

Auditing a Documentation System

Title: Auditing a Documentation System					
Auditor Manual: 08					
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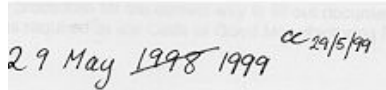
Audit Training Manual: 08

Auditing a Documentation System

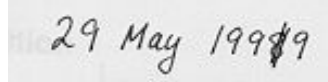
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Using a white correction fluid or writing over an entry to correct an error is not acceptable. If a correction is necessary, the incorrect information should be crossed out using one line. The correct information should be entered near the incorrect information accompanied by the initials of the person making the correction and the date the correction was made.

[Example of CORRECT way to correct errors]



[Example of INCORRECT way to correct errors]



If repeated information is required for several lines in a document, e.g., initials, no ditto marks (“”) or arrows (↓) should be used. Initials should be entered each time they are required.

Recording data

All data should be recorded directly onto the production batch record, appropriate record, logbook, form or worksheet. Errors, which are corrected based on information contained in another source document, must be referenced or the source document must be attached. Personnel who verify calculations must do so independently.

Numerical data

Numerical results must be reported using the same number of significant figures as required by the specification or standard.

Required significant digits to four places:	23.42
Wrong:	23.424
Wrong:	23.4

Analytical data rounding should follow the appropriate site SOP. Rules for rounding other numerical data are found below:

Rules for Rounding Numbers

For numerical data other than analytical data:

- Ø If the digit to the right of the digit to be retained is less than 5, **do not round up** to the next higher digit.

Example: 3 significant digits required

Result: 23.74

Round to: 23.7

- Ø If the digit to the right of the digit to be retained is 5 or greater, **round up** the result to the next higher digit.

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delayed due to shift change" or "machine down for repairs preventing in-process checks from being performed". Errors, which are corrected based on information contained in another source document, must be referenced or the source document must be attached. Reasons for problems must be explained in detail, initialed, dated and written on the corresponding pages.

Examples:

- Ø Writing "line down" (indicating a production line is down) on a batch sheet is not sufficient. Briefly explain the reason the line is down.
- Ø Writing "problem" on a batch sheet is not sufficient. Briefly provide information that clarifies what the problem is.

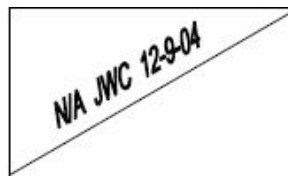
If a source external to the batch record is used to change data or statements, explain the source of information. Only authorized personnel are allowed to review and approve batch records.

Corrections to batch records should be made by the person who made the original entry. If this is not possible (e.g., the person no longer works at the site), efforts should be made to reconstruct the data using other viable or appropriate data sources.

Different sites may have different documentation rules regarding batch records.

Non-applicable pages of information

If a complete sheet of information on a document is not required by the process, a single diagonal line may be drawn from corner to corner. On the line "N/A" (Not Applicable) should be entered with the person's initials and date. If there are multiple pages that are not used, the site should have a defined procedure outlining the actions to be taken.



If critical data are not recorded, a deviation report must be initiated. The deviation report form number must be included on the applicable page(s) of the batch record. Critical data include equipment readings, time, temperature, pressure, and in-process checks. If changes or corrections are necessary to the batch record, they must be explained and approved by quality. Formal documentation, i.e., a memo or signed change request form, must be kept for each change.

Corrective Actions for Documentation Deficiencies

Document deficiencies may be classified. If a documentation deficiency is considered critical it should be investigated following local procedures.

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- Ø A description of the purpose of the system.
- Ø Storage and retrieval information.
- Ø Directions for handling atypical occurrences within the system.

Documentation may consist of logbooks, worksheets, electronic data, highly controlled paper documents, equipment readout or charts.

Revision of Documents

GMP document revisions should be properly controlled through a formal revision system as part of the document management system. Documents should be approved, signed and dated by appropriate and authorized persons, as defined in procedures approved by Quality Assurance. As part of the document management system there should be a method in place to assure that GMP documents are revised regularly to comply with the GMP requirement that states that all documents should be complete and accurate.

When revised documents are issued, there should be a method in place to promptly remove superseded revisions from the area. Only official records and procedures should be used by personnel.

If approved documents (e.g., validation reports, released batch records, etc.) need to be amended, only appropriate personnel who have proper authorization may amend the documents. There should be a system in place to manage proposed amendments to approved documents.

Retention of Documents

The site should have a record retention schedule for different types of documents. All records associated with a manufacturing lot should be retained for a minimum of one year after the drug product expiration date. Validation records or other records that are not specific to batches or lots may have to be retained longer.

Records may be retained as original copies or true copies, e.g. microfilm, scanned copies, etc. Documents may be stored off site but must be easily retrievable. Original raw data of manufacturing and the laboratory should be retained according to site procedures.

Signatures on Documents

Signatures on documents can signify different roles. One person may sign a "done or performed by" section on one document and the "checked by" section in another document. It is important to understand the distinctions.

Auditing a Documentation System

Documentation systems that should be audited are any systems that can impact the quality of the drug product. These include not only direct manufacturing documentation but also the supporting information necessary to show that the drug product process is in compliance.

Key Parameters in Auditing a Documentation System

Prior to the audit

- Review the types of documentation systems in use at the site
- Determine if there are any outstanding corrective actions from either internal audits or regulatory inspections involving documentation.

During the audit of the documentation system

- Ensure that the documentation system is operating in full compliance.
 - Ø Verify that all documentation within a system applies good documentation practices.
 - Ø For production, laboratory or training documentation,
 - Verify that personnel activity indicated in current SOPs is actual practice.
 - Verify that data added to process documents is correct and current with the process.
 - Verify that the system is working correctly by asking to retrieve a previously generated document
 - Verify that there is a procedure in place for double checking data if required for that documentation system.
 - Ø Verify that access to documentation is restricted to authorized personnel.
 - Ø Verify that all documentation contains approvals by appropriate personnel.
 - Ø Verify that completed documentation is reviewed by appropriate personnel including a quality representative.
 - Ø Verify that document distribution and circulation is controlled.
 - Ø Verify that documents are identified with appropriate control and access statements.
 - Ø Verify that the site has a method for assuring that only current versions of documents are used.
 - Ø Verify that documents are reviewed or revised either on a scheduled frequency or as needed, whichever is the shorter time interval.
 - Ø Verify that there are SOPs for managing each documentation system. This should include review and approval process for documents including those which require change control management.
 - Ø Verify that personnel understand the differences when signing in different capacities.
 - Ø Determine if documentation discrepancy/deficiency classifications are used by an audited site.