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A Comprehensive Review on Different Pharmaceutical Documentation System

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ABSTRACT:

Documentation systems are essential in the pharmaceutical sector for ensuring product quality, regulatory compliance, and traceability across the entire drug development and manufacturing lifecycle. This review comprehensively examines the various types of pharmaceutical documentation, such as Common Technical Documents (CTDs), Drug Master Files (DMFs), Batch Manufacturing Records (BMRs), Master Formula Records (MFRs), Standard Operating Procedures (SOPs), and audit trails. Each document type plays a critical role in ensuring operational consistency, safeguarding patient safety, and enabling regulatory inspections. The paper also explores the evolution from traditional paper-based documentation to modern digital systems such as electronic Common Technical Documents (eCTDs) and block chain-based audit mechanisms, assessing their benefits, challenges, and implications for data integrity. Emphasis is placed on Good Documentation Practices (GDP), which underpin the reliability and accuracy of pharmaceutical records. Through this analysis, the review underscores that robust documentation is not merely a regulatory obligation but a strategic element of pharmaceutical quality assurance and public health protection.

Key points :- SOP, BMR, MFR, DMF, CTD, eCTD, Audit Trial.

INTRODUCTION:

The construction business relies heavily on documentation to communicate different and complex information among participants. The term "document" refers to a paper-based information carrier that may be easily shared, stored, and handled. Construction documents are crucial in the business as they facilitate collaboration among project participants and provide access to shared or non-shared information sources. [1] Documenting an information system is essential for effective communication, control, and monitoring during development, operation, and maintenance projects. [2]

Proper validation is key for meeting GMP conditions and ensuring quality assurance. Documentation can take various forms, such as paper, electronic, or photographic media. [3] Data integrity in the pharmaceutical industry depends on Good Documentation Practices (GDP). They ensure that records are accurate, readable, traceable, long-lasting, and responsible, reflecting the true nature of this company. [4] Developing user-friendly computerized systems can help pharmacists track their clinical treatments and workload activities, addressing issues with manual documentation. [5]

One of the most heavily regulated industries in the world is the pharmaceutical industry, requiring extensive paperwork to assure regulatory compliance, product efficacy, safety, and quality. Documentation is essential within the research, development, production, and quality control processes. This includes validation protocols, regulatory papers as well as standard operating procedures (SOPs). This detailed analysis emphasizes the necessity of sufficient paperwork in adhering to FDA, EMA, and WHO criteria, maintaining operational consistency, and producing safe and effective pharmaceuticals. [6]

