

Good Documentation Practices

GLO-29002- REV- 005



For Internal Use Only

Documentation

Purpose

- This lesson defines the process and requirements for Current Good Documentation Practices (cGDP). Discusses cGDP components to ensure that cGDP are followed and processes for error correction.

Scope

- The scope of this lesson applies to all individuals in Qualitest that are performing cGDP function such as holding, storing, transporting, manufacturing, testing, supporting, and packaging FDA regulated materials and are documenting all actions on controlled documents.

Note: When a signature is placed on a cGMP document, the individual is signing a legal document.



Documentation

Backdating:

The practice of dating a prior event with the date it occurred, as if it were documented on that date.



Dated

Today

Comment:

All comments must include initials/date and in some cases an additional verification.

SJB
07/27/2014

Writing Over:

Writing over previously written data in order to make a change (i.e. to make a 3 become a 8).



WRONG **RIGHT**


Documentation

Performed by:

- Must be documented **at the time** of completing the step and prior to moving on to the next step.
- Do not move forward and execute a step if the procedure is not available for documenting data at time of execution.
- The following **may** initial and date:
 - Personnel already proficient in the task performed.
 - Personnel who are in training **under supervision** of their qualified trainer.

What does this mean to you?

What does documented at the time of completing the step and prior to moving on to the next step really mean?

- a) At the end of the shift
- b) After my break
- c) When I get time
-  As I complete the step

Documentation

Recorded by:

- Used when the performing individual is unable to initial and date immediately, due to working in a confined or restricted space such as a laminar flow hood.
- The following may initial and date:
 - Personnel who observe the procedure.

Verified by:

- Must be performed before moving on to the next step.
- At least one other person **must review** documentation for accuracy.
- Performers **may not** verify their own work.
- The following may initial and date:
 - Personnel already proficient in the task performed.
 - Personnel witnessing task, operation, or procedure to notate it was performed per written instructions and accurately documented.

Good Documentation Do's and Don'ts

DO:

- 1) Use blue or black water resistant ink, able to be photocopied or scanned.
 - Sharpies or markers may be used on room tags, pallet tags or other tags.
- 2) All entries ~~must be~~ recorded directly and promptly, completely, accurately, and legibly.
 - All data, observations, calculations, and conclusions must be recorded as entries that are clearly understood without additional explanation.
- 3) Entries shall be traceable to the person making the entry by either initial and date or signature and date.

SJB
07/27/2014

Sam Brown 07/02/2014

Good Documentation Do's and Don'ts

DO:

- 4) Enter raw data in chronological order, **as** the observations are made.
- 5) All data entries in the Batch Product Record (BPR), related to downtime, should be detailed enough to reference at any given moment.

5) Required Information:

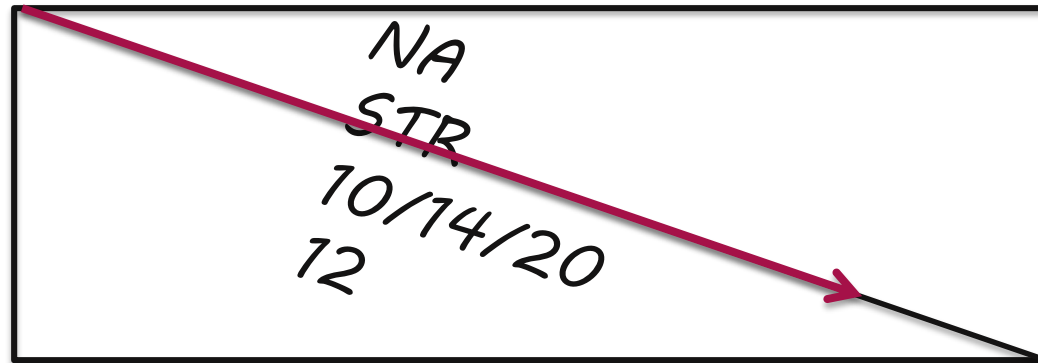
1. Time
2. Date
3. Equipment
4. Maintenance Actions



Good Documentation Do's and Don'ts

DO:

