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GOOD DOCUMENTATION PRACTICE: ONE OF THE WAY TO BE EXCELLENT IN QUALITY

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Abstract: This article presents some of the fundamentals of the good documentation practice as it is very essential for any pharmaceutical entity whether industry, academy or small firm to grow up with effective and powerful documentation to cope up the throat cut competition and to retain a large number of customers. From this article one can get the idea of the good practice for the content, creation, maintenance and procedure for acquiring practice for good documentation. This article focus on the types of the document, standards of the good documentation, elements of the document, common documentation errors and points to acquire good documentation practice.

As a part of any Quality Management System, to stick to that system one requires to maintain an inventory of documents. So good documentation constitutes an essential part of the Quality Assurance system and is key to operating in compliance with GMP requirements.

As per the above facts, an attempt is made to club the documents requirements as per different Quality Systems and GMP to prepare comprehensive related to good documentation.

Keywords: Documentation; Good documentation practice; GMP; Pharmaceutical Documentation

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INTRODUCTION

Documentation is an essential part of the Quality Assurance system with aim to define specifications for all materials, methods of manufacture and control to ensure required quality of the product as per customer's need.[1]

Quality Management System of the any manufacturer should clearly define the various types of the documents and media. Their objective is utilized to establish, control, monitor and record all the activities which directly or indirectly impact on all aspects of the quality of the finished products.

Good Documentation provides the future planning based on the manufacturing has done in the past and which is ongoing now. Good Documentation also reflects the effective quality assurance system.[2]

PHILOSOPHY OF THE QUALITY SYSTEM

The general philosophy of the any quality system is same like that for the ISO 9001 system which is "SAY what you do (document the processes), DO what you say (follow the procedures), and PROVE it (provide evidence of compliance)".[3]

WHAT IS DOCUMENTATION?

Documentation is the backbone of the pharmaceutical industry - the taken-for-granted support for GMP, GLP, GCP and many other regulations. Document covers what to do, how to do it, the expected result, the actual result, what went wrong, what we did about what went wrong, what we change, how we know the change was effective and so on.

The thinking that to document each and every activity which is performed by individual is documentation is totally wrong. Documentation is the process when one club the activities of recording of the data, approval of the document, issuance and disposal of documents, retrievability of document, presentation of document and review of the document which can be in the form of either paper, CD, Computer file or microfilm.

WHAT IS GOOD DOCUMENTATION?

"Right-first-time"approach for the document is to ensure, identity, authenticity and accuracy of records is Good Documentation Practice.

If your Document says "What actions took place in the development or manufacturing of product so that anyone including auditor or inspector has documented evidence that you did exactly what you said " that is Good Documentation Practice.

The most influential and frequently referenced regulatory bodies throughout the world for pharmaceutical products as far as documentation is concerned are as following :

- Guide to GMP for Medicinal Products Part 1, Chapter 4 Documentation: PIC/S PE 009-8 (Part I).
- Clause 4.2, Guidance on the general documentation requirements of the international Standard, ISO 9001-2008.[4]
- 21CFR58 : Good laboratory practice, Subpart J : Records and Reports.[5]
- Section 6, Documentation and Records, ICH Harmonized Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Q7, Current Step 4 version, November, 10 2000.[6]
- The guide to Good Manufacturing Practice for Medicinal Products of the European union (the EC GMP Guide).[7]
- The World Health Organization (WHO) good manufacturing practices.[8]

WHY GOOD DOCUMENTATION?

The current requirements for the “documented evidence” driven by the event of the death of the five people due to the nonsterile drug products which was designated as sterile and became contaminated. Investigations of the same revealed that an unwritten change to the autoclave operation, communicated orally between operators resulted in non uniformly sterile dextrose IV solutions.

Safety of the product was compromised with chain of events included inadequate maintenance, inadequate understandings of autoclave operation and regular deviation from the written production instructions often results into the equipment malfunctions. Together these factors resulted in a sterilization cycle that did not assure that all vials in the autoclave were sterilized thus some doses were safe while others let to sepsis in patients who received them. So overall if see, there is a violation of the some of the critical rules which we called today cGMP rules. And so that incident lead the pharmaceutical industry to define sterility assurance level, process and equipment validation and legal right of inspection.

