JOURNAL OF PHARMACEUTICAL SCIENCE AND BIOSCIENTIFIC RESEARCH (JPSBR)

(An International Peer Reviewed Pharmaceutical Journal that Encourages Innovation and Creativities)

A Concise Review on "Good Documentation Practice"

Binny Mehta*[1], Hemangini Makwana[2], Pinak Patel[3], Krunal Detholia[4]

1. Assistant Professor, Department of Quality Assurance, Smt. S. M. Shah Pharmacy College, Mahemdavad, Gujarat, India
2. Student of M.Pharm, Department of Quality Assurance, Smt. S. M. Shah Pharmacy College, Mahemdavad, Gujarat, India
3. Head of Department, Department of Quality Assurance, Smt. S. M. Shah Pharmacy College, Mahemdavad, Gujarat, India
4. Assistant Professor, Department of Pharmaceutics, Smt. S. M. Shah Pharmacy College, Mahemdavad, Gujarat, India

Article history:

Received 05 Jan 2019
Accepted 02 March 2019
Available online 10 April 2019

Citation:
Mehta B., Makwana H., Patel P., Detholia K. A Concise Review on "Good Documentation Practice" **J Pharm Sci Bioscientific Res**. 2019. 9(2):136-141

For Correspondence:
Binny Mehta

Assistant Professor, Department of Quality Assurance, Smt. S. M. Shah Pharmacy College, Mahemdavad, Gujarat, India.

(www.jpsbr.org)

ABSTRACT:

Documents are a mirror to show actual image of any pharmaceutical company. Such measures that collectively and individually ensure documentation, whether paper or electronic, is attributable, legible, traceable, permanent, contemporaneously recorded, original and accurate. Specific topics for discussion include documentation fundamentals, document creation, document management, best practices in style and layout, completing documents and record-keeping, electronic records, storage, errors including error correction, and associated topics

KEY WORDS: Good Documentation Practice, Pharmaceutical Company, Document creation, Document management.

1 INTRODUCTION [1-15]

The GDP can be defined as “Good documentation practice is an essential part of the quality assurance and such, related to all aspects of GMP” this definition is based on WHO.

Good Documentation Practices (GDP) are methods for recording, correcting and managing data, documents and records, to ensure the reliability and integrity of information and data throughout all aspects of a product's lifecycle. Clearly written documents prevent errors of various activities in pharma each and every activity is written in specific documents such as SOPs and strictly followed. Verbal communications may be create errors and there was no proof. So, to minimize error by good document practice that all important documents such as Master formula record, procedure and record must be free from errors and Documented.

1. Type of formulation
2. Country requirements
3. Availability of ERP or SAP system

SCOPE

- The Good documentation practices are target to both paper as well as electronic data or manually filled records or generated electronically in a GxP environment.

PURPOSE

- To provide the basic guide for good document practices with regard to creation, approval, review, maintenance, correction or errors, verification and archiving etc.
- To define the specifications and procedures for all materials and methods of manufacture and control.
- To ensure the existence of documented evidence, traceability and to provide records and an audit trail that will permit investigation.
- Ensures availability of data for validation, review and statistical analysis.
- To ensure that all personnel concerned with manufacturing know what to do and when to do it.
- To improve performance.
- Regulatory requirements.

GDP GOALS

TO CREATE: Complete, contemporaneous, legible, accurate and traceable records

TO GUARANTEE:

1. Quality of Research activities
2. Credibility of the data & result

The definition of Good Documentation Practice (GDP) describes standards by which documentation is created and maintained in the pharmaceutical industry.

CLASSIFICATION OF DOCUMENTATION [7]

Following are the classification of Documents

- For organization & Personnel.
- For Buildings & facilities
- For Equipments.
- For Handling of R.M.& P.M.
- For Production & process control.
- For Packaging & Labeling control.
- For Holding & Distribution
- For Laboratory Control.
- For Records & Reports.
- For Return & Salvaged finished products.

