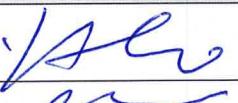


Document Authorization:

	Name	Date	Signature
Owner	Yuewei Zhao	10Apr2023	
Operation Management	Baozhong Zhao	10Apr2023	
Quality Assurance	Xibo Li	10Apr2023	

Changes from previous version:

Section	Summary of Changes	Change Control Number
ALL	1. New document	

1. PURPOSE

The purpose of this SOP is to describe the good documentation practices for recording and/or correcting data on documents.

2. SCOPE

This SOP encompasses all documentation related to the Synoligo personnel.

3. INTERNAL REFERENCES

Document ID	Title
QA001	Quality Policy

4. EXTERNAL REFERENCES

Document ID	Title
ISO9001	Quality management

5. RESPONSIBILITIES

Job Function and/or Department	Responsibility
All Personnel	It is the responsibility of all employees, including temporary employees and consultants, involved in recording, or reviewing information on documents to provide clear and consistent details on record keeping and follow good documentation practices to support the quality of work.

6. DEFINITION

Term	Definition
Current Good Manufacturing Practices (cGMP)	Regulations enforced by the FDA and provided for systems that assure proper design, monitoring, and control of manufacturing processes and facilities used in storage, manufacture, testing, release, and distribution of regulated products.

7. PROCEDURE

All records and data must meet the ALCOA+ principles:

- A** attributable to the person generating the data;
- L** legible and permanent;
- C** contemporaneous;
- O** original record (or true copy);
- A** accurate

The + relates to:

- C** complete;
- C** consistent;
- E** enduring, to ensure records are maintained and protected (secure from alteration, inadvertent erasures or loss);
- A** available, so that records are accessible when needed.

7.1. General Instructions

7.1.1. Record the entry per the document requirements. If a document calls for a signature, sign, and date the entry. The signature and initials when used to record an entry should be authentic and match the Signature Authentication Form on file with QA.

NOTE: All employees (including consultants and temporary) recording information on documents must have a signature on file.

7.1.2. Use blue indelible, ballpoint ink.

7.1.3. All entries should be clear and legible so that they are easily understood by anyone. DO NOT use a slashed zero (i.e. Ø) or "7" (i.e. 7) as it would indicate a cross out.

7.1.4. Date and time format

7.1.4.1. To ensure all recorded dates are clear and irrefutable, Synoligo applies the European standard recording dates: DDMMYY YYYY.

EXAMPLE: 01Jan2023

7.1.4.2. Military Time (24-Hour Format) is used: Two (2) digits to indicate the hour (00 to 23) followed by colon and two (2) digits to indicate the minutes (00 to 59).

EXAMPLE: 08:50, 18:20, 23:01, 00:01

7.1.5. Always record the displayed value and complete units of measurement where applicable (e.g., mm, mg, psig).

7.1.6. No handwritten changes or corrections should be made to an approved document. Any changes to an approved document should be handled through the change control process.

7.1.7. All copied documentation should be authenticated (initial and date) and marked as a copy.

7.1.8. All superseded documentation should be marked, signed, dated, and retained for traceability.

7.1.9. Do not approve, verify, or review your own work.

7.1.10. Instrument printouts should be properly labelled and attached to the parent document.

7.2. Making Data Entries

7.2.1. Records must be documented by the person doing the work/completing the form, at the time the data is being generated. Back dating and postdating are prohibited.

7.2.2. For manufacturing operations where a verification is needed, the person who performs the verification must verify the operation in real time/concurrently. This includes monitoring the operator's execution to ensure faithful execution, independent mathematical calculation, visual verification of instrument readout, and checking the accuracy of an entry.

7.2.3. Late entries should be avoided. Any late entry information must be objectively confirmed from supporting data/records.

7.2.4. DO NOT record data on non-official records (e.g., uncontrolled notebook, scrap paper, post-it notes); if additional pages are required, they must clearly indicate the document number and page number being appended and include initials and date.

7.2.5. Do not use 'ditto' marks to fill in information as they can easily be overwritten.

7.2.6. Do not use bracketing, continuation lines, or arrows to apply a value to multiple entries on a form.

7.2.7. 'Line through' any boxes/columns that are not used, mark with 'N/A' and initial and date. Do not leave blank spaces, as this indicates an omission. If there is an N/A check box, lining through blank spaces is not needed. If an N/A check box is checked, it means that the box is not applicable to the step or process.

Comments: None. g8 23 Oct 2017

Additional Comments Sheet Reference: None. g9 23 Oct 2017

Authored and/or Approved the Material		N/A
Task 1: Classroom Instruction	<input type="checkbox"/> N/A	
Basic Training	<input type="checkbox"/> N/A	
Task 2: Classroom Instruction	<input type="checkbox"/> N/A	
Intermediate Training	<input type="checkbox"/> N/A	
Task 3: Classroom Instruction	<input type="checkbox"/> N/A	
Advanced Training	<input type="checkbox"/> N/A	
Task 4: Performance – Observed Qualified Trainer	<input type="checkbox"/> N/A	
Task 5: Performance – Performed With Trainer Assistance	<input type="checkbox"/> N/A	
Task 6: Performance – Performed Independently With Trainer Verification	<input type="checkbox"/> N/A	

7.2.8. If an attachment is necessary and has multiple pages, start the pagination numerically, i.e., 1, 2, 3, etc.

7.3. Making Corrections

7.3.1. Changes should be made by the original person wherever possible. If additions are required to be added by someone else later, they must detail the reason/justification for the annotation.

7.3.2. When making corrections, DO NOT obscure the original entry. DO NOT use white out, correction fluid, or correction tape to make any correction.

7.3.3. To make a correction on a document, the following steps must be followed:

7.3.3.1. Draw a single line through the incorrect entry. The error should be legible through the cross-out.

7.3.3.2. Record the correct data legibly next to the original entry.

7.3.3.3. Initial and date the cross-out and the new entry.

7.3.3.4. Correction date is the date the correction to the document was made. (DO NOT backdate the correction).

7.3.4. When two people have signed the original entry, the correction needs to be done by the same individuals. A verifier is not needed if the correction is completed on the same date as the "Done by" "Verified by" sections of the record. If an individual is not available, then a supervisor/manager may sign and date for that individual.

7.3.5. The following error codes are accepted. These codes are intended to save time and space on documents but must NOT be regarded as a complete explanation if further justification is required. They must be supported with additional information as appropriate to clarify the need for the change. NOTE: Circle codes to avoid confusion with initials. The comment sections of records may be used for these cases and are verified.

- 7.3.5.1.  Entry Error
 - 7.3.5.2.  Transcription Error
 - 7.3.5.3.  Calculation Error
 - 7.3.5.4.  Inadvertently Cross-out
 - 7.3.5.5.  Illegible Entry – rewritten for clarity
 - 7.3.5.6.  Spelling Error

7.3.6. Example of correcting an incorrect entry:

Original: Correction:

Discipline

Discipline

NOTE: If the error code is not sufficient and more detail on the correction made is needed, put a notation number (e.g. ①) next to the correction and make a comment/explanation in the 'Comments' section (if applicable) or at the bottom of the page of the document and then initial and date. See the next step for further clarification.

7.3.7. Include a relevant explanation/description of events where necessary, (e.g., 'balance not working', 'engineer called' etc.), and also when things are fit for purpose (e.g., 'balance checked, OK for use'), by adding a notation using a circled number ① at the point where the explanation/description is needed and document the explanation/description in the designated comment area or in a blank space on the same page. Initial and date your explanation.