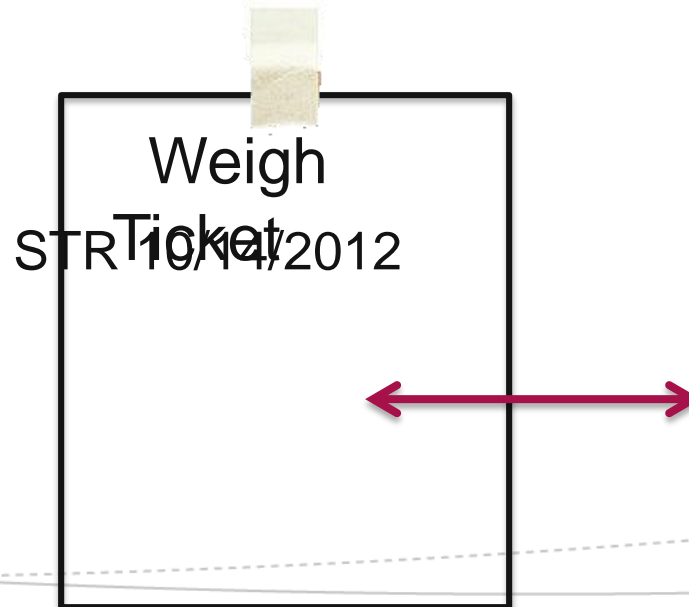
- 6) NA, initial, and date blank spaces if spaces do not need to be completed.
 - Comments or Notes pages do not need to be NA'd.
 - Blank spaces are crossed through at a diagonal from upper left to lower right side of the page (corner-to-corner) and initialed and dated.



Good Documentation Do's and Don'ts

DO:

- 7) Instrument printouts or other loose items such as weigh tickets must be attached using an adhesive product such as tape in a batch record, logbook, or lab notebook.
 - The printout should be signed and dated across the edge so that it is obvious an attachment was removed, if found to be missing.



Good Documentation Do's and Don'ts

DO:

- 8) Record numbers less than one (1) with a zero before the decimal place.

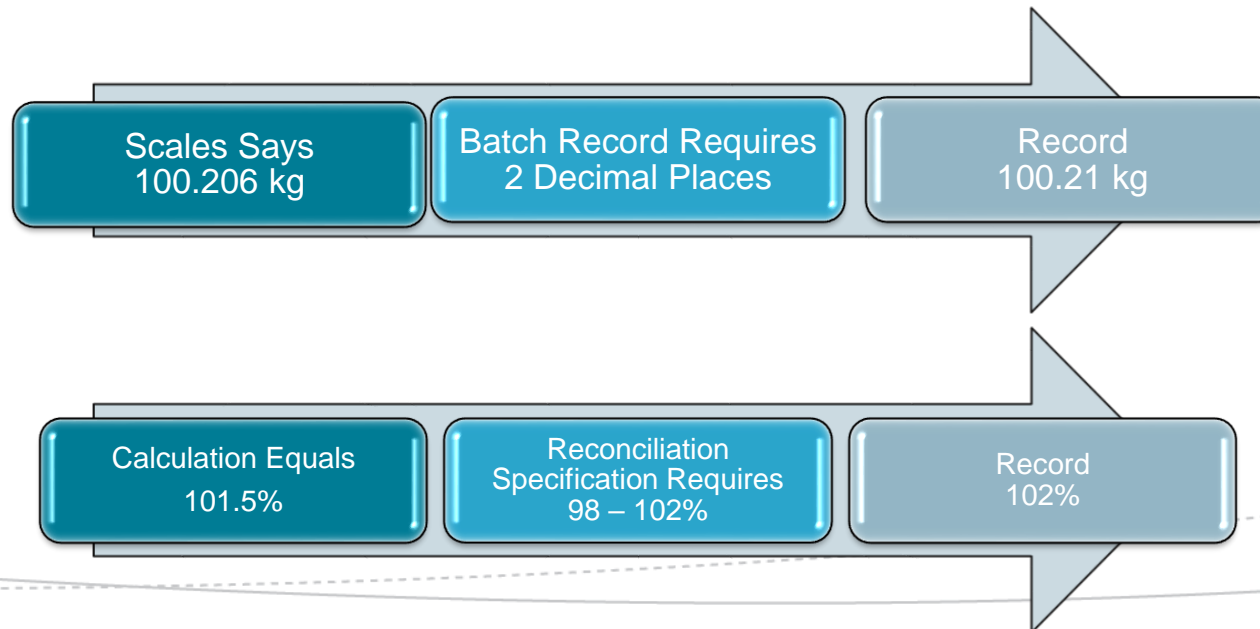
Incorrect	Correct
.26	0.26
.78	0.78
.12	0.12

Why?

