



# DOCUMENTATION IN PHARMACEUTICAL INDUSTRY: REVIEW

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## Abstract

Good documentation constitutes an essential part of the quality assurance system and is key to operating in compliance with GMP requirements.

The purpose of this work is to specify the GMP requirements on documentation within pharmaceutical industry. In this article firstly processing of documents like (preparation, issue, use, storage, retrieval, retention and disposal) and briefly information about PMD is described.

Secondly specifications that key documents Batch manufacturing record, Manufacturing formula record and other aspects like SOP are described.

Documentation within pharmaceutical industry is an essential part of both the Quality assurance and Quality control system. Documentation describes the specifications for all materials, methods of manufacturing and control. It will allow the personnel to decide whether or not to release batch for sale and also to permit investigation of history of batch of product through tool of audit trials.

**Keywords:** (GDP) Good documentation practices, (BMR) Batch manufacturing record, (MFR) Manufacturing formula record, (SOP) Standard operating procedure.

## Introduction

Good documentation constitutes an essential part of the quality assurance system and is key to operating in compliance with GMP requirements. [Pharma et al,2011]

Documentation may exist in a variety of forms, including paper-based, electronic or photographic media.

Documentation is a systematic procedure of preparation, checking, verifying, issuing, storing and reviewing of any documents.

The basic rules in any good manufacturing practice (GMP) regulations specify that the pharmaceutical manufacturer must maintain proper documentation and records.

Documentation helps to build up a detailed picture of what an activity has done in the past and what it is doing now and, thus, it provides a basis for planning what it is going to do in the future.

Effective documentation enhances the visibility of the quality assurance system. [Sharma et al,2021]

## Definition of Documentation

Document is any written statement or proof. Documentation is an essential part of Quality assurance and Quality control system and is related to all aspects of Good Manufacturing Practices (GMP). It is mainly defining the specifications for all materials, method of manufacturing and control. It also ensures that the personnel concerned with manufacturing should know information to decide whether to release the batch or not for sale it provides an audit trail which also allows the investigation of history of any suspected defective batch. [Potdar et al, 2013]

## Objectives of Documentation

- 1) Defines specifications and procedures for all materials and methods of manufacture and control
- 2) Ensures all personnel know what to do and when to do it.
- 3) Ensure that authorized persons have all information necessary for release of product.
- 4) Ensures documented evidence, traceability, provide records and audit trail for investigation.
- 5) Ensures availability of data for validation, review and statistical analysis. [Potdar et al, 2013]

## General Requirements

- 1) Good documentation constitutes an essential part of the quality assurance system.
- 2) Clearly written procedures prevent errors resulting from spoken communication, and clear documentation permits tracing of activities performed.
- 3) Documents must be designed, prepared, reviewed, and distributed with care.
- 4) Documents must be approved, signed, and dated by the appropriate competent and authorized persons.
- 5) Documents must have unambiguous contents. The title, nature, and purpose should be clearly stated. They must be laid out in an orderly fashion and be easy to check. Reproduced documents must be clear and legible.
- 6) Documents must be regularly reviewed and kept up-to-date. When a document has been revised, systems must be operated to prevent inadvertent use of superseded document: (e.g., only current documentation should be available for use).
- 7) Documents must not be handwritten; however, where documents require the entry of date, these entries may be made in clear legible handwriting using a suitable indelible medium (i.e., not a pencil). Sufficient space must be provided for such entries.
- 8) Any correction made to a document or record must be signed or initialled and dated, the correction must permit the reading of the original information. Where appropriate, the reason for the correction must be recorded. [Sharma et al, 2021]

## Types of Documentation

There are various types of procedures that a GMP facility follows. Given below is a list of the common types of documents.

**1. Quality manual:** A global company document that describes, in paragraph form, the regulations and /or parts of the

regulations that the company is required to follow.

