



Good Documentation Practices

Why are Good Documentation Practices so important to our customers?

- Some of our customers belong to highly regulated industries
- Documentation errors can lead to severe consequences:
 - product safety concerns
 - litigation
 - action by the regulators.



Clear, accurate and complete documents allow for:

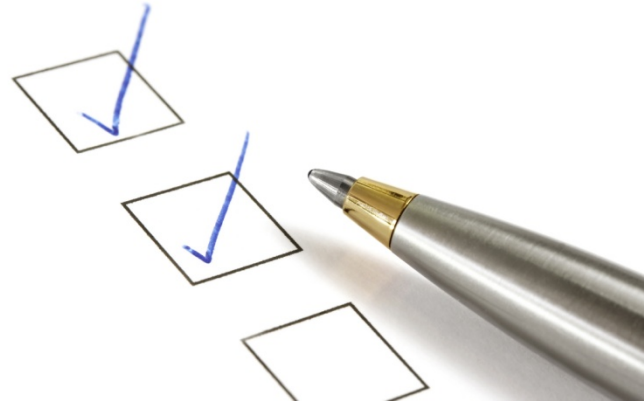
- Keeping track of activities
- Informing others
- Instructing others
- Creating a historical record
- Creating a legal document
- Complying with regulations

Documentation Types

- Manufacturing Order / Work Order
- Device / Batch Records
- In process inspection records / Check Sheets
- Packaging Order / Packaging Check Sheets
- Analytical Testing Results
- Deviation Requests / Reports
- Supplier packages
- Cycle count reports

The Nine Rules

- Permanent
- Legible
- Accurate
- Prompt
- Clear
- Consistent
- Complete
- Direct
- Truthful



Permanent information can't be changed, erased or washed off.

- Proper writing instrument,
 - No pencils
 - No felt tip pens.
- Permanent ink
 - **Black** or **Blue**
- Provides a consistent look and standard for documents.



Legible information can be easily read.

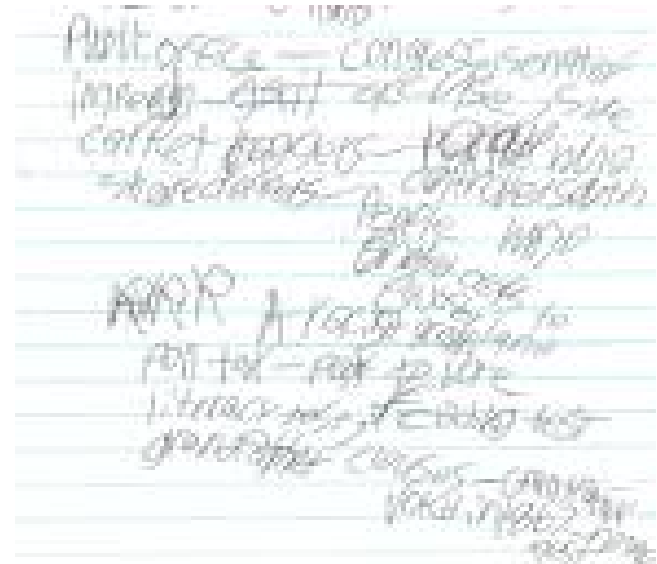
- Errors are properly corrected
- One line through the original entry
- Do not:
 - Scribble out or black out with pen
 - White out
 - Write over
- Explain reason for error (e.g.. Incorrect weight entered)
- Enter correct information
- Initial and date

Legible information can be easily read.

Problems to watch out for:

Legibility of numbers and characters

- 0 and 6
- U and V
- S and 5
- 1 and 7
- 3 and 8
- B and 8



Accurate calculations are correct and information is recorded with care

- Perform calculations at least **twice**.
- Have the calculation reviewed and verified by a second person.
- Present results in the units specified.
- Spelling of product names are correct.
- Lot numbers, serial numbers and product codes are double checked.

Prompt information is recorded in a timely manner.
Actions are documented immediately, never before.

- Document tasks immediately after they are performed.

Never pre-date or post-date documentation!

If you missed a step in a process, be truthful. Document it and complete the step at that time if possible, noting the actual date it was completed.

Clear everyone who reads the document has the same understanding of what it means.

- Looking at this document five years from now, would someone understand what I wrote?
- Areas identified as N/A or not applicable must have a documented reason, initials and date

Consistent information, such as dates, times, and abbreviations, are recorded to company standards. Records completed the same by all employees.

- **Date**
DAY MONTH YEAR using DD MMM YYYY format (example: 26 MAR 2009)
- **Time**
Specify a.m. or p.m. Military time can be used
- **Every form must be filled the same way every time**

Complete all information is included.

- No blank spaces, pages or portion of a page.
- N/A can only be used when it is very clear that a portion of a document, form, record does not apply
- Provide an explanation with the N/A (Example “N/A – testing repeated.” Initial and Date)
- For tables that are not applicable, draw a “/” through the table, and provide an explanation with the N/A, initial and date.
- Draw a “ Z ” through an unused page or portion of a page ,state “blank”, initial and date.

Direct information is recorded immediately onto the proper form, laboratory notebook or computer system.

- Original entry is made directly onto the GMP document.
- **No** scrap paper and **No** sticky notes
- Do not write on raw material containers, pieces of cardboard, gloves, etc.



Truthful all information included in the document is, to the writer's knowledge and ability is factual.

- Your signature/initial says information is **true**
- The information you report, must be factual.
Information must never be falsified!

Examples of Good Documentation Practices

- ✓ Date format
- ✓ Documentation at the time of the event
- ✓ Changes documented
- ✓ Deviations addressed
- ✓ Corrections effectively and accurately recorded
- ✓ Blank areas correctly identified and with a documented explanation