Good Documentation Do's and Don'ts

DO:

- 9) When documenting numbers such as weights, the number should be documented to the appropriate number of decimal places as listed in the BPR.
- When the number of decimal places is not specified, document the value as it appears below:



Good Documentation Do's and Don'ts

DO:

- 10) Record downtime experienced during a production run with an explanation.
- 11) Raw data that cannot be stored in its original format such as *thin layer chromatography plates* should be photocopied and/or captured in a durable form.

Good Documentation Do's and Don'ts

DON'T:



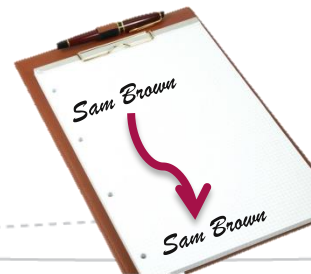
- 1) Do **NOT** use correction fluids or other type of correction device
- 2) Do **NOT** backdate or forward date.
 - The current date is to be recorded with an annotation of the date the work actually occurred.



Good Documentation Do's and Don'ts

DON'T:

- 3) Do NOT write over.
- 4) Do NOT record data **before** the action or event has occurred.
- 5) Do NOT approve, verify, or review your own work.
- 6) Do NOT write on scratch paper, your hand, uniform sleeves, post-its, or other surfaces and then later transcribe the data.
- 7) Do NOT destroy raw data.
- 8) Do NOT use “ditto” marks or arrows (except in Micro to reflect repetitive information).



Good Documentation Do's and Don'ts

DON'T:

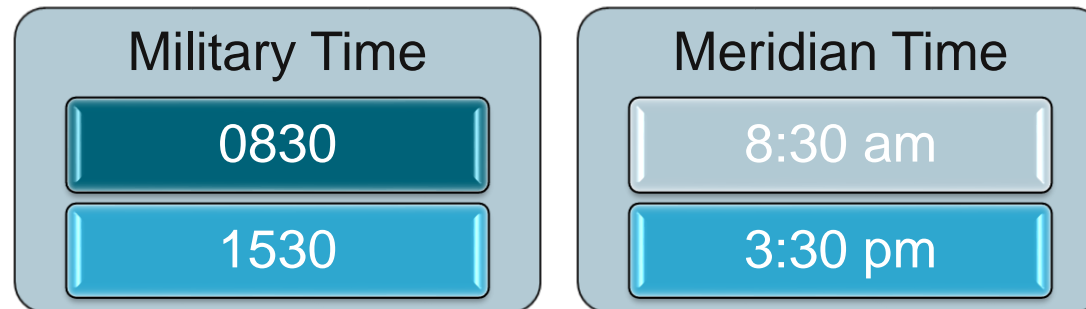
- 9) Do NOT perform hand-written changes or corrections to the printed text production or testing of product.
 - Notify management if an error is found.
 - Any formal change will require a Change Control.

- 10) Do NOT write one explanation for multiple unrelated errors on a page.
 - Each error should be corrected, initialed, and dated with an explanation.
 - Multiple **related** errors may have an asterisk placed by the entries and one explanation with initials and date will be sufficient.