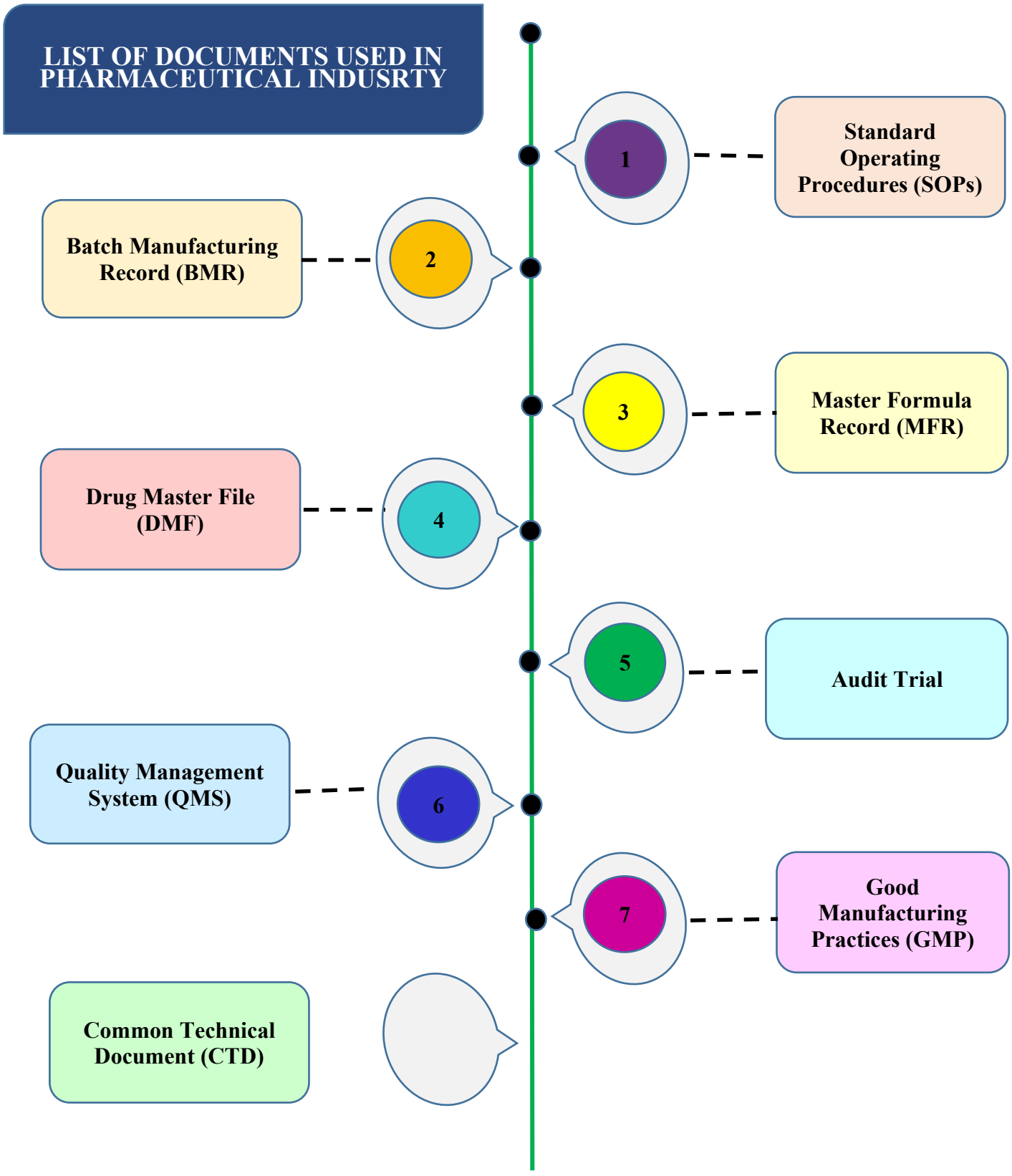
Systems for quality assurance and control that set standards for materials, production processes, and control depend primarily on documentation. It also helps with batch release decisions and audit trails. [7] A new approach has been put out to ensure consistent contact with medical colleagues and continuity of pharmaceutical care, as there is currently no globally approved approach to documenting pharmacotherapy evaluation. [8] Analytical documentation is crucial for pharmaceutical product quality by design (QbD) and continual improvement throughout its life cycle, from initial screening to post-approval. [9]

OBJECTIVES OF DOCUMENTS:

- Defines requirements and processes for all materials as well as manufacturing and control methods.
- makes ensuring that every employee knows what has to be done and when.
- Verify that authorized personnel have all of the data needed to distribute the product.
- Ensures recorded evidence, traceability, record-keeping, and auditing of trials for inquiry.
- Ensures data are available for validation, review, and statistical analysis. [3]

NEED OF DOCUMENTS:

- Defines the standards and procedures for all materials, as well as manufacturing and control methods.
- Control of the process guarantees that all employees understand what has to be done and when.
- Verify that authorized personnel have all of the data needed to distribute the product.
- Ensures traceability of documented evidence by providing documents as well as an audit trail for further research.
- provides data for statistical analysis, validation, and inspection.
- To improve performance.
- Regulatory requirements. [10]



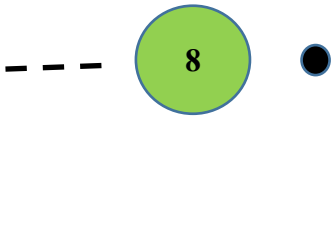


Fig. 1 : list of Documents used in pharmaceutical industry

STANDARD OPERATING PROCEDUREs (SOPs): [11]

SOPs, or standard operating procedures are written instructions for completing regular or recurrent tasks within a company. The term "SOP" may be used in a similar way with other terminology such as procedures, instructions, and worksheets.

Purpose of Standard Operating Procedures (SOPs):

- ✓ Describe the standard operating procedures in a company to enable systematic and efficient execution of routine operations. [12]
- ✓ Ensure consistent adherence to technical and quality standards, allowing for uniformity in processes and outcomes.
- ✓ To ensure data correctness and integrity, document consistent data collecting and handling processes.
- ✓ To direct numerous operations, such as programmatic tasks, technical procedures, and equipment maintenance, while maintaining clarity and reducing operational errors. [13]
- ✓ To improve quality control, assurance, and regulatory compliance by integrating organizational activities with international and national standards.
- ✓ Provide organization-specific instructions modified to the facility's needs, taking into account the operating context and available resources. [12]
- ✓ To underline the importance of well-written and clear instructions for improving usability and reducing confusion. [14]

Types of SOPs: [13]

- ➢ Technical SOP
- ➢ Non-technical SOP
- ➢ Administrative SOP
- ➢ Legal/Private SOP
- ➢ Productional or operational SOP.

