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GOOD DOCUMENTATION PRACTICES

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Abstract: Good Documentation Practice (GDP) is an integral part of good manufacturing practices Ensuring the integrity of data collection and reporting is imperative for supporting the development, registration, commercialization, and life-cycle management of pharmaceutical products. Documents serve as a mirror, reflecting the true image of any pharmaceutical industry. Various measures, both collective and individual, are in place to guarantee that documentation, whether in paper or electronic form, is attributable, legible, traceable, permanent, contemporaneously recorded, original, and accurate. This commitment to robust documentation practices not only meets regulatory requirements but also establishes a foundation for transparency and reliability throughout the pharmaceutical lifecycle.

Keyword **- Document, Compliance, Alcoa +, Quality, Data, Integrity.**

INTRODUCTION

Documentation is fundamental to all quality systems, serving as the cornerstone for ensuring clear, comprehensive, and accurate records across various operations and procedures. It applies to the production and control of pharmaceutical products, active pharmaceutical ingredients (APIs), excipients, dietary supplements, food ingredients, and medical devices. essential principles underlying proper documentation for GMP operations, assisting users engaged in GMP activities. By following USFDA guidelines, individuals can establish a robust foundation for a quality system that guarantees the integrity and control of documentation and records.[2]

PRINCIPLES OF GOOD DOCUMENTATION PRACTICES

All procedures associated with the manufacturing, testing, packaging, or storage of pharmaceutical products, APIs, excipients, dietary supplements, food ingredients, and medical devices must undergo thorough documentation. Principles of good documentation, applicable to both manual and electronic records, include the following:

1. **CLARITY AND ACCURACY**: Records should be clear, concise, accurate, and legible.

2. **TIMELY RECORDING**: Data entries must be recorded promptly at the time of the corresponding actions.

3. BACKDATING AND POSTDATING: Backdating and postdating are strictly prohibited.

4. CORRECTION PROCEDURES: Any corrections made to original entries should be initialed and dated (or documented in an electronic audit trail), with an accompanying explanation if the reason for the change is not evident.

5. TRACEABILITY: Data entries should be traceable to the individual responsible for making the entry.

7. INTEGRITY CONTROLS: Robust controls should be in place to safeguard the integrity of records.

8. VERIFICATION OF FADED INK: In cases where ink may have faded over time (e.g., thermal paper), a copy can be utilized, provided its accuracy is verified; the copy should be initiated and dated.

9. TRACEABILITY OF SUPPORTING DOCUMENTS: Notebooks, data sheets, and worksheets should be easily traceable.

10. DOCUMENTATION SYSTEM: An effective documentation system is essential to ensure data integrity and the availability of both current and archived records.

11. REGULATORY COMPLIANCE: Records should be retained by regulatory requirements and remain readable throughout the designated retention period.

12. PAGINATION: All pages, including attachments (supporting documents), should be paginated, with clear references to the parent document.

The document is a guideline for activities. A document is written, drawn, and presents approved instruction either in paper or electronic form which guides about how an activity shall be executed. Documents can be stored as paper or digitally. It can be changed and revised as needed.

Good documentation practices are applied to ensure documentation is attributable, legible, contemporaneously recorded, original and accurate, complete, available, consistent, and enduring (ALCOA+). These essential practices apply equally to physical, electronic, and hybrid records. [5]

▪ Information generated during GxP activities must be properly recorded and managed to provide documented evidence that Manufacturing Plant products have the safety, quality, identity, purity, and potency, that they purport to have, and these products are manufactured under cGMP.

▪ Documentation should be designed, written, reviewed, and distributed with care. Contents of documents must be clear, concise, accurate, and legible.

▪ GxP records are reviewed by regulatory agencies and are therefore considered legal documents. All GMP documents should be handled in a controlled manner by all associates.

▪ Data entries should be traceable to the person who made the entry.

▪ Uncommon abbreviations and acronyms should be defined.

▪ All corrections to the original entries should be initialed and dated (or captured within an electronic audit trail), with an explanation included in cases where the reason for the change is not obvious. (Follow CLIDE method).

▪ Backdating and postdating are not allowed. If any entry is missing, then it has to be corrected on the current date only with proper explanation.

▪ Controls should be in place to protect the integrity of the records.

▪ If ink may have faded over time (e.g., thermal paper), a copy can be used with verification of its accuracy; the copy should be initiated and dated.

▪ Notebooks, data sheets, Formats, and worksheets should be traceable.

▪ An adequate documentation system is needed to ensure data integrity and availability of current and archived records.

▪ Records should be retained per regulatory requirements and be readable during the retention period.

