BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title:	**Good Documentation Practices**
SOP Number:	**21409**
Revision:	**05**

TABLE OF CONTENTS

1. PURPOSE

This SOP defines the requirements for Good Laboratory Practices (GLP) and/or Good Manufacturing Practices (GMP) documentation to ensure that documents are legible, understandable, reproducible, permanent, and traceable.

2. SCOPE

This procedure applies to Biopharmaceutical Development Program (BDP) personnel completing documentation subject to regulatory review. BDP documentation includes, but is not limited to, batch production records, forms, logbooks, and laboratory notebooks.

3. RESPONSIBILITIES

3.1 Director of Regulatory Compliance

- Defines this procedure.

3.2 BDP personnel

- Complies with this Procedure.

3.3 BQA

- Provides Quality oversight.

4. CHARACTERISTICS OF GOOD DOCUMENTATION PRACTICES (ALCOA)

- **Attributable** - data generated or collected must be traceable back to the individual who generated the information.
- **Legible** – documentation must be easy to read and permanent.

- **Contemporaneous** - The results, measurements, etc. must be recorded at the time the work is performed.
- **Original** - original or source data are the record, report, notebook etc. where the data point was initially recorded.
- **Accurate** – documents must contain complete and accurate data and account of events.

5. GOOD DOCUMENTATION PRACTICES

5.1 Attributable

5.1.1 Entries should be traceable to the individual(s) performing the activity. Each notebook page, record, data form, etc., should be signed/initialed and dated, as required.

5.1.2 Signatures and/or initials on a record or document identify who was responsible for performing the work and who was responsible for checking or verifying the work.

5.1.3 Signatures and initials must be unique and legible. There must be a document available that correlates the person's initials with his/her signature and printed name. This log is maintained in the eDMS. See **SOP 21406 - Personnel Signature and Initial Verification System**.

5.1.4 Do not sign for someone else's work without authorization.

5.1.4.1 Refer to **SOP 21007** - **Alternate Signature Authority** for details on this policy.

5.1.4.2 The approved alternate would sign/initial the document, date it, and indicate the name of the person who was originally designated to sign the document.

For example, Tom Johnson was designated to sign Document A on September 20, 2023; he is unavailable, and Lori Jones is his approved alternate. She would sign Document A "Lori Jones, 09/20/23 for Tom Johnson."

5.1.4.3 If a document is being signed electronically, then the "for" is not required.

5.1.5 Data entries may require either a "Performed By" or "Recorded By" signature/initials to indicate the type of information being recorded. The date performed or recorded must be included when prompted on the document.

5.1.5.1 "Performed By" indicates that the step was performed by the individual signing/initialing the record.

5.1.5.2 "Recorded By" indicates that the entry or series of entries were written by the individual signing/initialing the record.

5.1.6 Operations/Steps requiring a second person's independent review (verification) of the operations conducted must be signed/initialed and dated as the operation is performed.

5.1.6.1 Critical steps or operations that require this type of "Verification" include calculations, measurements, addition of components, and other critical actions as defined in the Master Production Record (MPR).

5.1.6.2 The second person’s signature/initials indicates that they have personally observed/witnessed the entire step being performed and has accepted the responsibility for assuring that the entire step was performed completely and correctly.

5.1.6.3 Verifications of calculations attest that the calculation has been checked and the same result obtained. Calculations must be verified prior to proceeding with the next step that uses the results of the calculation.

5.1.7 If an operation requires a “Reviewed By” signature, it must be signed/initialed and dated at the time the review is performed. The reviewer’s signature/initials indicates that the data recorded has been checked for accuracy, completeness, clarity, and the need for any comments or explanations to the record have been made.

5.1.8 For GMP activities, use the approved form to document an activity. This allows the activity to be traceable to the process approved by BQA. Forms that are authorized for use are found in the eDMS and display information at the top left corner of the form that includes the form number, associated SOP number, revision level. This information is also on the info card in the eDMS.

5.2 Legible

5.2.1 Entries in records must be legible to reviewers of the document. Any illegible entries must be corrected per Section 5.5.9.

5.2.2 Signatures and initials must be clear enough to identify an individual who signed a record and must match the signature and initials on file with BQA.

5.2.3 Do not "overwrite." Overwriting can cause difficulty when identifying the intended data. In the case of an accidental overwrite, correct as described in Section 5.5.9 of this SOP.

5.2.4 Black and blue ink pens must be used to record data. Pencil and other colored ink are not permissible. The recorded data must be dark enough to be legible and to be copied or scanned by machines. Red ink is reserved to suggest changes to the revision of a drawing.