2. **Policies:** Documents that describe in general terms, and not with step-by-step instructions, how specific GMP aspects (such as security, documentation, health, and responsibilities) will be implemented.
3. **Standard operating procedures (SOPS):** Step-by-step instructions for performing operational tasks or activities.
4. **Batch records:** These documents are typically used and completed by the manufacturing department. Batch records provide step-by-step instructions for production-related tasks and activities, besides including areas on the batch record itself for documenting such tasks.
5. **Test methods:** These documents are typically used and completed by the quality control (QC) department. Test methods provide step-by-step instructions for testing supplies, materials, products, and other production-related tasks and activities, e.g., environmental monitoring of the GMP facility. Test methods typically contain forms that have to be filled in at the end of the procedure; this is for documenting the testing and the results of the testing.
6. **Specifications:** Documents that list the requirements that a supply, material, or product must meet before being released for use or sale. The QC department will compare their test results to specifications to determine if they pass the test.
7. **Logbooks:** Bound collection of forms used to document activities. Typically logbooks are used for documenting the operation, maintenance, and calibration of a piece of equipment. Logbooks are also used to record critical activities, e.g.; monitoring of clean rooms, solution preparation, recording of deviation, change controls and its corrective action assignment.[Tara et al,2022]

#### QUALITY DOCUMENTATION HIERARCHY

The 4 –tiered hierarchy has been established as a best practice for your Quality Documentation System [ Tara et al,2022]

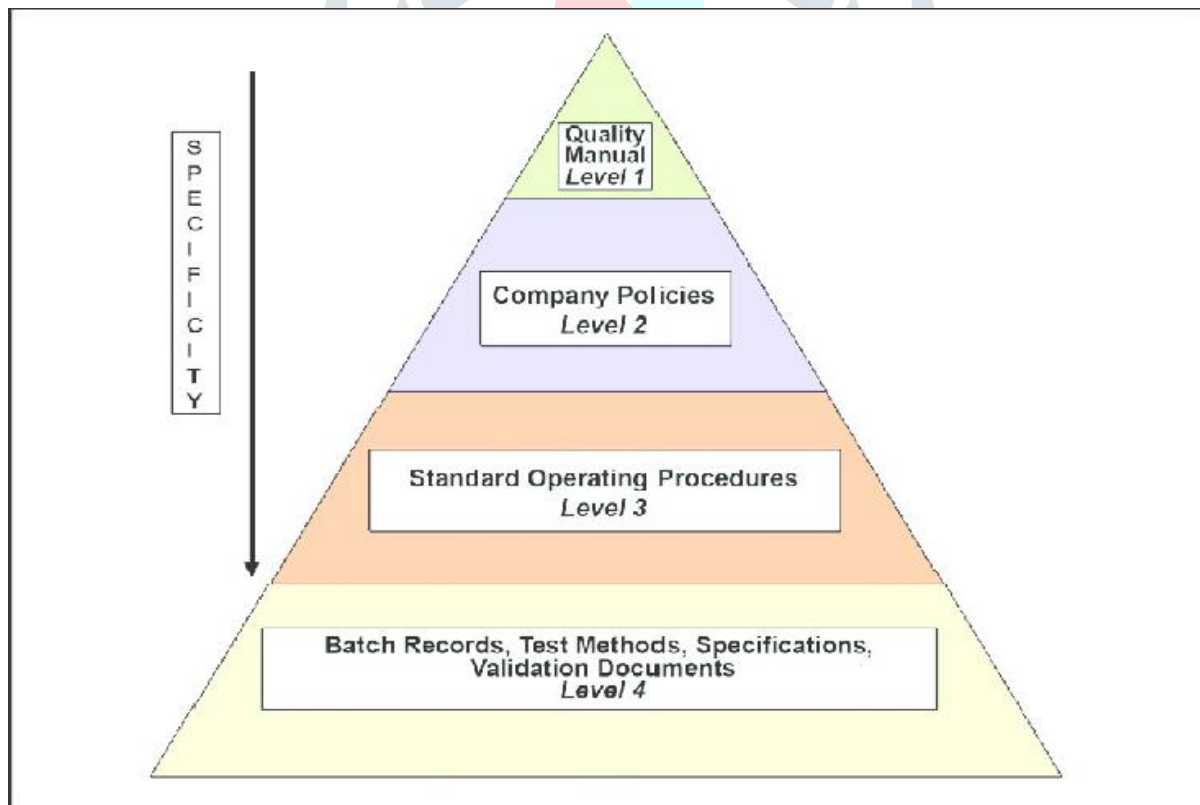


Fig 1 Quality Documentation Hierarchy

## Good Documentation Practices

### Introduction

Good Documentation Practice (GDP or GDocP), a term used in the pharmaceutical industry, is essential for the integrity of data collection and reporting for supporting development, registrations, commercialization, and life-cycle management of pharmaceutical products. Adhering to the GDPs assures preventing errors within the manufacturing environment and during the analysis of pharmaceutical products which could otherwise impact product quality, and safety of the patients, state of manufacturing facilities, and related activities. Compliance to GDPs is required by both the US and the European regulatory authorities, i.e., FDAs CFR (Code of Federal Regulations) and EMA (European Medicines Agency). In addition to the United States Pharmacopeia (USP) issuing a general chapter <1029>, the World Health Organization (WHO), Health Canada, and EudraLex (the collection of rules and regulations governing medicinal products in European Union) have published specific guidance related to GDPs. On the other hand, GDP is an important part of current Good Manufacturing Practices (cGMPs) in the US. [Kumar et al, 2017]