Finally the Validation was developed as a mean of documenting systematic evaluation of the process with safety factors and identifying the critical parameters that need to be controlled to assure the process performance. The current requirements for ‘documented evidence‘ may be driven by this event of Devonport as the preventing errors is more effective than finding rejects because it is not possible to detect all rejects.[4,9]

LIFE CYCLE OF THE DOCUMENT [6]

- Document creation & Approval : The process owner or the authorized person should write as per the specific format and template and circulate the document after getting approval of QA.
- Document use & Data collection : Responsibility of all technicians, engineers, scientists, operating persons who are trained and authorized to collect and record data.
- Data Verification : Responsibility of supervisors, managers and all individuals trained & authorized to review data.
- Record Review & Product disposition/Approval : Responsibility of QA or those trained & authorized to review records.
- Record Archiving : Records are accessible, retrievable, secure is the responsibility of QA & relevant departments.
- Record Destruction : As per SOPs that directs the destruction of documents.

TYPES OF THE DOCUMENTS

- **Commitment Documents** - Relationship between industry and the regulatory authorities. Exa : NDA, SMF
- **Directive Documents** - Relationship between the Management and Employees. Exa : Specifications, STPs, SOPs, MFRs etc.
- **Record Documents** - Relationship between the Employees and the Work they perform. Exa : Protocols, BMRs, Log Books, Calibration Records etc.

COPY OF THE DOCUMENT

- Master Copy - Original copy of the document which is signed by qualified responsible persons.
- Controlled Copy - The copy of the document from master copy and used in regulated environment signed and stamped by qualified responsible person.
- Uncontrolled copy - The copy of the document from master copy made for information purpose only.
- Superseded copy - Old version of the copy which is replaced by the latest version of the document.

- Obsolete copy - Copy of the document which is to be discontinued in use.

Any of the copy from the document should be [10,11,12] clear, legible, without error. No any copy is valid unless if it is stamped particularly.

GOOD DOCUMENTATION PRACTICE STANDARDS[6,13,15]

1. **Document creation** - Contemporaneous with the event they describe and must be checked for accuracy to have free from errors [14,11]

2. **Document approval** - Approved, signed, and dated by appropriate authorized personnel

3. **Document Signatures** - Document signatures are means for the approval and shows that it under the supervision of authorized person. It adds the value to the document.

- No signature pads, scanned signatures or duplicated original signatures shall be used to replace a handwritten signature by the person signing[16,17]
- Documents shall be signed in permanent ink
- Signatures shall be kept throughout the life of the document

4. **Handwritten entries**[10,18,19]

- Adequate space is provided for expected handwritten entries.[6,11]
- Handwritten entries are in indelible ink.[5]
- Critical entries must be independently checked (SPV or second person verified).
- No spaces for handwritten entries are left blank - if unused, they are crossed out or "N/A" (or similar text) entered.
- Ditto marks or continuation lines are not acceptable.[20,21,22]
- A stamp in lieu of a handwritten signature is not acceptable

5. **Document Maintenance**[10]

- Regularly reviewed and kept current.
- Record for the creating, issuing and modification should be there.
- Retained and available for appropriate duration & in appropriate condition.[17,23]

- Electronic document management systems are validated and electronic records are backed up.

6. Document Modification [10,11,14]

- Handwritten modifications should be signed and dated.[6]
- Where appropriate, the reason for alteration must be noted ("E.E." is a common abbreviated reason, indicating "Entry Error").[5]
- Controls should be existed to prevent the inadvertent use of superseded documents.
- Electronic versions can only be modified by authorized personnel and controlled by password or other means.
- A history must be maintained of changes and deletions to electronic versions as well as paper documents.[5]

7. Corrections or Additions

In Record

- Single line through the information that needs to be corrected and shall be signed and dated.
- Should not to scribble out the original data, use white out or write over data.[24]

In Document

- Only personnel who have already been approved to write or make changes to document can correct or add to documents.
- Non-typographical error corrections or additions indicating a change in data or acceptance status require a comment. And routed through full document Change control.
- Typographical error change or additions do not require approval.

8. Document review[25]

- Responsibility of supervisors, managers and all individuals trained & authorized to review documents and data at specific time interval.
- Document review will focus on the document's content, context, format and grammar.

- The document quality attributes of concern document review are correctness, usability, appropriateness and maintainability.
- Review factors and criteria are as below

- Adherence to standards
- Consistency and traceability
- Readability, comprehensibility, and general understandability
- Technical adequacy and feasibility of approach
- Degree of completeness
- Testability of requirements
- Use of appropriate requirement, design, or coding techniques
- Appropriate level of details

9. Designees

- If a designee is to be used then that person signs his/her name, adds the words “signing for” and adds the original printed name of the approver.
- Designees must have the knowledge, skills, and abilities to perform the assigned authorship, verification or approval activity.

10. Document Numbering

- All document shall have a unique document number.
- This is typically issued by a document control department or person generally Quality Assurance in the pharmaceutical.