5.2.5 Some pens are more prone to smearing and sensitive to water and alcohol or do not work well on waterproof paper and are therefore not recommended (e.g., gel ink pens). Felt tip or markers are also not recommended as they can spread on the page decreasing legibility.

5.3 Contemporaneous

5.3.1 Date records with the date on which the data is entered.

5.3.2 Entries into documentation and records must be made as each step is completed, not after the entire process is performed.

5.3.2.1 Continuous operations (e.g., performing aseptic processing in a hood) that may jeopardize the work being performed should the operator repeatedly stop to sign entries into a BPR, may be signed at the end of the operation by the operator. In such cases, verifiers, where required, shall initial and date each step as the written entry is completed.

5.3.3 Date and Time Format

5.3.3.1 Follow all requirements of a record if the date format is specified. (e.g., batch record, form). In the absence of a requirement, any method where day, month, and year is clear is acceptable.

Periods, dashes, or slashes can be used to delineate the date. If abbreviations of months are used, they should be 3- or 4-character abbreviations.

In the event only the month and year are recorded, use the full year to ensure clarity. (e.g., March 2024, or 3/2024 not 3/24)

PREFERRED FORMAT EXAMPLE for April 6, 2024:

06APR2024

5.3.3.2 For time, Military/24-hour standard with no colon is the preferred format used to document time without an AM/PM abbreviation.

5.4 Original

5.4.1 Record data directly into the Batch Production Record (BPR), logbook and/or laboratory notebook, form, or other data collection record.

5.4.2 If procedures require transcription of the data to a paper record or data entry into a computer, reference the original raw data, if possible, and keep the original raw data as part of the batch record package.

5.4.3 Information that is attached to another record (data printout, charts, raw data) must be linked to that record by including (as appropriate) the document number, project/part number, lot number, and section number (as applicable) on each page of the attachment. Data printouts, charts, or other data attached to another record must also be initialed and dated by the person attaching this information.

Pagination via PDF can be used on electronic documents to capture the aforementioned information.

For example – QCTRs

5.4.4 For data that is spliced or taped-in to the record, the initials and date of the person adding the data should be written across the splice of pasted/taped-in data.

5.4.5 Should a photocopy of a record be needed (e.g., oven or autoclave chart), the individual making the copy will confirm that the copy is a true and exact reproduction of the original document. The copy will be stamped or labeled as “Copy” or “True and Exact Copy,” and the individual making this confirmation will initial and date the copy near the stamp.

5.4.6 Do not use “sticky” notes, or paper towels, etc., to record data. However, if they were used and they contain raw data, they must become part of the permanent record and be identified properly.

5.5 Accurate

5.5.1 Entries must accurately represent the data or activity. Activities must be completely documented so that events can be reconstructed at a later time (for example, for troubleshooting, trending, etc.)

5.5.2 Documentation must be written so that anyone versed in the general field can follow the document and reach the intended outcome. Avoid the use of terms, symbols, phrases, etc., that may not be understandable to other potential reviewers of the document.

5.5.3 Calculations must be documented and easy to follow. Use formulas or equations to show how results were obtained. Calculations must include units of measure, conversion factors, and equivalency factors.

5.5.4 Decimal values require a place holder zero in front for clarity.

Example: .23 g (incorrect) vs. 0.23 g (correct)

5.5.5 Units shall be included unless the field has units hardcoded.

5.5.6 Do not leave blank or unused spaces on documentation or records.

5.5.6.1 If data is not going to be entered, mark the space with N/A and initial and date this entry.

5.5.6.2 An unused page or a sequential group of unused spaces/data entry lines may be marked with a single line through all of the spaces and N/A written across this line (including initals/date).

5.5.7 The use of extra pages to record additional information is acceptable and encouraged as long as the pages are properly identified (see Section 5.4).

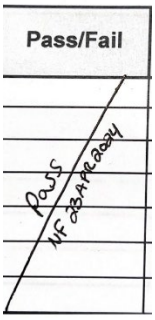
5.5.7.1 Raw data that is being attached to an additional page or to a page from a BPR or similar document must be attached firmly enough to preclude it from getting separated from the documents. Taping of the data to the page or placing it into a plastic sleeve are examples of acceptable methods.

5.5.8 Duplicate Entries

If the same entry needs to be made multiple times on the same record, a single line may be used, along with initials and date. One example is shown below.

Quotation/ditto marks are not permitted. Entries made on different days do not qualify as duplicate entries.