▪ All pages should be paginated. Attachments (supporting documents) should be paginated with a reference to the parent document.

▪ All dates should be expressed in a format that indicates the day, month, and year.

▪ Do not discard any GMP document after approval if any mistake occurs, this would be still required for traceability.

▪ All GMP records for data collection should undergo appropriate review and signature by a second person to confirm the accuracy, compliance, and completeness of the entries. Records used to make GxP decision shall require review by second person. These reviews should include a review of meaningful metadata, such as hand-written cross-outs on paper records and audit trails in electronic records, to evaluate changes that may impact essential GxP data and GxP decision-making. All GxP records related to a product require a final review and approval from Quality.

▪ Quality unit is responsible for approving documents where applicable in the GMP area.

▪ Personal information must be managed under applicable data protection and privacy laws.

PURPOSE OF DOCUMENTATION

• Defining specifications and procedures for all materials and methods of manufacture and control.
• Ensuring clarity for all personnel regarding tasks and timing.
• Providing authorized individuals with essential information for product release.
• Offering documented evidence, traceability, records, and an audit trail for investigations.

• Facilitating data availability for validation, review, and statistical analysis.

GDP CHALLENGES

In the pharmaceutical industry, maintaining proper records is, a challenge for companies concerning Good Documentation Practice (GDP). Compliance officers must address various issues, including:

Inadequate record-keeping during the transfer of documents between departments or facilities.

Oversight concerning document issuance, data collection, and document review.

Consistent labeling, encompassing identification codes, document revision codes, product identification codes, and product lot numbers.

Ensuring the security and proper storage of documents during the review process.
Consistent identification of all documents throughout various processes.
Ensuring that individuals understand the reasons behind their signatures on documents and the associated responsibilities.

DOS AND DON'TS WITH DOCUMENT HANDLING

Do's:

1. Use black or blue permanent, indelible ink.

2. Ensure entries are clear, complete, and legible.

3. Make entries Contemporaneously when an event occurs.

4. Correct errors in a legible and traceable manner, including crossing out the error, making the correction next to it, providing an explanation if needed, and initialing and dating the correction.

5. If a space should not be filled, mark it as "N/A," along with your initials and the date.

6. Adhere to established standard operating procedures (SOPs) such as document review and approval processes, version control, date and time formats, record retention, change control, and electronic signature protocols.

7. Provide comprehensive training to all personnel.

Don'ts:

1. Avoid using pencils or erasable ink.

2. Refrain from using "write-out" or masking devices.

3. Do not make untraceable corrections (e.g., overwriting entries without providing a date, initial, or explanation).

4. Avoid using sticky notes.

5. Do not Make back-date or post-date entries.

6. Avoid using confusing asterisks, especially for footnotes.

7. Do not transcribe data.

8. Avoid using unbound laboratory notebooks without page numbers to prevent doubts about missing pages.

TYPES OF DOCUMENTATION

- For Organization & Personnel.
- For Buildings & Facilities
- For Equipment’s.
- For Holding & Distribution
- For Laboratory Control.
- For Handling of R.M.& P.M.
- For Production & Process Control.

- For Packaging & Labelling Control.
- For Records & Reports.
- For Return & Salvaged Finished Products.

Organization & Personnel Documentation:

This type of documentation involves records related to organizational structure, roles, responsibilities, and personnel qualifications within the pharmaceutical company. It includes organizational charts, job descriptions, training records, personnel qualifications, and job-specific procedures. Proper documentation ensures clarity in roles, responsibilities, and qualifications, contributing to effective workforce management and regulatory compliance.

Buildings & Facilities Documentation:
Documentation pertaining to buildings and facilities ensures the proper management and maintenance of physical infrastructure used in pharmaceutical manufacturing. It includes building layout drawings, facility specifications, maintenance schedules, cleaning procedures, environmental monitoring records, and validation documentation. This documentation ensures that facilities meet regulatory standards for cleanliness, safety, and functionality.

Equipment Documentation:
Equipment documentation involves records related to the acquisition, qualification, calibration, maintenance, and usage of equipment used in pharmaceutical manufacturing processes. It includes equipment manuals, specifications, calibration certificates, maintenance logs, validation records, and cleaning procedures. Proper documentation ensures equipment reliability, accuracy, and compliance with regulatory requirements.

Holding & Distribution Documentation:

This type of documentation involves records related to the storage, handling, and distribution of pharmaceutical products. It includes inventory records, storage conditions, transportation logs, temperature monitoring records, and distribution records. Proper documentation ensures product integrity, traceability, and compliance with storage and distribution regulations.