### Definition

Good Documentation Practice (GDP) describes standards by which documentation is created and maintained in the pharmaceutical industry. Although the U.S. Food and Drug Administration (FDA) set some GDP standards, others fall under the Current Good Manufacturing Practice (CGMP). All pharmaceutical, bioscience and healthcare companies, as well as their vendor partners, must observe GDP or face warnings of penalties levied by the FDA.

As per WHO, the purpose of Good Documentation Practices is,

1. To define the specifications and procedures for all methods of manufacture and control.
2. To ensure that all personnel concerned with manufacturing know what to do and when to do it.
3. To ensure that authorized persons have all the information necessary to decide whether or not release a batch of a drug for sale.
4. To ensure the existence of documented evidence, traceability and to provide records and an audit trail that will permit investigation.
5. To ensure the availability of the data needed for validation, review and statistical analysis. [Bhattacharya et al, 2014]

### General Requirements For GDP

**Clearly Written Documentation:** All Documents Must Be Accurate and Written in A Manner That Prevents Errors and Ensures Consistency. If Documents Are to Be Used Together, E.G. An SOP And a Form, Then Each Should Reference the Other. Ensure There Is Traceability Between Two Or More Documents/Records Using Formal Document Numbers or Record Identification.

➤ **Using Indelible Ink:** All records must be filled out in indelible ink for long term legibility. Do not use pencil or ink that can be erased. Color should be specified by the company GDP procedure; often this is limited to blue or black because historically copy/scanning technology was limited in reproduction quality. However, this is less of a factor with the advent of high-resolution scanners and color copiers. Consistent use of blue and black ink on GMP documentation provides a more professional perception of your organization.

➤ **Legible Handwritten Entries:** A document is unusable if it cannot be read, so care must be taken to ensure that handwriting is legible. All entries must be made at the time the tasks are performed and should be legibly signed and dated. The same is true of electronic documents and records – language should be clear and unambiguous.

➤ **Reviewing And Approving:** Documents and records should be reviewed by someone who did not perform the task to ensure that the information is correct and accurate. A signature and date by the reviewer/approver confirm

that a review has taken place. Unsigned documents or records are incomplete and should not be used to perform any task or considered as evidence of a completed task.

➤ **Staff Signatures:** Handwritten signatures must be unique to the individual and listed within the site signature register to ensure that the signature is traceable to a member of staff (or contractor). Staff are not permitted to sign for another member of staff unless delegated. Signatures must never be forged. The management of the signature record should be governed by a procedure and routinely reviewed so that it remains current – new staff should sign the signature register during induction, the signature register must indicate the date staff exit the company. Electronic signatures must meet the same general documentation requirements –refer to eu annex 11: computerized systems or pic/s annex 11: computerized systems for additional regulatory requirements.

➤ **Signed Delegation of Responsibility:** In the event that a critical member of staff is absent for a time, they must delegate responsibility to another qualified person. The delegation must be either: 1. Proceduralised in a document (sop, wi etc.), or

2. Documented with names of all people involved and signed by the person that is delegating their responsibility. The delegation should also be approved with the signature of a more senior member of staff.

➤ **Page Numbering:** GMP Documents Should Have Page Numbers Using The Following Standard „X Of Y“ To Indicate The Total Number Of Pages In A Document. [Bhattacharya et al,2014]

Paper size: Letter

Company name: XYZ limited

#### Title: Procedure on Good Documentation Practices

Document no: LAP-QA-001	Version no: 00	Effective date: 21-07-2022
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Objective:

Scope:

Responsibilities:

Definitions:

Procedure:

Sign & date:	Prepared by: Kaya; 22/07/2022	Reviewed by: Rama; 22/07/2022	Approved by: Kent; 22/07/2022
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Page no: 01 of 10

Format no: F/LAP-QA-005/01.01

This image is for demonstration purpose only and should not be replicated in real world.