Some examples of documentations used in the pharmaceutical environment are (but not limited to): Laboratory Note Books, Batch Record, Bills of Materials, Specifications, Policies, Protocols, Standard Operating Procedures (SOPs), Work Instructions, Test Methods, Check Lists, Forms/Log Sheets, Training Assessments, Electronic and Hardcopies of Quality Records, Certificate of Analysis, Certificate of Compliance, Technical Transfer Reports, Validation Documents etc.

2 MATERIAL AND METHODS

Constituents of Good Documentation:

- Approve, review and update documents
- Changes & current revision status of documents identified
- Relevant versions of applicable documents available at points of use
- Documents remain legible and readily identifiable
- Documents of external origin identified, and their distribution controlled
- Prevent unintended use of obsolete documents, and archivin

TYPES OF DOCUMENTS USE IN PHARMACEUTICALS:

Specifications: as per MHRA Specifications describe in detail the requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.

We need specification for:

1. Documentation System and Specifications
2. Equipment Cleaning and Use Record
3. Records of Raw Materials, Intermediates, API Labeling and Packaging Materials
4. Master Production Instructions (Master Production and Control Records)
5. Batch Production Records (Batch Production and Control Records)
6. Laboratory Control Records
7. Batch Production Record Reviews
8. Intermediate and semi-finished product
9. Finished product

SOPs: it is a written, authorized functional instruction used as a reference by the person responsible for performance and are also used for training new operators in the performance of the procedure.

- Test method: it is a written and approved document describe the detailed testing procedure.
- List: Documents contain a catalog of any object such as list of equipment's.
- Certificates of Analysis: it is an authentic document shows the analytical reports and decision of acceptance/rejections
- Label
- Records
- Organ gram
- Job description

Batch Manufacturing records: it is an important document issued for every batch of product to assure, review and record keeping of any product batch. There are following major content of BMR.

To record should be checked before issuance to assure that it is the correct version and a legible accurate reproduction of the appropriate master production instruction. If the batch production record is produced from a separate part of the master document, that document should include a reference to the current master production instruction being used.

These records should be numbered with a unique batch or identification number, dated and signed when issued.

Documentation of completion of each significant step in the BMR (batch production and control records) should include

- Appropriate Date, times
- Identity of major equipment
- Specific identification of each batch, including weights, measures, and batch numbers of raw materials, intermediates, or any reprocessed materials used during manufacturing
- Actual data of critical process parameters
- Signatures of the persons performing and directly supervising or checking each critical step in the operation;
- In-process and laboratory test results
- Actual yield at appropriate phases or times
- Description of packaging and label for intermediate or API
- Deviation record
- Result of examine made

DOCUMENT ERROR (5-7)

Common documentation errors that commonly appear in FDA warning letters and reports from other regulatory authorities include [4]:

- Documentation not contemporaneous
- Document error correction not signed/dated, and didn't include a reason for the correction
- Write-overs, multiple line-through and use of "White-out" or other masking device
- Use of ditto marks
- Failure to use ink as specified by procedure, Incorrect ink used for entries causing illegible data when a substance was spilled
- Records should be completed at time of activity or when any action is taken
- Obscured original data
- Use of pencil
- Inaccurate records
- Sample sequence table and audit trail not documented (to draw on the commonly used phrase: "if it is not documented, it didn't happen")
- Handwritten changes not dated, Write-overs, multiple line-through, and use of "white-out" or other masking device
- Don't assume knowledge.

The most common GMP citation occurs with correction of errors when information is recorded. Correction of documentation errors should include:

- Draw a single line through the error,
- Make the correction next to the error,
- Write an explanation for the error,
- Sign and date the correction.

It is recommended that these common errors are highlighted in training on the creation and use of documentation.