Laboratory Control Documentation:

Laboratory control documentation includes records related to laboratory testing, analysis, and quality control measures. It encompasses test methods, analytical procedures, sample preparation protocols, raw data, test results, quality control charts, and validation reports. Proper documentation ensures the accuracy, reliability, and traceability of laboratory testing processes and results.

Handling of Raw Materials (R.M.) & Packaging Materials (P.M.) Documentation:

This type of documentation involves records related to the receipt, inspection, handling, and usage of raw materials and packaging materials in pharmaceutical manufacturing. It includes material specifications, supplier qualification documents, receiving records, sampling protocols, material handling procedures, and material usage logs. Proper documentation ensures the quality, traceability, and compliance of raw materials and packaging materials used in production.

Production & Process Control Documentation:

Production and process control documentation encompasses records related to the manufacturing processes, procedures, and controls employed in pharmaceutical production. It includes batch records, standard operating procedures (SOPs), process validation protocols, equipment logs, in-process testing records, and deviation reports. Proper documentation ensures consistency, reproducibility, and compliance of manufacturing processes with regulatory requirements.

Packaging & Labelling Control Documentation:

Documentation related to packaging and labelling control involves records pertaining to the packaging and labelling of pharmaceutical products. It includes packaging specifications, labelling artwork, packaging material usage logs, labelling reconciliation records, and packaging line clearance records. Proper documentation ensures the accuracy, integrity, and compliance of packaging and labelling processes with regulatory standards.

Records & Reports Documentation:

Records and reports documentation encompasses all documentation generated throughout the pharmaceutical manufacturing process. It includes batch records, logbooks, change control records, deviation reports, corrective and preventive action (CAPA) documentation, and quality management system records. Proper documentation ensures comprehensive documentation of all activities, decisions, and outcomes, facilitating regulatory compliance and quality management.

Return & Salvaged Finished Products Documentation:

This type of documentation involves records related to the handling, investigation, and disposition of returned or salvaged finished products. It includes return authorization records, investigation reports, disposition decisions, and rework/reprocessing documentation. Proper documentation ensures appropriate handling, investigation, and disposition of returned or salvaged products, maintaining product quality and compliance with regulatory requirements.

Equipment Maintenance and Usage Log

In pharmaceutical operations, maintaining accurate records of equipment use, cleaning, sanitization, and maintenance is vital. Here are the key points to include in the equipment cleaning and usage log:

Date and Time: Document the date and, when applicable, the time of each equipment operation, cleaning, sanitization, or maintenance task.

Product and Batch Details: Specify the product and batch number processed in the equipment during each operation. This ensures traceability and helps prevent cross-contamination.

Personnel Information: Record the name and signature of the individual responsible for carrying out the cleaning and maintenance tasks. Additionally, include the names and signatures of personnel involved in double-checking the cleaning and maintenance work.

Chronological Order: Ensure that entries in the log are recorded in chronological order to maintain a clear and accurate timeline of equipment usage and maintenance activities.

To mitigate the risk of cross-contamination, implement the following technical or organizational measures:

Segregation of Production: Products with a high risk of cross-contamination, such as penicillin's or live vaccines, should be manufactured in segregated areas or by campaigns with appropriate cleaning procedures between batches.

Air Locks and Extraction: Install air locks and effective air extraction systems to minimize the risk of contamination from untreated or insufficiently treated air.

Protective Clothing: Require personnel to wear protective clothing inside areas where products with a special risk of cross-contamination are processed.

Effective Cleaning Procedures: Implement cleaning and decontamination procedures that have been proven effective, as ineffective cleaning is a common source of cross-contamination.

Closed Systems: Utilize closed systems of production to minimize exposure to external contaminants.

Residue Testing and Cleaning Status Labels: Regularly test for residues and use cleaning status labels on equipment to indicate its cleanliness and suitability for use.

In situations where equipment is dedicated to manufacturing a single intermediate or active pharmaceutical ingredient (API), separate equipment records for cleaning, maintenance, and batch logs may not be necessary if the batch record provides complete traceability of this information. However, in formulation manufacturing, it is crucial to establish appropriate cleaning procedures to ensure the removal of any residues from previous products, thereby maintaining product quality and preventing cross-contamination.[4]

LABORATORY CONTROL RECORDS

Laboratory control records play a vital role in ensuring compliance with established specifications and standards. These records should encompass thorough data derived from all tests conducted, including examinations and assays.

Here is what should be included:

Sample Description: Provide detailed information about the samples received for testing, such as the material name or source, batch number, manufacturer/supplier details (if applicable), distinctive code, date of sample taken, quantity of the sample, and date received for testing.