Documentation

Time Recording:

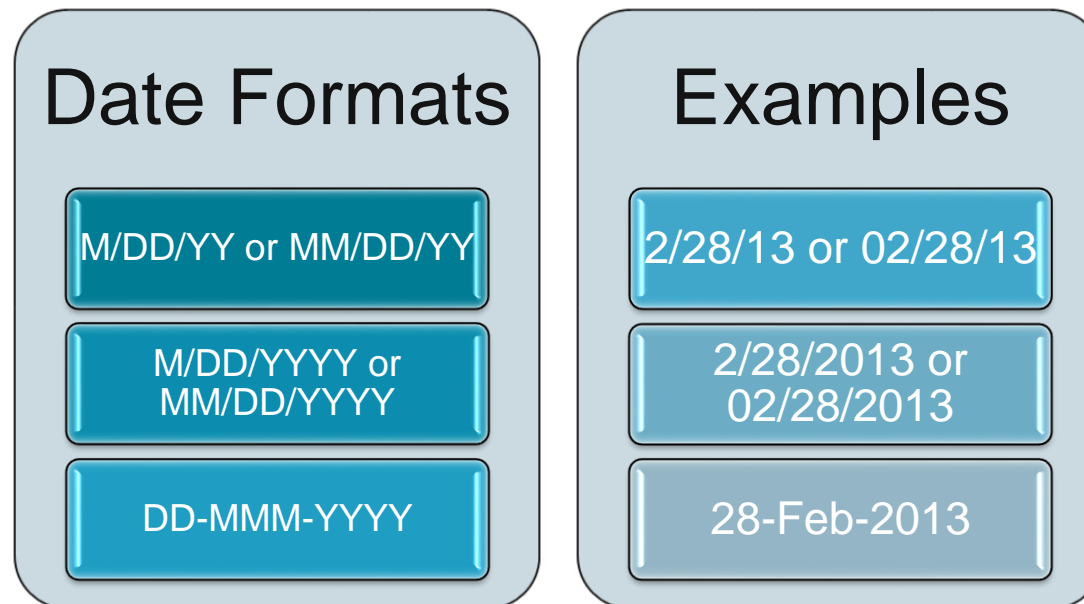
- **Military Time**
 - Two (2) digits to indicate the hour (00 to 23), followed by two (2) digits to indicate the minutes (00 to 59).
 - Example: 0850 and 1750
- **Meridian Time**
 - One (1) or two (2) digits to indicate the hour (1 or 12), followed by two (2) digits to indicate the minutes (00 to 59), then the morning (AM) or afternoon (PM) designation.
 - Example: 8:50 am or 5:50 pm (same as Military Time example above).



Documentation

Date Format:

- There are three acceptable date forms:
 - Either slashes (/) or dashes (-) may be used to separate numbers and letters.



Documentation

Manual Corrections:

- 1) Place a single line through the incorrect entry.
- 2) Initial and date adjacent to the cross-out.
- 3) Write a brief explanation for the cross-out.
- 4) Enter the correct data near the original entry (if possible).
 - Use an asterisk and write at the bottom of the page or in the margin if there is no space
- 5) The error must be readable throughout the correction.
- 6) The date of the correction is the date the correction was made, NOT the date the error was made.

<i>Sam Brown</i>	07/25/2014
Signature	Date

<i>Sam Brown</i>	07/27/2014 <i>SB</i>
<i>Sam Brown</i>	07/25/2014
Signature	Date

* Wrote wrong
date for today's
date.

Documentation

Manual Correction Examples:

– Date Error

~~3/12/2013~~ 3/21/2013 date error STR 3/21/2013

– Transposed Numbers

~~573.0 kg~~ 537.0 kg transposed numbers, verified by weight tape DTW 4/30/2013

– Calculation Error

96.7% *
* 98.0% calculation error PXB 6/15/2013


OR

96.7% '
' 98.0% calculation error PXB 6/15/2012

Documentation

Missing Data with Supporting Data:

- 1) If data is missing at the completion of a step, use an asterisk or other indicator as a place holder.
 - Comments explaining the missing information should be added on the same page.
- 2) If the missing information is critical to the integrity of the batch or validation.
 - A deviation may be initiated as appropriate by QA.



<u>5.8</u>
<u>6.2</u>
<u>5.1</u>
<u>6.3</u>
*
<u>5.9</u>
<u>6.1</u>

* Missing data re-measured tablets and recorded data on back of batch record. BCA 05/12/2013

Documentation

Missing Data **without** Supporting Data:

5.8

6.2

5.1

6.3

*

5.9

6.1



* Missing data. No documentation to support. PR 1234 initiated to investigate. BCA 05/12/2012

Signature Logs

New Hires:

- Obtained by Training Department and forwarded to Document Control to maintain.