SOPs Writing Style:

- SOPs should be written in a detail, step- by- step, easy- to- follow manner.
- Information shouldn't be difficult to understand.
- It is best to use the present tense and active voice.
- It must be brief and uncomplicated. [3]
- The routine operations that are brief and need a few judgments can be stated in a basic step structure.
- When writing broad procedures with further than 10 way, use graphical or hierarchical way.
- Procedures that require multiple sentences should be validated along with a flowchart in Figure.2 & Figure. 3 [15]

General Information	
Process Title :	Department:
Connect Info :	SOP ID:
Effective Date:	Revision NO.

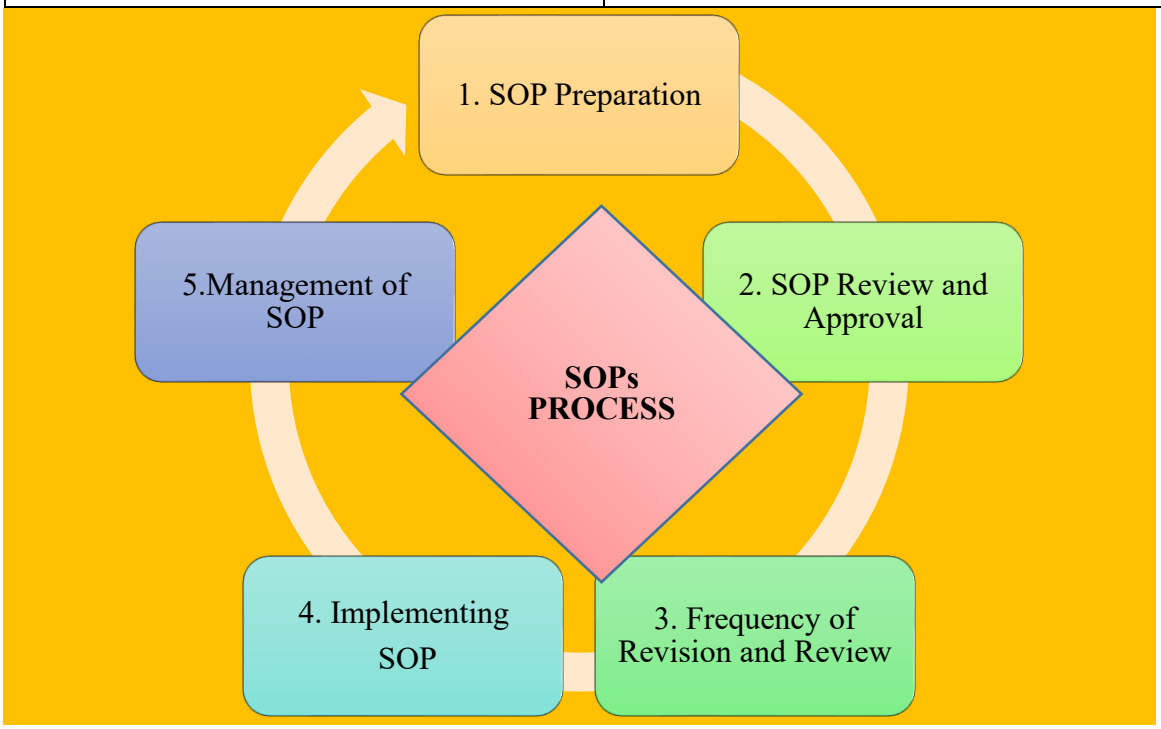


Fig. 2: SOPs Process

Standard Operating Procedure

Process Overview

Process Description:
[Define the goal of the task or process]

Purpose & Scope:
[Explain the rationale for the SOP and detail the who or what the procedure applies to]

Definitions & Related Documents:

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

[Define terms as needed, attached relevant documents if any]
Fig. 3: Format of Standard Operating Procedure (SOP's)

BATCH MANUFACTURING RECORD [BMR]:

A comprehensive written document known as a Batch Manufacture Record (BMR) is created during the pharmaceutical manufacturing process to record every step and actual data from the batch production. It acts as verification that the batch was correctly manufactured and quality-tested. BMRs must be created for each intermediate, API, or formulation and include all relevant production and control data. Before using them, they must be checked for accuracy and version, and if separated from a main document, they must refer to the correct master instructions. Before processing, equipment and workstations must be inspected for cleanliness and readiness. Each record should be assigned a distinct batch number, signed and dated, as well as stored in a log or electronic system, along with information such as product identity and batch size. [16] Large datasets from pharmaceutical manufacturing processes can be systematically analysed using data mining techniques, allowing for the automatic recovery of operation-relevant information for batch verification and identification. [17] In the batch product records (both the batch product and control records), proof of completion of each important step should be included:

- Dates and, where applicable, timings.
- Identify significant equipment, such as mills, driers, and reactors.
- Identify each batch by weight, measure, and batch number.
- Raw, intermediate, or reprocessed materials utilized in manufacturing.
- Actual data were acknowledged for significant process variables.
- Any samples that have been collected.
- Signatures of those executing, monitoring, or checking crucial steps in the operation.
- The outcomes of laboratory and in-process testing.
- The actual yield throughout specific periods.
- Describe packing and labeling. [16]

	Pharmaceutical Guidelines **Delhi, India** **Batch Manufacturing Record**		Page No. 1 of 16
Product	: Atorvastatin Tablets IP 40 mg	**B.M.R. No.**	XX/XXX/000
		B.M.R Revision No./ Date	00/ddmmyyyy
Batch Size	: 2,00,000 Tablets	**Ref. M.F.R. No**	XX/XXX/000
Batch No.	: XXXXX/XX	**M.F.R. Revision No. & Date**	00/ddmmyyyy

Batch Quantity	: 35.00 kg.	**COMPOSITION:** **Each Film Coated Tablet contains:** Atorvastatin Calcium IP Equivalent to Atorvastatin ------ 40 mg Color :Titanium Dioxide IP
Reworking Added (If any)	:	
Theoretical Yield	:	
Mfg. Date:		Exp. Date:
Document issued by: Date:		Document Received by: Date:
This Document Supersedes	: None	
Reason for Change	: New	
Mfg. Licence No.	: XXXX/XX/XXXX	Material code No. - XXXXXXXX
Shelf Life	: 36 Months or expiry of active ingredient whichever is less.	
Storage Condition	: Store in cool, dry & dark place.	
Marketed by	: XYZ Pharmaceuticals Ltd.	
Serial No.	:	

	Granulation	Compression	Coating
Date of Commencement:			
Date of Completion:			
Area Used:			
Previous Product Processed:			
Batch No:			
Checked by Pharmacist: Date:			

This batch has/has not been completed according to the instructions given in M.F.R. No. XX/XXX/00. Deviation sheet attached: Y/N	
Actual Yield:_____Tablets Reworking Generated:_____Kg. Total Yield: _____%	Date of Packing: Quantity:
Final BMR Checked By: Date:	Final BMR Checked By: Date:

Prepared By	**Checked By**	**Reviewed By**	**Approved By**
Quality Assurance	**Production**	**Production Head**	**QA & QC Head**
Date:	**Date:**	**Date:**	**Date:**

Fig. 4: Format of Batch Manufacturing Record (BMR)

MASTER FORMULA RECORD [MFR]:

A document that describes the starting materials, packaging materials, procedures, and in- process controls demanded to produce a specific volume of finished product. [10] MFR, or Master Production Record, is another name for the Master Formula Record. Manufacturing units' employ Using MFR as a standard while generating batch manufacturing records (BMRs). The company's research and development team prepared it. It includes all applicable information on the product's manufacturing process. Any pharmaceutical product's Master Formula Record (MFR) is an extensive document. MFR is significant. Records of the Master Formula must exist for all product systems for every product and production batch size. The relevant expert personnel, such as the head of product and quality control, must develop and approve these. A Master Production Record can be based on the knowledge of good people, similar as manufacturing or logical druggists, or on a batch production log for a specific batch size. [18]

Master Production Record gives:

- Product information, similar as the production company's name, trademark, and address.
- Name of pharmaceutical form, both the general name and the brand name.
- Each constituent's product code and marker claim.
- The product description mentions the packing type, pack size, and batch size. Conditions of Storage and Shelf Life. Replace the MFR number and date with the MFR number and date.
- The batch number that works.
- The product and quality assurance head's approval.
- All of the equipment listed necessary machinery and equipment used in the production process, including their volume. [16]

Form Number MF-001-V1 Date Original Issue: JULY 2021 Date Revised: Page 1 of 1	**MASTER FORMULA**

PRODUCT NAME:			
FORMULA REFERENCE:			
FORM PREPARED BY:			
		LOT NUMBER:	
		THEORETICAL YIELD:	
START DATE:		FINISHED PRODUCT SIZE:	
MIX TANK:		BATCH SIZE IN LBS:	