DOCUMENT MANAGEMENT (6-9)

Each pharmaceutical organization should have a system for documentation management. This sets out the rules and mechanisms for creating and controlling a document. GMP makes certain requirements of a documentation system such as:

- Assigning responsibility to an individual for control of the system
- Ensuring layout, approval, authorization and unique identification of all documents is provided for often by a master documentation SOP
- Having a master documentation SOP to include:
- Procedures for issue, retrieval, re-issue, maintenance of currency and traceability
- Procedures for determining the need for documents
- Identification of documents to be included in batch dossiers (for batch release)
- Linkage of documents to licenses and regulatory requirements
- Outlining audit requirements for the documentation system
- Ensuring that only the most up to date version is ever used Retention times and archiving

DOCUMENT CONTROL (8-12)

Further considerations regarding the system controlling documentation include:

- Documents should be available at point of use
- There is control over format
- There is a system for changes, approval, and re-issue
- There is control of documents of an external origin.

The majority of these requirements also make up the elements of the "documentation lifecycle" -- From document creation, through its use, to its storage and archiving, and then to its eventual retirement and possibly replacement by a revised version.

The control of documents necessitates the following steps:

Documentation creation

- Documents must be contemporaneous with the event they describe
- Documents must not be handwritten (except for handwritten entries)
- When electronically produced, the documentation must be checked
- For accuracy Free from errors For some types of data, the documentation must be in a format that permits trend evaluation.

Document approval

- Documents must be approved for use. They must be approved, signed, and dated by appropriate authorized personnel.

Handwritten entries

- Adequate space needs to be provided for expected handwritten entries
- Handwritten entries must be in indelible ink
- Critical entries must be independently checked (second person verified)
- No spaces left empty for handwritten entries. If unused, they are crossed out or "NA" (or similar text) entered
- Ditto marks or continuation lines are not acceptable
- Use of stamp in place of signature.

Document copies

- Copies need to be clear and legible
- Errors must not be introduced
- Documents should be regularly reviewed and kept current,
- Documents should be retained and readily available for audits
- Archived documents must be retrievable for the appropriate duration
- Electronic document management systems must be validated
- Electronic records must be backed up.

Document modification

- Handwritten modifications are signed and dated
- No obliterating the text through crossing-out
- Use appropriate, with suitable reason the
- Controls exist to prevent the inadvertent use of superseded documents
- Electronic versions not modified or any changed done must be easy to trace.
- Access to electronic documents must be controlled by password or other mean

An audit trail must be maintained of changes and deletions to electronic documents. Document must be done at every aspect of the process, activities, and operations involved with drug and medical device manufacturers. If the documentation showing how the product was made and tested not correct and in order, then the product does not meet the required specification and could be considered to be tamper with document.

Batch Documentation:

A major element in the final product release should be a review of all the relevant batch documentation to ensure the presence of all necessary information and the satisfactory completion of all necessary records. They must include sterilizer charts, microbiological testing COA, process data records, test results data.

Procedures and Record:

In addition to the instruction and associated records described above, specific procedures including material receipt, sampling, testing rejection, complaints, and other documents are also required.

Depending of the type of document GMP expectations are that the document carries:

- Product name
- Description of the item
- Reference number and item code
- Pack or batch size
- List of materials
- Specific precautions or instructions
- Names of associated personnel
- Dates and times Version number
- Approvals.

3 BEST PRACTICE FOR DOCUMENT CREATION AND USE [6-10]

A company should continually evolve good practices for creation of documents. It is important that documents are designed, prepared, reviewed, and distributed with care. Documents also must be approved, signed, and dated by the appropriate competent and authorized persons. Further, documents must be regularly reviewed and kept up-to-date. When a document has been revised, systems must be operated to prevent obsolete documents. It is especially important that only current documentation

should be available for use. Best practices extend to the writing of the document. Using words that everyone can understand – minimizing jargon, acronyms, and abbreviations and using words with unambiguous meaning can help the reader to more easily understand and interpret the document. Key "readability" qualities for a document include [8]:

To help with efficient location of records, attention should be paid to numbering including the version number for traceability. Simple sequential number of documents only works for a small number of documents. In most cases a defined structure to the numbering system is needed. For example, 001-100 could represent regulatory documents; 101 – 200 could represent QC testing documents, and 201-300 could represent production documentation. This system may still limit. The numbering system may need to include references to the site, a system (production, QC, validation, and so on) as well as its sequential number.

