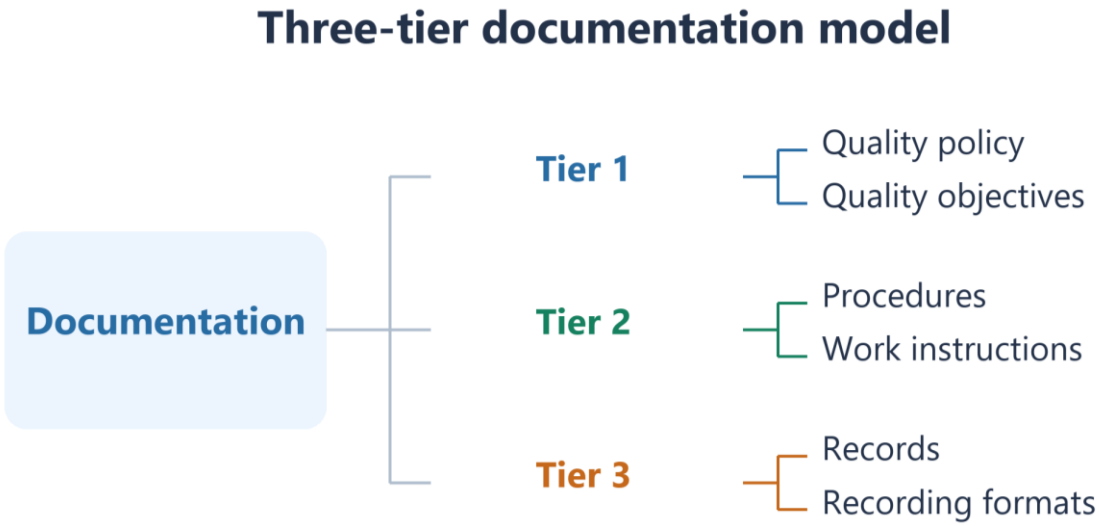
Documentation in Pharmaceutical Industry

Three Tier Documentation

- The pharmaceutical industry follows a three-tier documentation system to organize quality documents in a logical and systematic manner.
- Each level provides different types of information, from overall company policies to detailed work instructions and records.



This three-tier model links quality direction, instructions and evidence of completed work

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Tier 1 – Policy Documents

- Policy documents describe the overall quality philosophy and objectives of the organization.
- These documents explain what the company intends to achieve regarding quality.

Contents of Policy Documents

- Quality policy.
- Quality objectives.
- Organizational structure.
- Management responsibilities.
- Commitment to GMP and regulatory compliance.

Purpose of Policy Documents

- To establish the company's quality management system.
- To define overall quality goals.
- To provide direction for lower-level documents.

Tier 2 – Procedures and Work Instructions

- Procedures explain how a particular activity should be performed.
- Work instructions provide detailed step-by-step guidance for specific tasks.

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Procedure Documents

- Procedures describe responsibilities and sequence of activities.
- Procedures are broader than work instructions.
- Procedures apply to an entire department or process.

Work Instructions

- Work instructions explain each step of a specific activity.
- They contain detailed operating instructions.
- They are usually used directly by operators and technicians.

Tier 3 – Records and Formats

- Records provide evidence that activities have actually been performed.
- Formats are blank documents prepared for recording information during manufacturing and quality control activities.

Examples of Records

- Batch Manufacturing Records.
- Laboratory records.
- Equipment logbooks.
- Cleaning records.
- Calibration records.
- Training records.
- Environmental monitoring records.

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Examples of Formats

- Equipment cleaning format.
- Equipment usage format.
- Batch manufacturing format.
- Training attendance format.
- Temperature recording format.

Importance of Three-Tier Documentation

- Organizes documents systematically.
- Improves consistency of operations.
- Supports regulatory inspections.
- Ensures proper traceability.
- Reduces documentation errors.

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Policy, Procedures, Work Instructions, and Records (Formats)

Policy

Meaning

- A policy is a written statement issued by top management that defines the organization's quality goals and commitment.

Characteristics

- Policies should be clear and easy to understand.
- Policies should support regulatory compliance.
- Policies should apply throughout the organization.

Procedures

Meaning

- Procedures describe how activities should be performed to achieve quality objectives.

Characteristics

- Procedures should be approved before implementation.
- Procedures should clearly define responsibilities.
- Procedures should be reviewed periodically.

Work Instructions

Meaning

- Work instructions explain each step of a specific task in detail.

Characteristics

- Work instructions should be simple and easy to follow.
- Work instructions should include safety precautions whenever required.

Records (Formats)

Meaning

- Records are documents that provide evidence that activities have been completed according to approved procedures.

Characteristics

- Records should be completed immediately after the activity.
- Records should be accurate, complete, and legible.
- Records should not contain unnecessary blank spaces.

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Differences

Document	Purpose
Policy	Explains what the organization wants to achieve.
Procedure	Explains how an activity should be performed.
Work Instruction	Explains each step of a particular task in detail.
Record	Provides evidence that the activity has been completed.

Basic Principles of Documentation (How to Maintain, Retention, and Retrieval)

Basic Principles

- Documentation should always follow Good Documentation Practices (GDP).
- Every activity should be properly documented.
- Documentation should be complete, accurate, and traceable.

Rules for Maintaining Documents

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1. **Accuracy**
   - Information should be recorded correctly without mistakes.
2. **Legibility**
   - Handwriting should be clear and easy to read.
3. **Completeness**
   - All required information should be recorded.
4. **Timeliness**
   - Entries should be made immediately after performing the activity.
5. **Original Entry**
   - Original records should be maintained whenever possible.
6. **Corrections**
   - Incorrect entries should be corrected by drawing a single line through the mistake.
   - The original entry should remain visible.
   - The correction should be signed, dated, and justified if necessary.
7. **No Blank Spaces**
   - Blank spaces should be avoided.

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- Unused spaces should be marked appropriately.

Document Retention

Meaning

- Document retention means preserving documents for a specified period according to regulatory requirements.

Requirements

- Documents should be stored securely.
- Documents should be protected from damage, moisture, insects, and unauthorized access.
- Electronic records should be backed up regularly.
- Retention periods should comply with GMP and regulatory guidelines.

Purpose of Retention

- To provide historical information.
- To support investigations.
- To comply with legal requirements.
- To facilitate product recalls.

Document Retrieval

Meaning

- Retrieval means locating and obtaining documents whenever required.

Requirements

- Documents should be indexed properly.
- Records should be easy to locate.
- Only authorized personnel should access confidential documents.

Importance

- Proper documentation supports inspections and audits.
- It improves traceability and accountability.
- It helps investigate deviations and complaints.

Standard Operating Procedures (SOPs) (How to Write)

Meaning

- A Standard Operating Procedure (SOP) is a written document that describes the approved method for performing a routine activity.

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