PRODUCT DESCRIPTION: 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.
RESPONSIBILITY: 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.
MATERIALS/EQUIPMENT/SUPPLIES: 1. Mix tank 3 2. Scale X 3. Bowls 4. Blender 5. Measuring cups/beakers 6. Thermometer

INGREDIENTS:		
Phase A		%
Phase B		%
Ingred #		
Ingred #		
Ingred #		
Ingred #		
Ingred #		
Ingred #		
TOTAL		100.00

Fig. 5: Format of Master Formula Record (MFR)

DRUG MASTER FILE (DMF):

A document created by a pharmaceutical or excipient producer and submitted to regulatory bodies in their intended market is known as a Drug Master File (DMF). chemistry, packaging, cGMP status, stability, purity, and excipient profile. [19]

The DMF provides secret and complete information on facilities, procedures, and objects used in drug manufacturing, packaging, and storage. Filing a DMF is optional and not compulsory for guidelines. [20]

A DMF does n't replace an operation for an export, IND, NDA, or ANDA. Only when reviewing an IND, NDA, ANDA, or export application is the technical content of the DMF reviewed; it is neither approved nor denied. If a producer refuses to provide sensitive information to the application, a DMF is required. [21]

Generally, DMF's have two parts

(1) Applicant Part: This part consists of non-confidential information that the license holder must examine for marketing purposes.

(2) Restricted Part: This section includes private data associated to the manufacturing process that should only be shared to authorities. [22]

The function of DMF: -

- ✓ The DMF documents the efficacy, potency, and purity of medications in the Chemistry, Manufacturing, and Control department.
- ✓ Support for drug registration and approval documents.
- ✓ Protect confidential and proprietary information. [23]

Types of DMF:

Type-I: includes the personnel, facilities, operating procedures, and the manufacturing site.

NOTE: The DMF type I is no longer used, according to the January 12, 2000, federal register (volume 65, number 8). Date of effect: July 10, 2000.

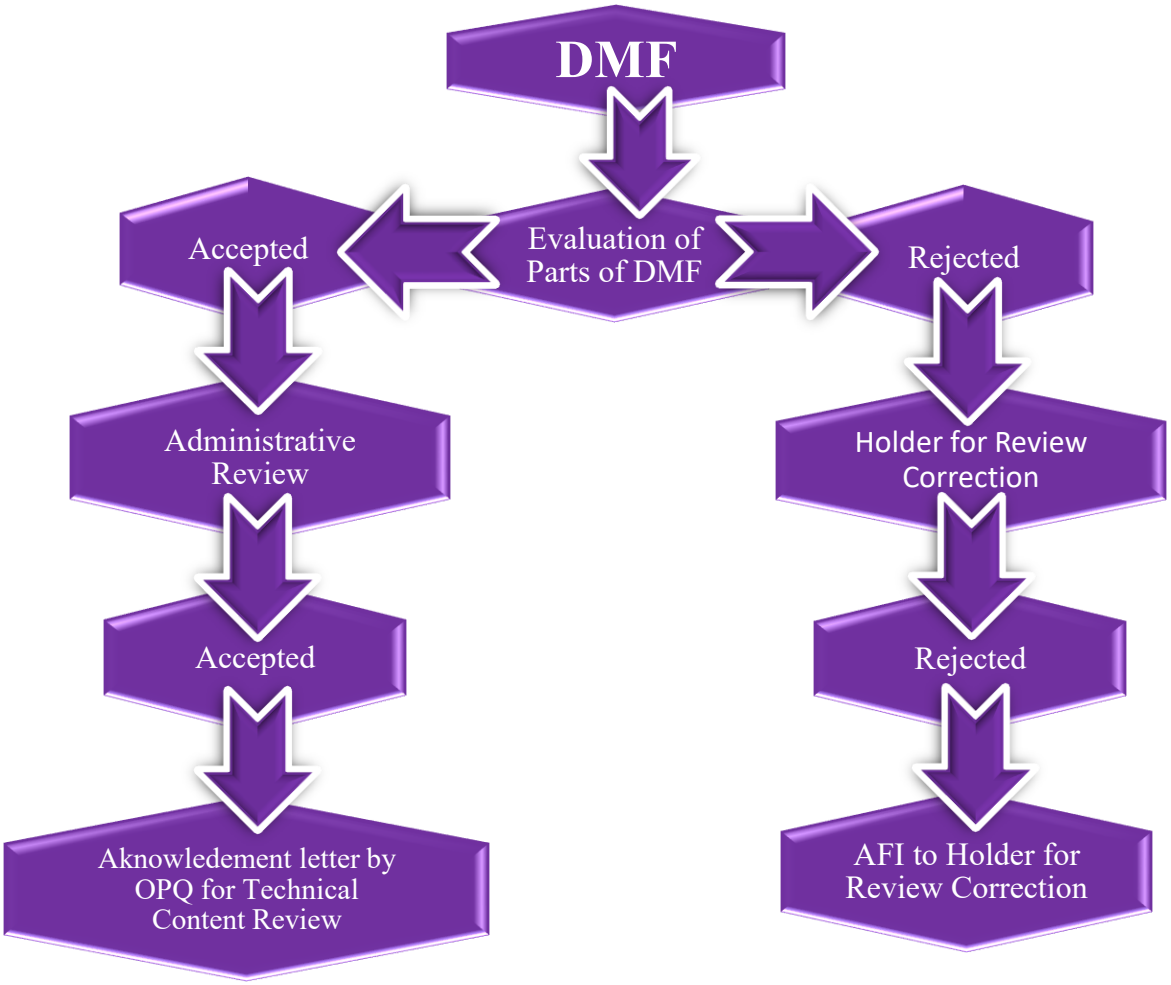
Type-II: includes drug products, as well as the materials, intermediates, and substances used in their manufacture.