COMPLATING DOCUMENTS AND RECORD-KEEPING (11-12)

After documents have been designed, prepared, and approved, they must be used and completed properly. For example, where documents require the entry of data, these entries must be made in clear legible handwriting using a suitable indelible medium -- not a pencil. Sufficient space must be provided for entries. With such entries, it is important that any correction made to a document or record must be signed or initialed and dated; the correction must permit the reading of the original information. Where appropriate, the reason for the correction must be recorded.

With record-keeping in general, a record must be kept at the time each action is taken. All activities concerning the conduct of preclinical studies, clinical trials, and the manufacture and control of products must be traceable.

DOCUMENT STORAGE

Storage of critical records must at secure place, with access limited to authorized persons. In relation to this, 21CFR 211.180(d) states "…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."

The storage location of document must ensure adequate protection from loss, destruction, or falsification, and from damage due to fire, water, and other disasters. Records which are critical to regulatory compliance or to support essential business activities must be duplicated on paper, microfilm, or electronically, and stored in a separate, secure location in a separate building from the originals. If electronic, photographic or other data processing systems are used for the retention of documents, an appropriate storage for required duration is necessary to protect against loss or damage. It is particularly important that during the period of retention, the data can be rendered retrievable and legible within an appropriate period of time. This means having a validated system of data recall. The data should also be available in a legible form. Rapid retrieval of reports and data is essential for audits.

4 CONCLUSION

This paper has presented an overview of the main types of documentation found within the pharmaceutical and medical device sectors. It has provided suggestions for good practice examples of how the documentation can be designed, produced, and controlled as part of a compliant GMP system. Good documentation practices are an essential part of GMP and compliance. When implemented, the recommendations presented in this paper will help with maintaining control and ensuring compliance in a GMP environment.

5 REFERENCES

1. Snell JJ, Brown DF, Roberts C, editors. Quality assurance: principles and practice in the microbiology laboratory. Public Health Laboratory Service; 1999.

2. Documentation Requirement; Website of GMP quality. quality.com/documentation.html , 2010

3. EudraLex; The Rules Governing Medicinal Products in the European Union Volume - 4; Good Manufacturing Practices Part I Basic Requirements for Medicinal Products. http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-4/index_en.htm ,2010

4. Göbel C, Baier D, Ruhfus B, Hundt F. GCP inspections in Germany and Europe following the implementation of the Directive 2001/20/EC. GMS German Medical Science. 2009;7.

5. Good Documentation and Quality Management Principles. Retrieved from:

http://apps.who.int/prequal/trainingre

6. Hargreaves P. Good manufacturing practice in the control of contamination. In Guide to Microbiological Control in Pharmaceuticals and Medical Devices 2006 Dec 26 (pp. 136-157). CRC Press.

7. Kumar K, "Data Integrity in Pharmaceutical Industry". J Anal Pharm Res 2(6): 00040, 2016.

8. MHRA Presentation - Good Documentation Practice a refresher Session 2, 2018.

9. Patel KT, Chotai NP. Pharmaceutical GMP: past, present, and future–a review. Die Pharmazie-An International Journal of Pharmaceutical Sciences. 2008 Apr 1;63(4):251-5.

10. Patel KT, Chotai NP. Documentation and records: Harmonized GMP requirements. Journal of young pharmacists. 2011 Apr 1;3(2):138-50.

11. Denyer SP, Baird RM. Guide to microbiological control in pharmaceuticals and medical devices. CRC Press; 2006 Dec 26.

12. Sandle, T. and Alexander.B, Electronic Pack 1: "Best Practices in Microbiological Documentation", Pharmaceutical Microbiology Interest Group, UK, 2011.

13. Sandle T, Lamba SS. Effectively Incorporating Quality Risk Management into Quality Systems. Saghee, MR. 2012.

14. Sandle, T. Best Practices for Microbiological Documentation in Hodges, N and Hanlon, G.(eds.): Industrial Pharmaceutical Microbiology Standards and Controls, Euromed Communications, England, Supplement 9, 2009.

15. www.ivtnetwork.com