Duplicate Entry Example:



5.5.9 Appropriate Corrections (Explanation and Error Codes)

5.5.9.1 Documentation corrections must allow the original entry to remain legible. All corrections must be clear and legible and include initials/dates and the explanation for the change.

5.5.9.1.1 Do not use correction fluid or tape or cross out entries so that the original entry becomes unreadable. Erasures and overwriting of data are not allowed.

5.5.9.2 To correct an entry, the individual who made the mistake must line out the mistake by putting a single line through the entry, write the correct information next to the entry, provide an explanation for the change, and initial and date the new entry.

5.5.9.3 If there is insufficient room to write the correction next to the entry, then place a **numbered asterisk** or **circled number** next to the entry and record the correct information elsewhere on the page or use the comments section of a BPR or similar document.

5.5.9.4 Indicate the reason for the correction and/or use the Correction and Abbreviation codes in Attachment 1. It is recommended to circle the code so that it is easily distinguishable.

NOTE: If the reason for a change is not apparent, a written explanation must be included.

5.5.9.5 If any of the changes have a significant impact on the documentation or process they are used in, or result in (or cause) a deviation from specified requirements, bring it to the Supervisor's/Manager's attention.

5.6 Forward and Backward Traceability

5.6.1 Logbooks, laboratory notebooks, and data sheets have consecutively numbered pages for accountability. Do not remove pages from bound notebooks or logbooks.

5.6.2 Records must contain sufficient identifying information so that it is possible to trace the activity forward and backward in time to associated documentation. Record sample names, part numbers, lot numbers, and QC test request numbers.

5.7 Handling of Deviations

5.7.1 Data that represents a deviation from specified requirements must be registered as a deviation following **SOP 21301 - Deviations** or **SOP 21526 - Engineering Event Management.**

5.7.2 Data associated with a deviation must be identified in the record by cross-referencing the deviation number. This allows traceability to the record that documents the review, assessment of product impact, corrective/preventive action, and approval of the deviation.

5.8 Documentation and Records

5.8.1 Documentation and records must be stored in a manner that ensures integrity, security, and accessibility. Documents completed in accordance with GMPs and GLPs must be forwarded to BQAD for storage (see **SOP 21402 – Document Storage and Archival Process**).

5.8.2 Documentation is retained as per the requirements specified in **SOP 21407 Record Retention.**

6. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21007	Alternate Signature Authority
21301	Deviations
21402	Document Storage and Archival Process
21406	Personnel Signature and Initial Verification System
21407	Record Retention
21526	Engineering Event Management
22004	Managing Out-Of-Specification Test Results or Unexpected Test Results

7. ATTACHMENTS

Attachment 1: List of Error Codes

Attachment 1: List of Error and Comment Codes

Code	Definition	Information
LE	Late Entry	This is used to reflect the fact that a required entry was not made at the time the step was being completed and that data is being added at some point later. This code is not used to correct previously recorded data. **NOTE:** Backdating of information is not allowed. The entry must clearly show that information is being added currently and must not be signed with the date the work was performed.
CE	Calculation Error	Used to explain that recorded data is being revised as a result of a calculation or math error.
UR	Upon Review	Used to indicate that a change or addition is being entered as a result of a review by, including, but not limited to, supervisor, peer and QA review.
RE/EE	Recording Error/Entry Error	Used to indicate that a result is being corrected at the time of entry by the recorder (e.g., entering data into the wrong space or recording the wrong date, etc.).
SE	Sample Error	Used to indicate that data is being changed because the sample used to generate data was improperly collected, handled, etc. **NOTE:** This code would not be used if the assay was completed and generated an Out-Of-Specification result (OOS). **Refer to SOP 22004 - Managing Out-of-Specification Test Results or Unexpected Test Results.**
AE	Assay Error	Used to indicate that data is being changed because an assay was determined to have been improperly conducted. **NOTE:** This code would not be used if the assay was completed and generated an Out-Of-Specification result (OOS). **Refer to SOP 22004 - Managing Out-of-Specification Test Results or Unexpected Test Results.**
TE	Typographical Error	This code is used for spelling errors and changes in sentence structure, etc.
ES	Equivalent Substitution	Used when an equivalent substitution is being made for a requirement (e.g., raw material substitution, using a higher resolution balance to conduct weighing, etc.).
VD	Verbal Data	Used to indicate that data was recorded based on a verbal communication of information. The entry must include the names of the individual who provided the verbal data and who recorded it. (This is not the same as recorded by for work performed by one person and recorded by another.)
N/A, NA	Not Applicable	Used to indicate that a data record section will not be filled out or completed because the information is not applicable to the activity being conducted.