Type-III: Packaging. [24]

Type-IV: includes ingredients used in preparation, such as excipients, colorants, Flavors, or essences.

Type-V: includes Reference Data Accepted by the FDA. [25]

Fig. 6: Schematic representation of drug master file mechanism. [26]



DMF Submission Process:

- To submit a DMF to the FDA, follow the eCTD format. The DMF must include a Letter of Authorization (LOA), which permits other companies to use the DMF in their drug applications.
- Guidelines for DMF Submission:
    - Confidentiality: DMFs hold confidential information about manufacturing processes and materials.
    - Responsibility: The DMF holder is responsible for updating the file, filing annual reports, and creating suitable changes. [10]

DMF submissions should be include: -

- ✓ A letter of transmission,
- ✓ Information related to administration, and
- ✓ The DMF has particular details.

The following should be included in the transmittal letter for an original DMF: -

- Submission identification: subject, type, and originator;
- List of applications that the DMF is meant to support, together with each sponsor, applicant, or holder's name and address.
- The holder's authorized representative or agent's signature.
- Name and title of the signer.

The following administrative information is needed.

The following people's names and addresses need to be supplied.

- DMF holder.
- Headquarters of the corporation.
- A facility for manufacturing and processing.
- Contact details for the FDA, including phone number, fax number, and email address.
- If relevant, identify any agents.
- Each person's specific responsibilities.
- A commitment statement.
- The holder's signed statement confirming to the DMF's currentness and their commitment to abide by the statements.[27]
- The FDA delivers "Overdue Notification Letters" to companies that do not submit DMF reports every three years to ensure they are up to date. The holder's annual report and response must be sent within ninety days. Their DMF might be closed if they don't respond. [23]

Letter of Authorization:

DMF holders must provide an authority letter to the FDA when applying to make use of the DMF.

The following information should be included in the DMF:

1. Date,
2. Holder's name,
3. The DMF number,
4. Authorized individual,
5. Specific products covered,
6. Section and page numbers,
7. Statement of commitment to compliance, and
8. The signature of the qualified individual. [28]

DMF Filing, Assessment & Review:

- ❖ To submit a DMF, The FDA must receive two copies from the holder.
- ❖ The DMF is then registered in a database and assigned a number.
- ❖ To request FDA approval of a DMF, applicants must attach a duplicate of their authorization letter for their application.
- ❖ An acknowledgement letter is sent to the holder. If the reviewer identifies any problems, they will send a letter to the holder without describing the nature of the deficiencies. [23]

COMMOM TECHNICAL DOCUMENT (CTD):

The International Council for Harmonization (ICH) developed the CTD in order to standardize submission formats for different regulatory bodies. Prior to the CTD, pharmaceutical businesses faced duplicative work due to different country-specific submission standards.

