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Overview

Purpose	This work instruction outlines the principles for Good Documentation Practices (GDocP) applicable to all quality documents, both paper and electronic. GDocP is critical to the integrity of the data and records supporting product quality and safety and demonstrates control over our products and processes. This procedure is to be used in conjunction with Document and Record Controls procedure.
Scope	This work instruction pertains to all [Company] locations and personnel responsible for the creation, review, approval, and maintenance of quality documents. Out of Scope: • Non-quality documents and records
Roles	All associates (internal and external) responsible for the creation and/or maintenance of quality related data or records are responsible for complying with this process. Refer to process details section for specific responsibilities.

Terms and Definitions

Term	Definition
ALCOA+	The acronym ALCOA defines that data should be Attributable, Legible, Contemporaneous, Original, and Accurate. In addition, the "+" in ALCOA+ guidance recommends that data is also Complete, Consistent, Enduring, and Available.
Audit Trail	Detailed chronological record whereby quality records, project details, or other data are tracked and traced.
Data	Factual recorded information such as times, dates, and disposition.
GDocP	Good Documentation Practices Note: GDP may also be seen used as an alternate abbreviation for Good Documentation Practices, but to maintain the distinction between Good *Documentation* Practices and Good *Distribution* Practices (also abbreviated GDP), we will use the industry recommended abbreviation GDocP.
GxP	GxP is a general abbreviation for the "good practice" quality guidelines and regulations. The "x" stands for the various fields, for example good manufacturing practice, or GMP. "C" or "c" is sometimes added to the front of the initialism to indicate "current", for example cGMP.

Term	Definition
Original Data	Data that shows or proves that something exists or is true. Objective evidence can be collected by performing observations, measurements, tests, or using other suitable methods.
Quality records	Documented evidence that processes are executed according to the quality systems plan and requirements, such as inspection results, audit results, calibration data, data sheets, etc.

Process Details

1. Expectations

Step	Role	Action
1.1.	All Associates	Documented information in quality records are expected to explain: • What was done • When it was done • How it was done • Who did it

2. Data Collection and General GDocP Principles

Step	Role	Action
2.1.	All Associates	• Avoid vague/confusing meanings that could prevent understanding of the information. • Do not use “ditto” marks (“) to indicate the same entry in the record as above / previous. • Indicate that not completing a field/space is deliberate, e.g. by ‘not applicable’ with a rationale. • Measurements should be recorded using the correct unit of measure and significant digits.

3. Signatures

Step	Role	Action

3.1.	All Associates	• Signatures should include the full name of the person, to identify/clarify the person signing and the date of signature.
		• If signature delegation is required, the appropriate delegation should be documented, if possible, as part of the document.
		  ○ The person being delegated to should have the necessary skill set to approve the document, such as someone who has completed the same level of training.
		  ○ Delegation to supervisor level or above does not require written delegation.
		  ○ If delegation is applicable, this delegation can be identified as part of the signature statement. Example: John Doe signing for Joe Smith.
		• Signatures and dates are required with the actual date the record is signed. No backdating or no post-dating is permitted.
		• When documenting with initials only, document at minimum the first letter of your first name and the first letter of your last name. Include the date on the document/record.
		• Once a complete signature has been entered on a page, initials may be used in lieu of a complete signature. Anyone writing an employee initials other than his/her own is considered to be falsifying a record; this is not permitted.
		• For the purpose of recording meeting attendance, by remote attendees, unable to physically sign the applicable attendance record, it is permissible for the meeting host to record their attendance as such.
		  ○ The meeting host must include their initial/date or signature/date on the document or via electronic means as a testimony of that individual's presence during said meeting.

4. Notes

Step	Role	Action
4.1.	All Associates	• Do not use post-it notes as part of official paper records. • Do not make notes on signed-off / authorized / executed test protocols / reports or records; this includes handwritten notes on electronic records, as this practice may lead to confusion and questions.