<http://www.learnaboutpharma.com>

Format of Good Documentation Practices[killi et al,2022]

## BATCH MANUFACTURING RECORDS [BMR]

### Definition:

Batch manufacturing record is a written document of the batch, prepared during pharmaceutical manufacturing process. It contains actual data and step by step process for manufacturing each batch. Batch manufacturing record is like a proof that batches were properly made and checked by quality control personnel. Batch production records should be prepared for each intermediate and API/formulation and should include complete information relating to the production and control of each batch. The batch production 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. Before any processing begins, a check should be performed and recorded to ensure that the equipment and workstation are clear of previous products, documents, or materials not required for the planned process and that the equipment is clean and suitable for use. These records should be numbered with unique batch or identification number and dated and signed when issued. In continuous production, the product code together with the date and time can serve as the unique identifier until the final number is allocated. The batch number should be immediately recorded in a logbook or by electronic data processing system. The record should include date of allocation, product identity, and size of batch. Documentation of completion of each significant step in the batch production records (batch production and control records) should include:

- Dates and, when appropriate, times.
- Identity of major equipment used (e. g, reactors, driers, mills, etc.)
- Specific identification of each batch, including weights, measures, and batch numbers
- Raw materials, intermediates, or by reprocessed materials used during manufacturing. Actual results recorded for critical process parameters.
- Any sampling performed.
- 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.
- Representative label (commercial supply). [Taral et al,2022]



Form Number MF-001-V1		<b>MASTER FORMULA</b>	
Date Original Issue: JULY 2021			
Date Revised: Page 1 of 1			
PRODUCT NAME:			
FORMULA REFERENCE:			
FORM PREPARED BY:			
		LOT NUMBER:	
		THEORETICAL YIELD:	
START DATE:		FINISHED PRODUCT SIZE:	
MIX TANK:		BATCH SIZE IN LBS:	
<b>PRODUCT DESCRIPTION:</b> Example: Anhydrous emollient skin balm, white in color. Bulk product is manufactured by xxx and packaged in white stick with orange cap. Then sent to third party for label and tag application and shipped to client from there.			
<b>RESPONSIBILITY:</b> The person in charge of making products is responsible for making this product. This formula is confidential, and should not be shared with others outside the company.			
<b>MATERIALS/EQUIPMENT/SUPPLIES:</b> 1. Mix tank 3 2. Scale X 3. Bowls 4. Blender 5. Measuring cups/beakers 6. Thermometer			
<b>INGREDIENTS:</b>			
Phase A		%	
Phase B		%	
Ingrid #			
Ingrid #			
Ingrid #			
Ingrid #			
Ingrid #			
Ingrid #			
TOTAL		100.00	

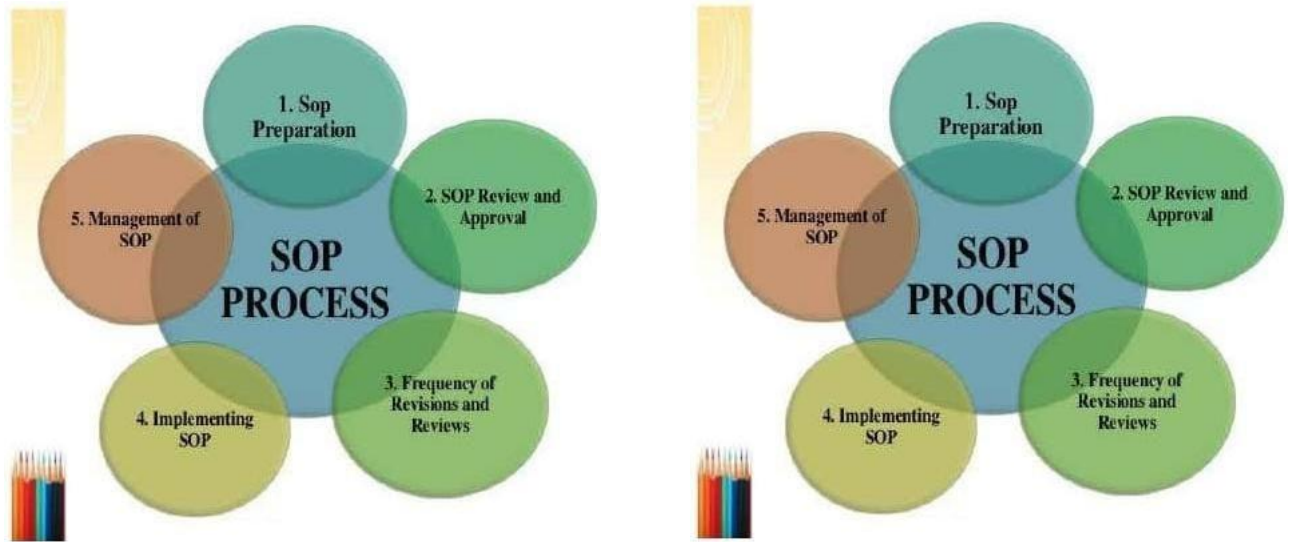
### Format of Master Formula Record[Barberes et al 2021]

