

1. **PURPOSE**

This document defines the general documentation practices utilized by employees in accordance with the Quality Manual.

2. **SCOPE**

This procedure applies to documentation that may be used for or in support of cGXP processes, procedures, activities, and products at UOC USA.

3. **REFERENCES**

- 3.1 QM-01-00001: Quality Manual
- 3.2 US FDA 21 CFR PART 820 Quality System Regulation

4. **DEFINITIONS AND ACRONYMS**

- 4.1 SOP: Standard Operating Procedure: A document that defines standard methods for performing operations
- 4.2 cGXP: current Good Manufacturing, Laboratory, or Clinical Practices

5. **RESPONSIBILITIES**

- 5.1 Quality function
 - Responsible for reviewing, approving, and following this procedure.
- 5.2 All Personnel
Responsible for understanding and following this procedure.

6. **PROCEDURE**

- 6.1 Handwritten entries
 - All handwritten entries will use black or blue indelible ink.
 - Red ink may be used to mark up edits for revisions of controlled documents.
 - No pencils or erasable ink will be used.
 - All data is to be recorded directly onto the appropriate document or record. No use of scrap paper is preferred. However, if scrap paper is used, the paper should be attached to the corresponding document.
 - Data will be clearly labeled with the initials and date of the recording individual.
 - All original data will be retained. Note: If original data requires correction, refer to section 6.3 of this procedure for the appropriate correction method.
 - No write-overs are allowed

6.2 Electronic entries

- Electronic documents and records that are to be utilized outside of the electronic system responsible for creating and storing them, must be printed, verified, signed or initialed, and dated in order to be considered official copies. NOTE: This does not apply to documents and records created and stored in validated systems.
- If printed data is to be taped into a logbook or other similar document, the recorder must initial and date across the page boundary.
- Any data printed on “thermal tape” or other nonpermanent media will be photocopied and the photocopy included along with the original.

6.3 Corrections

- Whenever a correction is required the entry will be lined out with a single line through the entire entry in a manner that does not obscure the original entry. The correction will be made with the initials and date of the recording individual. A brief explanation of the correction should be provided if the reason for the correction is not obvious.
- If there is not enough space at the site of the correction, a symbol may be placed at the site of the correction to reference another location on the page where the explanation (if applicable), initials, and date will appear.
- It is acceptable to use a symbol multiple times for the same correction. In this instance the number of times the symbol appears on the page will be denoted at the site of the explanation. For example, if a date error is made 4 times on the page, the recorder may put a symbol such as a triangle by the corrected date and at the site of the explanation denote this as “4Δ” followed by an explanation of the corrections such as “date error” and the initials and date of the recorder.
- It is not acceptable to use the same symbol for different corrections on the same page. For example, a triangle could not be used to denote both a “date error” and a “rewritten for clarity”.
- No correction fluid or correction tape may be used.

6.4 Blank Space

- No blank space is to be left blank.
- If there is a blank space on a page:
 - Draw a line through the space
 - Write “Blank”, “Blank Space” or “N/A on the line
 - Initial and date
- If there is a space on a form that does not apply, enter “N/A” for Not Applicable. Explain any entry of N/A whenever the reason is not obvious.

6.5 Date Format

- Any date format is acceptable so long as the date is written with the month first, the day second and the year third (i.e. MM/DD/YY)
- When providing an “Initial and Date” for any controlled document or record, back dating the initials is strictly prohibited.

6.6 Abbreviations

- Abbreviations will be used only when it is obvious what the abbreviation is intended to represent.
- Abbreviations may be also used if they are defined by the document in which they appear.

6.7 Units of Measure

- Units of measure will always be recorded along with any numeric value when applicable.

6.8 Rounding

- In performing calculations, all digits will be carried until the final result. The final result will be rounded as follows:

< 5 remains unchanged

≥ 5 rounds up to the next numeric value

- For example the listed final results would result when rounding the listed result to the nearest tenth.

Result	Final Result
78.48 mm	78.5 mm
78.45 mm	78.5 mm
78.42 mm	78.4 mm

7 END OF PROCEDURE