5. Templates and Forms

Step	Role	Action
5.1.	All Associates	When documents are created or revised, always access the official (QMS) document control source for the latest version of the templates/forms to ensure the most current version is used. Not doing so may lead to non-compliances as a revision to the template/form may include critical changes to meet regulatory requirements.

6. Data Entry

Step	Role	Action

6.1.	All Associates	• Data is recorded immediately after the observation has taken place and shall not be falsified.
		• Documents must be legible and completed in permanent ink.
		  ○ Pencil/erasable ink is not permitted.
		  ○ Red ink is permitted only for use in markups.
		• All data entries should be dated on the date of entry and signed or initialed by the person entering the data.
		• Dates should be recorded using the same format throughout the document.
		• When editing/working in a record/document, verify that the intended record / document was selected for editing/data entry. This is particularly important when multiple records are being worked on at the same time.

Step	Role	Action
		• Use caution when entering numbers, to ensure that digits are not transposed or omitted. • When multiple records are being worked on at the same time, use caution to ensure that content intended for one record is not inadvertently documented in another (wrong) record. • Clearly indicate the date the activity was performed and the date the activity is recorded on the document. • Write the information in each required field. Do not cross-out multiple lines in a table and add a single entry. Multiple lines can be crossed-out only to indicate that a section or part of a document is not applicable.

7. Corrections

Step	Role	Action
7.1.	All Associates	• When correcting an error (spelling error, typos), the original record must remain legible. The original entry must not be written over with another letter or number. If the correction of the error is not obvious (self-explanatory), provide a concise explanation for the correction. • A voided or rewritten original document is filed with the new document to which it relates. Alternately, traceability from the new document to the original must be provided. The person involved signs and dates the document and records the reason for voiding or rewriting the document. • Correcting errors on paper documents requires considerations to ensure that the change is clear and does not obscure the original entry. It is necessary that the original entry is still readable, otherwise one is suspected of tampering. • Draw a single line through the entire entry error, add the correct entry, add the signature and name the first time on the page or your initials/employee number subsequently (so that it is clear the correction is deliberate) and date (record of when the change was made). Do not backdate or forward-date the entry. • Do not use correction fluid or correction tape. • Do not make multiple cross-outs (scribble out) to obscure the original data.

Step	Role	Action
		• Record the correction close by the error. If the corrected information cannot be written next to the original entry, write it in the margin or available space nearby and designate by use of an asterisk (*) or a circled number to identify. Use two asterisks if another correction with an asterisk is on the same page. • If the record becomes too congested with corrections, an attachment may be used, however the original record should indicate the number of pages attached and the attachment should reference the original record (cross-reference). • Sign and date the change (do not back-date or forward-date the entry) Example: **Procedure(s) / Work Instruction(s) / Other** / **Document #** (as applicable) Cybersecurity, Rev. ~~5.00~~ * 6.00 — A04 ~~Product Cleaning Controls~~ ** Product Cleanliness Controls — QP-25 * = Corrected revision level. L.Bello, 2024-Mar-26 ** = Corrected title misspelling. L.Bello, 2024-Mar-26

8. Blanks

Step	Role	Action
8.1.	All Associates	• Do not leave blank data fields/unused pages when filling out a record, as this may lead to questions of missing data. All fields on a record should have an entry, even if it is “NA” (not applicable). It is recommended to provide a rationale for why the section is not applicable. • For paper records, it should be ensured that data cannot be added at a later date (as original data) without appropriate record correction and indications that not completing a field/space is deliberate. • The following examples are relevant: ○ Cross out the field/section with a single diagonal line, write “N/A” above the line and sign/initial and date to show that the field/space is not applicable

References

Number	Title
[ID#]	Document and Record Controls procedure
[ID#]	Document and Record Controls work instructions