#### STANDARD OPERATING PROCEDURE

Standard Operating Procedure is a set of step by step written instructions intended to document how to perform a routine activity. SOP is back bone of pharmaceutical industry.

#### SOP WRITING STYLE

- SOPs shall be written in concise, step by step, easy to read follow format.
- Information should not be complicated. The active voice, and present verb tense should be used.
- Should be simple and short.
- Routine procedures that are short and require few decisions can be written using simple steps format.
- Long procedures consisting of more than 10 steps , should be written along with graphical format or hierarchical steps.
- Procedures that require many decisions should be written along with flowchart.



CONTENT OF SOP

1. Company name and pagination
2. Title
3. Identification
4. Review and approval
5. Purpose
6. Scope
7. Responsibility
8. Procedure [Potdar et al 2013]



## Standard Operating Procedure (SOP)

General Information	
Process Title:	Department:
Contact Info:	SOP ID:
Effective Date:	Revision Number:

## Process Overview

## Process Description:

[Define the goal of the task or process]

## Purpose &amp; Scope:

[Explain the rationale for the SOP and detail the who or what the procedure applies to]

## Definitions &amp; Related Documents:

[Define terms as needed, attached relevant documents if any]

Process Steps		
WBS	Task	Owner
1.0	[Description of task]	[team member]
1.1		
1.2		
2.0		
2.1		
2.3		

Format of SOP [Project Manager et al 2023]

## Quality Audit

A systematic and independent examination to determine quality activities and related results comply with the planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Quality audit is typically performed intervals. Any failure in their proper implementation may be published publicly and may lead to revocation of quality certification.

### TYPES OF QUALITY AUDIT:

- Adequacy audit/ document audit:

This is also known as system or management audit and is normally documented system represented by the quality manual and the associated procedure adequately meets the need of the application standard.

- Compliance audit/ on-site audit:

This is the audit which seeks to establish the extent to which the documented system is implemented and observed by the workforce, .i.e. are the people complying with the system.

- External audit:

This is the most important type of audits, which requires the company to look into its own suppliers or subcontractors. Purpose of external audit is to gain confidence in the partnership arrangement. This ensures that requirements are understood. There is a reduction of in-house Q.C testing of starting materials and reduces the risk of failure.

- Internal audit:

This is the most important types of audits, which requires the company to look into its own systems, procedures and activities in order to ascertain whether they are adequate and being complied with. It provides the management with the information on whether or not their policies are being met, if the system is an efficient and as effective as it

should be and whether any changes are needed. It can provide a line of communication throughout the company and be a great motivator.

- Product/ process audit:

Product review refers to an in-depth examination of a particular product/service to evaluate whether it conforms to product specifications, performance standards and customer requirements. Process audit refers to an analysis of elements of process and appraisal of completeness, correctness of conditions and probable effectiveness. [Nagdev et al,2018]

QUALITY AUDIT REPORT		
FORMAT NO.:		
AUDIT DATE :	AUDIT NUMBER:	
DEPARTMENT:	MANAGER:	
PROCESS:	AUDITOR:	
PREVIOUS AUDIT DATE:	AUDITEE(S):	
<b>GENERAL FINDINGS</b>		
<b>PROJECTED</b>	<b>ACTUAL</b>	
<b>AUDITORS</b>		
1. _____	SIGNATURE _____	DATE _____
2. _____	SIGNATURE _____	DATE _____
3. _____	SIGNATURE _____	DATE _____
<b>CORRECTIVE ACTION VERIFICATION AND COMMENTS</b>		
VERIFIED:	MANAGEMENT REPRESENTATIVE SIGNATURE _____	

Format of Quality Audit

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