Test Methods: Clearly state or reference each test method used in the analysis.

Sample Measurement: Specify the weight or measure of the sample used for each test according to the method. Additionally, include data on or cross-reference to the preparation and testing of reference standards, reagents, and standard solutions.

Raw Data: Maintain a comprehensive record of all raw data generated during each test, including graphs, charts, and spectra from laboratory instrumentation, all properly identified to indicate the specific material and batch tested.

Calculations: Document all calculations performed in connection with the test, including units of measure, conversion factors, and equivalency factors.

Test Results: Provide a statement of the test results and how they compare with established acceptance criteria.

Signature and Date: Ensure the signature of the individual who performed each test and the date(s) on which the tests were conducted.

Second-Person Review: Include the date and signature of a second person who reviewed the original records for accuracy, completeness, and compliance with established standards.

In addition to the above, complete records should be maintained for:

Modifications to Analytical Methods: Document any changes made to established analytical methods.

Instrument Calibration: Keep records of the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices.

Stability Testing: Record all stability testing conducted on active pharmaceutical ingredients (APIs) and formulations.

Out-of-Specification (OOS) Investigations: Document investigations conducted in response to out-of-specification test results.

It is imperative to maintain records of testing and standardization of laboratory reference standards, reagents, and standard solutions, as well as periodic calibration of laboratory instruments, apparatus, gauges, and recording devices, to ensure thorough documentation and adherence to quality standards.

GOOD DOCUMENTATION PRACTICE (GDP) STEPS

Initial/Date:

All entries in a cGMP document must be accompanied by the identity of the person (initials or signature) and the date of the entry. This requirement, mandated by the Code of Federal Regulations (CFRs), serves as a tracking method to confirm task completion, and identify responsible individuals.
Initials are typically used for identification, although some operations necessitate a signature, such as in an "Approved By" space. Standardized signatures and initials are recorded by various companies to address potential conflicts, especially in larger organizations.

Recording Time:

Time can be recorded in military time (00:00 to 23:59) or in meridian time (1:00 AM/PM to 12:59 AM/PM), depending on company standards.

Corrections:

Handwritten changes or corrections are prohibited in approved cGMP documents. Consultation with a supervisor is required for error discovery, and changes must be implemented through the established quality system.
Correction procedures include crossing out the incorrect entry, initialing and dating near the correction, ensuring legibility of the original mistake, and dating the correction with the correction date, not the error date.

Performed By:

Documentation of task performance must occur at the time of completion and before moving on to the next step. Tasks should not be executed if the manufacturing procedure is unavailable for documenting necessary data.
Personnel proficient in the task or under training supervision can initial and date the "Performed By" space.

Recorded By:

In situations where the operator cannot immediately initial and date the operation due to confined space, another person must record the data and initial and date the "Recorded By" space before proceeding.

Verified By:

Verification must precede the next step and cannot be performed by the same individual executing the task. At least one other person must review documentation for accuracy before initialing or signing and dating the "Verified By" space.

Deviations:

Deviations from written procedures require supervisor notification and documentation using the appropriate quality system.

Missing Data:

Blank entries must be marked with an asterisk or similar notation. Comments explaining the reason for missing information and providing the proper information must be documented on the same page, initialed, and dated at the recording time.

Voiding Records:

Errors in in-process material execution may necessitate voiding documents, approved by a supervisor and Quality Assurance (QA), to prevent confusion. "Void" must be written across the front of the document, including initials and date.

Recreating And Rewriting Records:

Recreating or rewriting records should be avoided unless necessary, with supervisor and QA approvals required. Recreated documents must be labeled as "Rewrite" and reference the sources of information.

Rounding of Rules:

Rules for rounding off numbers must be followed meticulously, either carrying extra digits through calculations or rounding according to predefined guidelines.

Approved By:

The signature of a qualified individual, such as a supervisor or designee, signifies that the documented information is complete, accurate, and acceptable.[10]

PREPARATION, ISSUES, AND USES OF DOCUMENTS

Documents must be meticulously prepared and organized to prevent misuse and ensure clarity of information. Each document should include the following elements:

- Company name
- Purpose and title of the document
- Identification number and revision number
- Date of authorization
- Date of review
- Signature of individuals responsible for preparation, checking, and authorization
- Distribution list
- Page number
- Documentation of the reason for revision
- Abbreviations and references

Documents should be clear and legible, preferably in a computerized format for easy readability. When issued, documents should be signed by a responsible individual to indicate verification. Any corrections should be made by a single line with a signature and date, avoiding overwriting. Sufficient space should be provided for filling in information, and ball ink pens should be used for handwritten entries.[6]

HIERARCHICAL DOCUMENT SYSTEM

The regulatory requirements governing the company (e.g., USFDA/EU GMP/ICH/Schedule M) should be at the top of the document pyramid, guiding the directives of sublevels.

