.2.10 Signatures and initials on records shall be verified/identified from the *Official GMP Signature List* (Form 079), which is maintained by QA. All PPL-SD personnel are required to sign and initial the log within the first 2 weeks of employment with PPL-SD.

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8.3 Criteria and General Requirements for data integrity and Security

8.3.1 All GXP must follow the ALCOA+ principles.

8.3.2 Definition of ALCOA+:

A	Attributable	Identification of the individual who performed the activity.
L	Legible	Data can be read with any associated metadata. Original data that has been changed or modified should not be obscured.
C	Contemporaneous	Documented (on paper or electronically) at the time of an activity.
O	Original	Written observation, printout, certified copy, or original electronic record including all metadata of an activity.
A	Accurate	No errors or editing without documented amendment.
+	Complete	All data present (no omission, no deletion) including original data, processed data, calculation, metadata, associated paper record (if hybrid system) etc.
	Consistent	All elements are in logical sequence and do not contradict each other. Data file is date and time stamped in the expected order.
	Enduring	Recorded on authorized media that can last throughout the record retention period.
	Available	The complete collection of records can be accessed or retrieved for review over the lifetime of the record.

8.4 Standard Date and Time Format

8.4.1 Date format: MM/DD/YY or MM/DD/YYYY, where two digits are recorded for the month and the day, and two or four digits are recorded for the year. For example June 01, 2008 will be written as: 06/01/08 or 06/01/2008. Slashes and dashes are equally accepted: 06/01/08 or 06-01-08.

Note-1: Documents signed for customers, auditors, inspectors, etc. other date format may be used, depending on customer/auditor requirements. Example: 01 June, 2008, or June 01, 2008, or 01-Jun-2008.

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Note-2: Some PPL Global electronic systems (Qumas, ERP/AX system, etc.) may have their own date format and approved for use at PPL-SD. Example: 01 June, 2008, or June 01, 2008, or 01-Jun-2008.

- 8.4.2 Time format: Meridian time: one (1) or two (2) digits to indicate the hour (1 to 12) followed by a colon, then by two digits to indicate the minutes, and finally with the units AM (morning) or PM (afternoon): For example: 8:00AM, 8:00PM.
- 8.4.3 Document all activities in chronological order. Dates and times used to record these activities should have the same chronological order.