Appendix A

ALCOA+ Definitions and Examples of Non-Conformances

*Some of these examples may fall into multiple categories

Principle	Definition	Examples of Non-Conformance*
Attributable	Information is linked to the data source. Attributable to the person or system generating the data Linked to the source of the data	• Missing Signature • Missing ID number for equipment that provides the source data • Handwritten corrections that are not signed • Recording data using another's user's ID and password
Legible	Human-readable Original data and any subsequent modifications are not obscured	• Handwritten data that is illegible • Screen prints that are illegible • Blurred, faint or obscured copies of records that are illegible • Write-overs or cross-outs that obscure original data
Contemporaneous	Information is recorded at the time of data generation, event, or observation	• Inspection data not documented at the time of observation • Back dating or predating records • Cleaning or Preventive Maintenance activities are not recorded stepwise but rather after all activities have been completed
Original	Data is not a copy, unless 100% verified as true and exact. Source of data is available. Original data is the first recording of data, or a "true copy" which preserves content or meaning	• Data written on scratch paper or another unofficial document and then transcribed to a controlled document • Using a copy in place of the original without verifying that the copy is a true and accurate representation of the original. • Discarding original records or test results • Deleting original data from computerized systems before its retention period and no true copy is available.
Accurate	Verified as correct via repeatable calculation, algorithm or analysis Free from errors No editing performed without documented amendments Conforming to truth or standard	• Failure to record data with the correct number of significant digits • A completed record is not independently reviewed for accuracy

Principle	Definition	Examples of Non-Conformance*
Complete	All data are present. No data has been selectively excluded. All data, and relevant metadata, including any repeat or re-analysis performed	• Failure to record date with signature • Failure to record a reason for a non-obvious change • Failure to record data such as last piece inspection results • Failure to record unit of measure • Blank fields or rows not marked N/A
Available	Accessible anytime by anyone who needs the data Available and accessible for review, audit, or inspection throughout the retention period	• Loss of work order • Lost pages or forms from work order • Failure to use a validated location to store electronic records
Consistent	Data are free from variation and non-contradictory Application of good documentation practices throughout any process The application of data and time stamps in the expected sequence	• Data not documented in proper sequence • Inconsistent date or time format • Recording data on a previous or obsolete version of a form
Enduring	Data are preserved and retrievable during its lifetime according to the data type retention period Recorded in a permanent, maintainable form for the retention period	• Use of gel pens or other non-permanent ink that can smear or fade with time • Use of pencils or erasable ink • Electronic files are not readable after change of IT technology

Appendix B

Common Signature Label Definitions

Signature spaces on records will include the significance of the signature, and when appropriate the signatory's title, department, or function.

Signature Label	Definition
Approved By	Person performing a data review to determine the data acceptability; for example, conformity to applicable procedure, calculations, data sets, test results, summary conclusions, etc.
Authored By / Written By	Person who compiles the data, information, or results in a report or document
Calculated By	Person performing the computation of data
Checked By / Verified By	Person verifying accuracy of the data, record, or other information. This will not be the same person who collected the data or performed the task. Verification can be done by another person, automated system, or validated data source
Observed By / Witnessed By	Person observing the operation and/or task who is not responsible for the conduct of the task (independent)
Performed By	Person performing the task, operation, test, inspection, etc.
Recorded By	Person recording (but not performing) the task, results, etc. If "Recorded By" is used in the record, the person performing the task or test will also be documented.
Released By	Person certifying that all requirements have been met and documented and that the product/material is acceptable for use or distribution.
Reviewed By	Person certifying that the data is accurate and complete and in compliance with applicable specifications and/or procedures
Supervisor or Supervised By	Supervisor or designee responsible for the operation to which the record pertains. For documents containing a disposition, the signature certifies the correctness of the recorded disposition

Revision History

Rev.	Revision date	DCR #	Description of change(s)
A	15-Sep-2022	DCR-XXX-023	Initial creation
B	25-Apr-2024	DCR-XXX-051	Updated to add Appendix B "Common Signature Label Definitions" and example in step 7.1.

Approval

Name, Date, and Signature	Title
	Approver
	Reviewer
	Author / Editor