Annual Updates:

- Managed and stored by Document Control each year.

Name Changes or Signature Changes:

- See Document Control to make updates.



Signature Logs

Include:

- Printed Name
- Signature
- Initials (3)

Sam Brown	<i>Sam Brown</i>	SJB
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If an employee does not have a middle initial or their initials are the same as someone else in the department, Document Control or Training (in the case of a new employee) will assign a middle initial.

Documentation

Voided Records:

- Can only be voided by QA and only with supporting documentation.
- All voided records require an explanation and approval by QA.

Re-Creating and Transcribing Records:

- Rarely occurs.
- Requires QA and Management approval.
- Acceptable instances when recreation might be required:
 - Original is unreadable.
 - An incorrect document or form was used.
 - The record is not repairable.
 - The original is in a format that won't retain the data (ex., thermal paper).

Significant Figures

Significant figures are defined as:

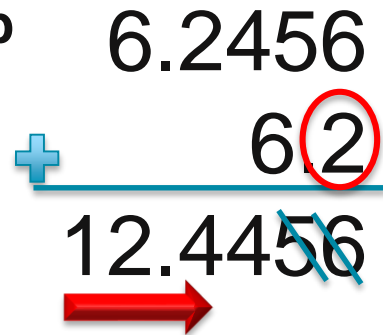
- Any digit that is not zero. **1-9**
- Zeros between non-zero digits. **202**
- Numbers greater than 1 and all digits to the right of the decimal point (i.e. 523.25 = 5 significant figures). 12.25 = 4 significant figures
- If the number is less than 1, then only zeros that are at the end of the number and between non-zero digits are significant (i.e. 0.02050 = 4 significant figures).
- For numbers that do not contain decimal points, trailing zeros may or may not be significant. At Qualitest numbers are considered significant unless stated otherwise (i.e. **2000 = 4** significant figures).
- Defined and counted quantities have an unlimited number of significant figures.
- Zeros to the left of the first non-zero digit are not significant. 0.25

Use of Significant Figures in Calculations

Addition or Subtraction:

- Do the math, determine the number of significant figures required and round accordingly.
- Number of significant figures (3) is determined by the lowest number of significant figures to the right of the decimal point.

1st
Step

$$\begin{array}{r} 6.2456 \\ + \quad 6.2 \\ \hline 12.4456 \end{array}$$


2nd

Step Round to 12.4
using 2nd
number to the
left of decimal
point.

Round to 12.4

Use of Significant Figures in Calculations

Multiplication and Division:

- Do the math, determine the number of significant figures and then round as necessary

1st Step


$$\begin{array}{r} 6.2456 \\ \times 6.2 \\ \hline 38.72272 \end{array}$$

2nd Step

$$\begin{array}{r} 6.2456 \\ \times 6.2 \\ \hline 38.72272 \end{array}$$

3rd Step

Round to 38.7



Rounding

How to Round?

- Fixed numbers are not rounded.
 - Fixed number of digits after (and sometimes also before) after the decimal point.
- A digit less than 5 is eliminated and the preceding number stays the same. Ex., 1-4 12.43 – 3 drops and number is 12.4
- A digit greater than 5 is eliminated and the preceding number is increased by one. Ex., 6-9 12.47 – the 7 drops and number is 12.5
- If the digit equals 5, the 5 is eliminated and the preceding digit is increased by one. Ex., 12.35 - five drops and number is 12.4

Intermediate Values

Intermediate Values

- Calculated results that are used in further calculations and are not to be rounded.

1 st	2.5
Step	4.2
	6.9
	8.4
+	<u>3.6</u>
	25.6

2 nd
Step
$25.6 \div 5 = 5.12$

Average the numbers



Certification

- All personnel who perform cGMP tasks are required to be certified through participating in the class and completing the assessment.
- Recertification to be completed every two years (more often as deemed necessary).
- All personnel required to sign the Good Documentation Practices Certification Memo.
- Memo will be kept on file and
- training documented.