Objective: Standardization reduces complexity and allows for simultaneous submissions to multiple locations. [29]

The CTD Triangle

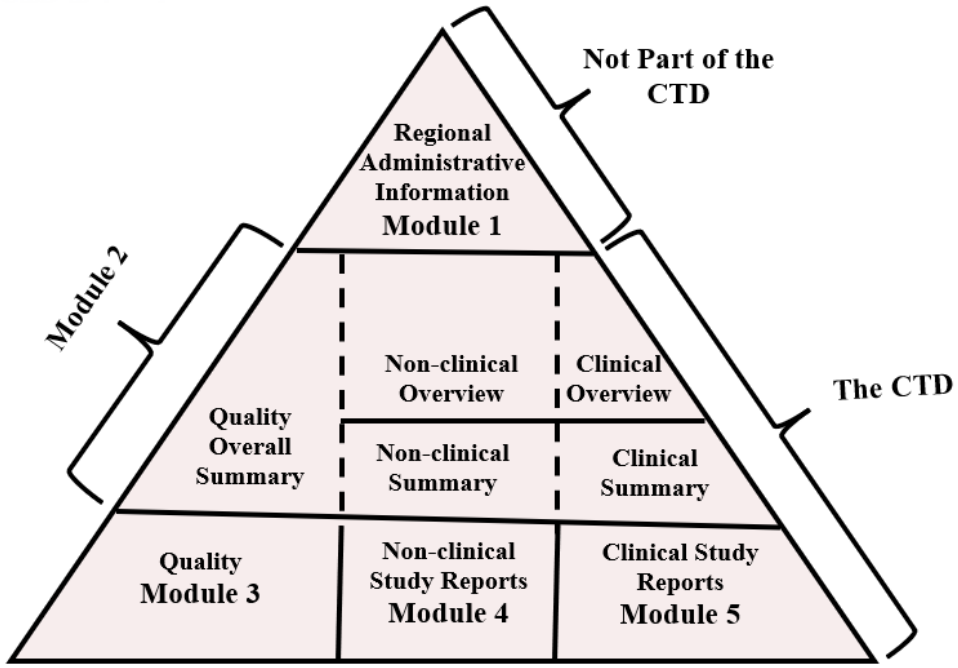


Fig.7: Common Technical Document (CTD)

CTD Structure and Content:

- Module 1 (Regional Administrative Information): Contains specific to that region documentation such application forms, labels, and risk management plans.
- Module 2 (Common Technical Document Summaries) summarizes and provides an overview of the Quality (CMC), Nonclinical (Pharmacology/Toxicology), and Clinical (Efficacy and Safety) parts.
- Module 3 (Quality) provides thorough information on medication manufacture and controls.
  Data on stability, manufacturing location, and specifications are provided.
- Module 4 (Nonclinical Study Reports) includes studies on animal pharmacology and toxicology to evaluate the drug's safety.
- Module 5 (Clinical Study Reports): Provides data from human clinical trials proving the drug's effectiveness and safety. [22]

ELECTRONIC COMMOM TECHNICAL DOCUMENT (eCTD):

Introduced eCTD to increase electronic submissions and accessibility for regulatory authorities, replacing CTD. The FDA and EMA have mandated the use of eCTD for specific applications, including DMFs and new drug applications. [30]

eCTD Structure:

- Similar to CTD with five modules, but with extra capabilities such an XML backbone, metadata, and life cycle management (tracking changes and modifications to submissions).
- Advantages of eCTD include easy navigation and review using hyperlinks, bookmarks, and organized documents. [31]
- Document Lifecycle Management: Simple tracking and management of changes and updates, including amendments, annual reports, and supplements. [32]
- Improves cost and time efficiency by reducing paperwork and speed up submissions, causing faster regulatory review timeframes.
- Global Standardization: Adopted by key regulatory bodies such as FDA, EMA, PMDA, Health Canada, and others. [33]

