

Documentation

Rules for Completion

I. Reason for This Training

II. Introduction

The complete and accurate recording of processes, policies and procedures provides a documented history and reliable record demonstrating operations are in a “State of Control”.

This demonstrated control means that processes and systems are continuously managed in accordance with the GMP regulations.

How documentation is maintained is just as important as what is retained.

III. The Regulation

21CFR 211.180(e): Records and Reports.

“Written records...shall be maintained so that data therein can be used for evaluating...the quality standards of each drug product...”

IV. Discussion Points *(Sample responses are in italics.)*

- Why is it important for GMP documents to contain signatures? *(Because our signature means that what we have done is correct according to procedure.)*
- Why is it necessary that GMP documentation is completed at the time work is performed? *(To assure the accuracy of information.)*
- What is the purpose of maintaining GMP documentation? *(To provide a documented history of the production of our products.)*

V. Opening Activity

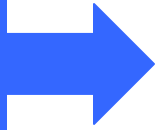
Ask the group to work in pairs and brainstorm a list of the documents used in their work area. In addition to the ones requiring the signature of the person doing the work, have them also identify the documents that require approval signature(s). Flipchart all responses.

VI. Presentation

Training suggestion: This is a good place to review your company's documentation policy and procedures. Be certain to emphasize employee responsibility to assure compliant documentation practices.

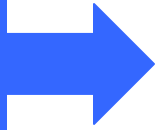
Completing Documents

- Enter detailed, complete and accurate information at the time work is performed.
- Enter signature or initials (according to procedure)
- When one or more person complete a task, all must sign.
- Never sign your name for performance of a job for work actually performed by someone else.
- Date the entry at the time work is performed.
- Use ballpoint ink in the approved color (Other inks may smudge and cause the entry to be illegible.)
- Limit the use of abbreviations and acronyms.



Error Correction

- Enter a single line through the error. *This allows the original entry to remain legible.*
- Enter the correct information. *As near to the original entry as possible.*
- Enter your signature or initials near the new entry. *This identifies who made the correction.*
- Enter the date the correction was made. *As near to the original entry as possible)*
- When the reason for the correction is not obvious, for example writing April 6th when it is the 7th, the reason for the correction should be described in a notation.
- When two people signed the original entry, and then another changes the entry, the second person must also sign for the change.
- **REMEMBER! Your signature means that the work is correct and it is correct according to procedure. *GMP documents are legal documents!***



Error Description

Note: The following is offered as example of notations that may be used to describe error corrections. Consult your site SOP for the specifics in this regard.

- Calculation error
- Transposition
- Illegible entry
- Scale zero error
- Non-calibrated instrument
- Wrong instrument

Error descriptions must aptly clarify the understanding of the correction. Never enter opinions or comments such as, "I can't believe this batch is going to be released." When uncertain about what to enter, speak with the area supervisor.

Double Check Process

The double check process is used when one person performs the task and the second person verifies that it has been performed correctly.

Double checking our work provides additional assurance that no mistakes were made. The person who is the “verifier” must be clear as to what they are verifying by affixing their signature to the document.

Specific Examples:

- Adding raw materials
- Adding components
- Completing documentation
- Auditing

Uses for the double checking process:

- Second performance of a task
- Witnessing task performance
- Verification of task performance
- Accuracy confirmation
- Document completion

It is very important to be certain why you are signing as the verifier for a particular task. The second signatory has the ultimate responsibility for defending the accuracy of the performance of the task.

Document Retrieval

Each manufacturer is responsible for proving that their product is pure, safe and effective. When it is not possible to produce the required documents in support of processes, it may not be possible to prove position.

When entries are made to a document, and a signature is affixed, it is a good idea to maintain that document according to acceptable documentation practices.

When maintaining documents, we must be able to assure that the FDA can be easily provided a copy during an inspection.

21CFR 211.180(d) ...These records or copies...shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph.” (See Electronic Records, Topic 7 for more information on this subject.)

VII. Closing Activity

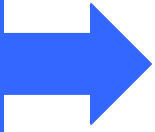
- Divide the class in to 3-4 teams.
- Ask each team to record the documents that are used in their work area and indicate the ones that require a second signature as a “double-check” of the work that is performed.
- Ask each team to share their list.
- Ask for explanation as to why (or why not) the double check is used for each document they have listed.
- Link the discussion to the importance of proper documentation practices.

VIII. Summary

- Documentation is a record of our product history.
- GMP documents are legal documents.
- The “double check” assures that our work is correct.
- All work should be documented at the time work is performed.
- Use only approved inks in approved colors.

IX. Excerpted 483 Citations

- Failure to use ink as specified by procedure.
- Incorrect ink was used for entries in a lab notebook causing illegible data when a substance was spilled.
- Logbook corrections failed to identify person who made the changes.



Trainer Notes: