Auditing a Documentation System

Goals

When you have completed this module, you should be able to:
· Perform an audit of a documentation system
· Use a range of tools and information, including the contents of this unit to support the audit of a documentation system
· Understand and apply appropriate GMP standards/regulations to an audit of a documentation system
· Recognize compliance or non-compliance of documentation systems to applicable regulations

Explanation of Topic

Introduction
Good documentation is essential for providing assurance that drug products are safe, pure, effective and of the highest quality. It is expected from any pharmaceutical processes. Through the use of established documentation systems, the company and its suppliers are able to provide a complete written record or proof of all activities used in producing a quality drug product.

This module is focusing on written documentation but data may be recorded by electronic data processing systems, photographic or other reliable means. If electronic systems are used the requirements for the documentation in principle is the same.

Good Documentation Practices for Written Documentation
Good documentation practices should be universally used in all documents that are considered part of GMP documentation.

General Documentation Practices

All required data should be recorded directly into production batch records, applicable logbooks, forms or worksheets. Before signing a document or confirming that an activity was performed, the person signing should both read and understand the step in the process or the statement. Initials and signatures of individuals working in that department should be maintained. Entries may not be made in advance or for another person. Entries may not be backdated. Unfamiliar terms should be defined within the document.

Recording information in the document itself

Only permanent ink, preferably blue or black, should be used to complete a document. Red ink might be used to highlight proposed changes in a document. All recorded information should be clear, legible, and accurate.

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<u>Batch records</u>

Comments made to clarify data or statements must be initialed and dated. Extended downtime during a production operation that prevents in-process checks from being performed must be noted with an explanation on the batch record, i.e., "in-process checks 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.

<u>Non-applicable pages of information</u>

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.
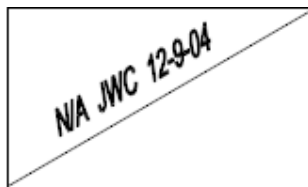
If critical data are not recorded, a deviation report must be initiated. The deviation report form number must be included on the applicable page(s) of the batch record. Critical data include equipment readings, time, temperature, pressure, and in-process checks. If changes or corrections are necessary 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.

Type of signature	Meaning
"done by" "performed by" "run by" "conducted by"	This is a signature or e-signature of the actual person who performed the work/test.
"checked by" "reviewed by"	This signature should reflect that the correct procedure was followed and the data recorded was accurate. The person who signs in this capacity does not have to be present but should have knowledge of the procedure.
"witnessed by"	This signature represents someone who actually watched the actual person performing the work. This person should know the actual procedure and steps in the procedure.
"approved by"	This signature reflects that documentation is accurate, and complete. It also indicates that, in the case of technical SOPs, the technical information is correct.

Electronic data

If data is recorded in electronic systems, detailed procedures relating to the system in use should be available and the accuracy of the records should be checked. Only authorized persons should be able to enter or modify data in the computer and there should be a

record of changes and deletions; access should be restricted by passwords or other means and the result of entry of critical data should be independently checked. Batch records and other critical documents electronically stored should be protected by back-up transfer on magnetic tape, microfilm, paper or other means. It is particularly important that the data are readily available throughout the period of retention.

Responsibilities of Quality Unit/QA for Documentation

The Quality Unit/QA should review and approve all appropriate quality-related documents including production records as part of the release process, procedures and specifications.

Summary

Documentation provides a data trail that shows that the manufacture of the drug product was in complete control. It is the formal proof that all steps, tests, and activities needed to produce a quality drug product were performed.

To ensure that the data trail is complete a documentation system should be well managed. It should be all inclusive from generation of documents to revision and removal of