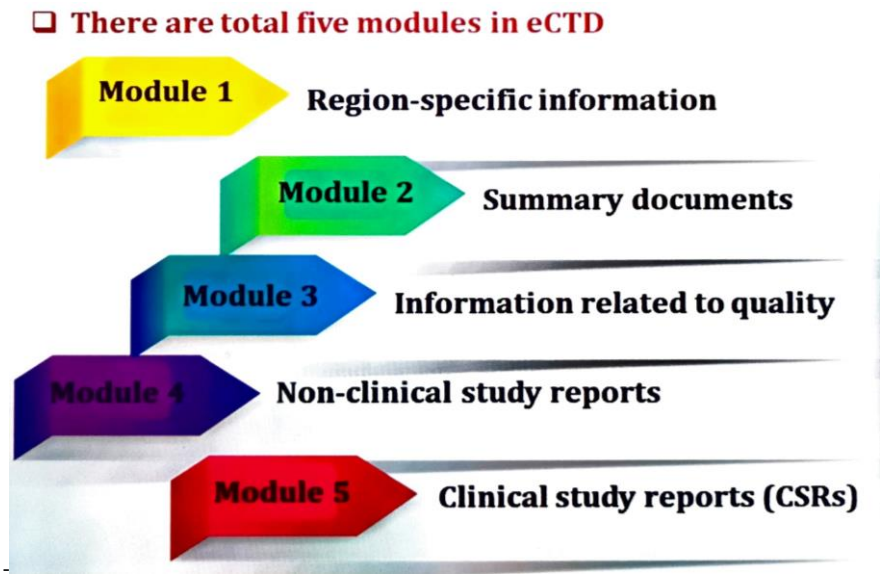


Fig.8: Electronic Common Technical Document (eCTD)

AUDIT TRIALS:

The pharmaceutical industry works largely on audit trails as a quality mechanism to meet worldwide regulatory requirements. Audit Regulators and industry organizations understand the importance of trails in addressing data integrity issues and maintaining quality systems in the pharmaceutical business. Audit trail review requires a risk-based approach and flexible standards to support the process. [34] Block chain technology can protect data integrity and traceability by improving the security and immutability of audit trails in pharmaceutical systems. [35] Within the pharmaceutical sector, adequate documentation is critical for controlling and ensuring quality. It allows judgments about batch releases as well as product history investigations via audit trails. [36]

Types of Quality Audits:

- Adequacy audit/ document audit: A system or management audit is a defined process that ensures the quality manual and associated procedures fulfill application standards. [37]
- Compliance audit/on-site audit: This audit determines how successfully the documented system is implemented and followed by personnel, hence assuring compliance.
- External audit: The most important audit is the external audit, which involves investigating the corporation's vendors and employees. An external audit's objective is to increase trust in the agreement for the working together. This verifies that the conditions are understandable. The risk of failure is reduced by reducing the amount of in-house quality control testing of beginning materials. [39]
- Internal audit: Internal audits evaluate an organization's systems, processes, and activities to verify compliance. It informs management about whether their regulations are being followed, whether modifications are necessary and whether the system is as effective and efficient as it should be. It promotes communication and motivation inside the firm. [40]
- Product/Process Audit: A product review evaluates whether a product or service meets specifications, performance criteria, and customer expectations. A process audit analyzes and evaluates process elements for completeness, correctness, and effectiveness. [41]

SUMMARY:

The pharmaceutical industry relies basically on a well-organized documentation system to assure product quality, regulatory compliance, and data integrity throughout the drug research and manufacturing process. This review focuses on critical types of pharmaceutical documents, such as Batch Manufacturing Records (BMRs) and Standard Operating Procedures (SOPs), Master Formula Records (MFRs), Common Technical Documents (CTDs), Drug Master Files (DMFs), and audit trails, each of which plays a unique role in ensuring consistency, traceability, and regulatory preparedness. SOPs give uniform instructions for normal activities, whereas BMRs and MFRs ensure complete documenting and standardization of manufacturing processes. DMFs protect private manufacturing information and facilitate regulatory filings, whereas CTDs, like eCTDs, streamline worldwide regulatory submissions through standardized structures. The transition from traditional paper-based systems to electronic formats like eCTD and block chain-based audit mechanisms reflects the industry's growing emphasis on data security, accessibility, and lifecycle management. Furthermore, Good Documentation Practices (GDP) underpin all documentation activities, ensuring that records are accurate, legible, and tamper-proof. Audit trails and various forms of quality audits (internal, external, compliance, and process audits) further reinforce the integrity and accountability of pharmaceutical operations. Overall, this paper underscores that robust documentation is not only a regulatory requirement but a cornerstone of pharmaceutical quality assurance and patient safety.

CONCLUSION:

Pharmaceutical documentation is essential for quality assurance, regulatory compliance, and operational efficiency at all stages of drug research and manufacturing. As this overview has shown, a strong documentation system includes a variety of critical components such as SOPs, BMRs, MFRs, DMFs, CTDs/eCTD, and audit trails, each of which serves a specific but closely linked purpose to ensure transparency, traceability, and consistency.

The transition from traditional paper-based systems to advanced digital platforms—such as electronic batch records and block chain-enabled audit mechanisms—has greatly improved data integrity, accessibility, and compliance. However, this digital revolution brings new difficulties, such as system validation, cybersecurity, and user training, that must be carefully handled.

Finally, effective documentation is a crucial tool that protects patient safety, accelerates regulatory clearances, and promotes ongoing quality improvement. Maintaining clear, accurate, and timely documentation is critical to the success of pharmaceutical operations and public health.

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