1.0   PURPOSE:

The purpose of this procedure is to provide instruction and guidance for good documentation practices to be used on all official documentation at QA Consulting Inc.

2.0   SCOPE:

This procedure applies to all official documentation at QA Consulting Inc.

3.0   REFERENCE DOCUMENTS:

3.1.   FRM-4.2-7   Approved Signature Log

3.2.   21 CFR Part 58   Good Laboratory Practice for Nonclinical Laboratory Studies

3.3.   ASTM E29   Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

3.4.   Taylor, B.N. (1995)   NIST Special Publication 811. Guidance for the Use of the International System of Units (SI). United States Department of Commerce, National Institute of Standards and Technology

4.0   DEFINITIONS:

4.1.   Backdate

To record a date earlier than the actual one; also to make retroactive

4.2.   Legible

Capable of being read or deciphered by any individual

4.3.   Official Documentation

Documentation required to implement the Quality Management System

4.4.   Overwrite

Writing over previously recorded information to make a change

4.5.   Rounding

To replace a number having a given number of digits with a number (called the rounded number) having a smaller number of digits.

4.6.   Transcription

Copying from an original document onto a new/different document

5.0   PROCEDURE:

5.1.   Good Documentation Practices guidelines are shown below in **Table 1.**

Table 1 Guidelines for Good Documentation Practices

Do	Do Not
• Use blue or black, indelible, ball-point ink • Make all entries legible (readable) • Initial and date all entries (unless a signature is required) as required by form/document • Document each step before moving to the next • N/A, initial, and date spaces if it is not appropriate to fill them in • Record numbers less than one with a zero before the decimal point • Round numbers in accordance with ASTM E29-08	• Overwrite • Use liquid correction fluid • Backdate • Record data before the action or event has occurred • Use ditto marks • Leave required data spaces blank • Approve, verify, or review your own performance

5.2.   Initialing and Dating

5.2.1. All entries to an official document must be accompanied by the identity of the person (initials or signature) and the date that the entry was made. This may be at the end of the document rather than each line, as required by the document/form.

5.2.1.1.   Logs that have a "Reviewed by" section at the bottom do not require initials/signature and date for every entry made.

5.2.2. Initials are the accepted standard method of identification. However, some operations require a signature. For example, an "Approved by" space must be filled with a signature, not initials.

5.2.3. Dates written in certain formats may be interpreted in different ways (e.g. 05/07/10 is not clear which number is the month, day, or year). In order to avoid this occurrence, the date shall be written in the format DD MMM YYYY, where D= the numeric day, M= the alphabetic month, and Y= the numeric year (e.g. 05 Jul 2010).

5.2.4. **FRM-4.2-7** contains each individual employee's full signature and initials and will be utilized in order to positively relate signatures to initials and assure identification of the individual.

5.3.   Corrections

5.3.1. No handwritten changes or corrections will be made to the printed text of a controlled document. Consult with your supervisor if you discover an error. Any changes required to an controlled document shall be implemented through the established quality system.

5.3.2. When correcting a data entry error, manually:

5.3.2.1. Place a single line through the incorrect entry

5.3.2.2. Initial and date adjacent to the cross-out

5.3.2.3. Enter the correct data near the original entry (if the correction is a date, circle the corrected date)

5.3.2.4. The mistake must still be legible through the cross-out (never use liquid correction fluid)

5.3.2.5. Date of the correction is the date the correction was made, not the date the error was made.

5.3.3. Electronic strikethroughs may not be used to indicate corrections on electronically generated/maintained documents. Electronic strikethroughs and/or graying-out in entry fields shall be used to indicate that an entry is void, obsolete, or no longer in use.

5.4. Backdating

5.4.1. Backdating is the practice of going back to a previously completed task that has not been properly signed, initialed, or dated and placing the date that the task was completed on the date line, as though filling in the date had been done in the past. This practice is not allowed on any document.

5.5. Additional Data

5.5.1. If information is not complete at the time entered or additional information is needed, the entry shall be marked by an asterisk or other notation. The use of each unique character (e.g. 1, 2, 3, a, b, c) is limited to one per page. Comments explaining the reason for additional data shall be documented on the same page of the record. The explanation shall be initialed and dated at the time of recording.

5.5.2. A reason or reason code for the correction may be documented in a footnote. This is required when complying with Good Laboratory Practices per 21 CFR Part 58 (**Reference 3.3**).

5.6. Overwriting

5.6.1. Overwriting refers to writing over previously recorded information to make a change. Overwriting is never allowed on any document.

5.7. Transcription

5.7.1. Transcription is generally discouraged as it may invalidate original data, but may be helpful in situations when:

- The original record is difficult to read
- An incorrect form or document was used
- The original record is irreparable or damaged
- The original was in a format that could not be maintained over time (e.g. thermal paper strips)

5.7.2. Any transcription should be clearly marked as a transcription and the original data retained with the transcribed copy.

5.7.3. The use of intentionally recording raw data on scrap paper, such as post-it notes or other non-official records, is a set-up for transcription and is therefore prohibited.

5.8. Rounding

5.8.1. Rounding shall be conducted in accordance with ASTM E29-08 (**Reference 3.4**) and Taylor (1995) (**Reference 3.5**). The general/ most commonly needed rules are as follows:

5.8.1.1. If the digits to be discarded begin with a digit less than 5, the digit preceding the 5 is not changed. (e.g. 6.9749515 rounded to 3 digits is 6.97)

5.8.1.2. If the digits to be discarded begin with a digit greater than 5, the preceding digit is increased by 1. (e.g. 6.9749515 rounded to 4 digits is 6.975, 6.9749515 rounded to 2 digits is 7.0)

5.8.1.3. If the digits to be discarded begin with a 5 and at least one of the following digits is greater

than 0, the digit preceding the 5 is increased by 1. (e.g. 6.9749515 rounded to 5 digits is 6.9750)

5.8.1.4. If the digits to be discarded begin with a 5 and there are no digits beyond this 5, or all of the following digits are 0, the digit preceding the 5 is unchanged if it is even and increased by 1 if it is odd. (Note this means that the final digit is always even.) (e.g. 6.9749515 rounded to 7 digits is 6.974952 and 6.9749505 rounded to 7 digits is 6.974950)