11. Date & Time[26]

- A legal date is comprised of a month, day, and year although not necessarily in that order. Local conventions are assumed unless otherwise specified in an SOP.
- It should be in uniform format. For example : DD/MM/YY or DD/MM/YYYY
- Postdating means entering a date of the future is not permitted

- Backdating means entering a date on a day after the entry was made or the task was performed is not permitted
- If times are required, procedures identifying approved guidelines for documenting date and time (AM/PM or 24 hr) shall be defined.
- **Document Effective Date**[27]

- Date of the change or the date from which the document become live.
- Effective date changes on every new change in the document and each change should be recorded at change history at the front page of the document

- **Document Review Date**

- Date given to the document after the respective departmental head review the document in consultation with actual user.
- After approval all the master and controlled copies are stamped as "REVIEWED" on the document with review and next review date.

12. Document Revision[10]

- All documents shall have a revision level & latest document should live.

Two type of the revision

Routine revision :

- No technical or editorial modification but at the end of the two years of the effective date, HOD will review and if there is no any change then HOD shall send internal communication that this document doesn't need revision.
- If yes then review the document and stamped as "REVIEWED"

Technical or editorial revision :

This type of the revision shall be carried out by document change control procedure and recorded.

COMMON DOCUMENTATION ERRORS

- Missing signature and dates at the time the activity is performed.
- The "write over" and the "scribbler".

- Non uniform date and signature entry.
- Data entries that do not correspond to the batch record instructions.
- Writing a note that activity was performed on one day and signed for on other day.
- Blanks on batch production records.
- Pre-recording of data.
- Incomplete references.
- Review not signed.
- Illegible writing.
- Too many corrections.

Common Documentation Error

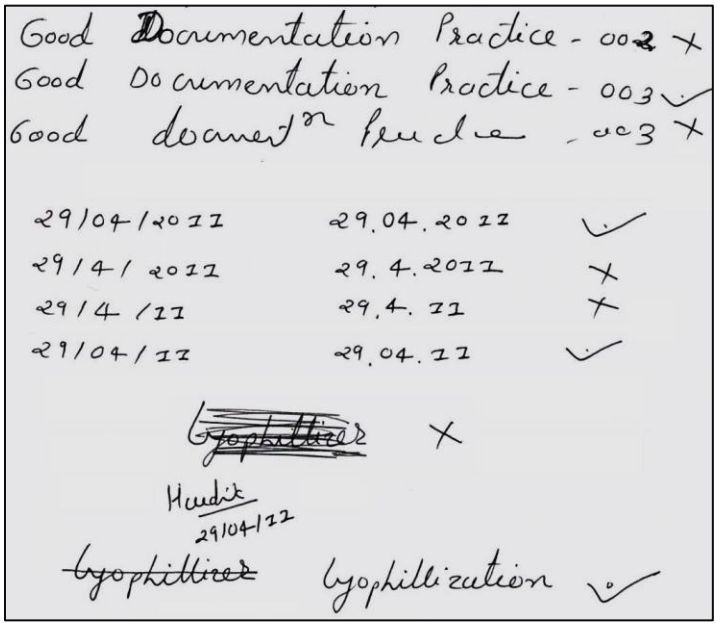

Figure 1. Common Documentation Errors

TIPS TO ACQUIRE GOOD DOCUMENTATION PRACTICE[28]

- FDA statement should drilled into you from day one ‘'If you didn't document it, then it didn't happen‘'.
- On one hand do the work, on other make the document.

- Use indelible (water-resistant) blue or black ink and never use white ink to remove error.
- Do not use pencil or felt-tipped marker
- Never overwrite or scribbled the entry. Just single cut the error with sign and date.
- Never leave space or blank in the document and Draw a diagonal line through any blank fields or empty spaces at the bottom of a page and include 'N/A' along with your initials and date
- Never back date, Never post date and date in uniform format.
- Each page in a controlled notebook should be chronologically.
- When entering repetitive data, do not use ditto marks.
- For instrument printouts, adhere with clear adhesive tape and include your signature and date where the printout is attached.
- Signature logs must be maintained, indicating each employees printed name, signature and date.
- We should forget the syndrome “We can fix the documentation later ”.

CONCLUSION

There are many potential benefits of Good Documentation Practice. Some of them are

- Unlock the potential of individual using the document.
- Amplify the value of your product.
- Build confidence in your quality.
- Good Documentation helps to save the papers.
- Reduce the efforts to compliance with regulatory bodies.
- Good documentation enables to achieve the results that you are seeking for.

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