Level 1 documents, such as the Quality Manual, break down regulations into specific parts relevant to the company, establishing overall principles and guidelines for developing, documenting, and implementing a compliant quality system.

Level 2 documents further break down regulations into specific subjects or topics, providing guidelines for subordinate-level procedures to ensure consistency across departments.

Standard Operating Procedures (SOPs) represent the next level in the hierarchy, offering specific step-by-step instructions for operational tasks discussed in previous levels and are department or function-specific.

Level 3 documents, the most specific, such as batch records or validation procedures, provide detailed instructions for production-related tasks, equipment, or processes and may override instructions given in higher-level documents.
This hierarchical structure provides a systematic way to organize a company's documents, ensuring compliance with regulatory requirements and consistency across departments.

Sr. No.	Types of Errors	Explanation to be given while correcting the error
1	Signature missing (Done by/ Checked by/ Reviewed by/ Approved by etc.)	Missing sign was done on a current date with an explanation.
2	Data missing (Critical / Non-critical) - Critical data to be handled by raising deviation or event investigation e.g., The drying temperature not mentioned. Non-critical data to be entered against available raw data e.g., Equipment ID missing.	- Reason is not applicable as deviation/ event needs to be raised. - Data mentioned based on available raw data.
3	Wrong data mentioned	Transcription error hence corrected (data proof to be verified)
4	The wrong date/time mentioned	Date/ Time corrected (with proper explanation)
5	Overwritten entry / Number turned / scribbled out	Writing errors are corrected with proper explanation or by verifying online or by verifying the data proof. (If due to overwrite there is a change in results or impact on the product, or no evidence is available then it calls for a deviation)
6	Multiple rounding errors	Rounding figure corrected
7	If any other ink is used other than blue	Wrong ink was used hence re-signed using the required ink.
8	Misspelling (Spelling Mistake)	Spelling corrected
9	Wrong result due to calculation	Calculation error corrected
10	Human Error	Error by an individual caused due to due to lack of attention, fatigue, overwork, distractions, performing task incorrectly, non-routine work, memory gaps, etc. [14]

Table 1- Types of errors (Examples)

DOCUMENT CONTROL

Initially, documents are prepared by the concerned department as drafts, which are then reviewed by the department head. Once finalized, the draft is sent to the Quality Assurance (QA) department, where it is converted into a final document and checked and approved by an authorized person. Control copies of the approved documents are issued to the concerned department, and records of issuance are maintained.
Following the approval of documents such as Standard Operating Procedures (SOPs), Quality Assurance ensures that all users in the concerned department receive training before the implementation of the SOPs. Records of such training must be maintained. A training coordinator, preferably the head of the user department or a designated individual, is responsible for organizing the training sessions. Upon successful completion of training on any SOPs, the SOPs become effective.
The original SOPs are stamped as "MASTER COPY" with red ink and stored under supervision. Photocopies of the master copy, duly stamped as "CONTROL COPY" in blue color, are distributed. A distribution list for SOPs should be maintained for issuance records. Any changes to SOPs require initiation through a change request process, and all issued copies are retrieved. New copies are then implemented after providing training on the changes. [3,6,8]

CONCLUSION

Implementation of Good Documentation Practice (GDP) for pharmaceutical products is essential for ensuring compliance with Good Manufacturing Practice (GMP) standards and regulatory bodies. The primary objective of GDP is to establish a manufacturer's system of information and control to minimize the risks associated with oral or informal written communication, provide clear procedures to be

followed, ensure confirmation of performance, enable accurate calculations, facilitate batch history tracing, and maintain product quality.[10]

By establishing robust systems for information management and control, GDP minimizes the risks associated with errors and misinterpretations in documentation, thereby enhancing the reliability and accuracy of pharmaceutical processes. Furthermore, GDP ensures transparency, traceability, and accountability throughout the manufacturing lifecycle, enabling effective monitoring, auditing, and inspection by regulatory bodies. [2,9]

In essence, the adoption of Good Documentation Practices is not only a regulatory requirement but also a fundamental necessity for the pharmaceutical industry. It underscores the industry's commitment to quality, integrity, and continuous improvement, ultimately safeguarding public health and fostering trust in pharmaceutical products worldwide.

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