Documentation in Pharmaceutical Industry

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Basic Idea

- Documentation is one of the most important components of Quality Assurance (QA) and Quality Control (QC) in the pharmaceutical industry.
- Documentation provides written evidence that all activities are performed according to approved procedures and regulatory requirements.
- Proper documentation ensures product quality, product safety, data integrity, traceability, and regulatory compliance.
- The principle followed in pharmaceutical documentation is often expressed as: "If it is not documented, it is considered not done."

Objectives of Documentation

- To provide clear instructions for performing activities.
- To ensure consistency in operations.
- To maintain traceability of all manufacturing and testing activities.
- To facilitate audits and inspections.
- To provide evidence of compliance with Good Manufacturing Practices (GMP).
- To support investigation of deviations, complaints, and product recalls.

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Importance in Quality Assurance and Quality Control

- Documentation ensures that processes are performed correctly and consistently.
- Documentation helps identify errors and deviations.
- Documentation provides historical records for review and analysis.
- Documentation supports continuous quality improvement.
- Documentation protects both the manufacturer and the patient.

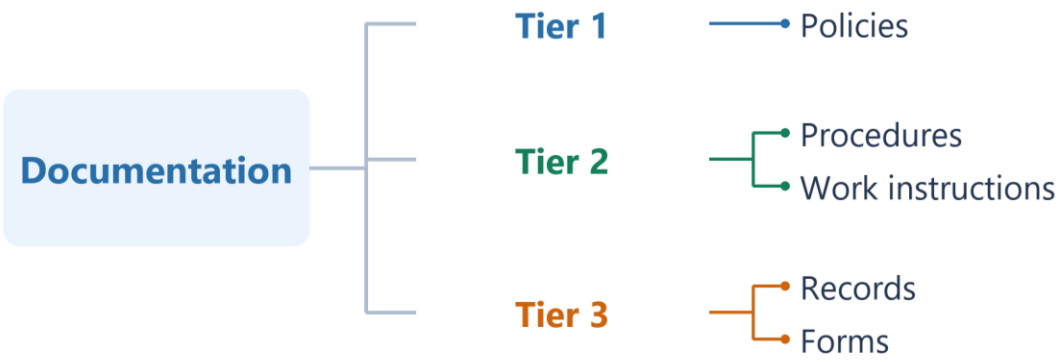
Three-Tier Documentation System

Basic Idea

- Pharmaceutical documentation is commonly organized into three levels or tiers.
- Each tier serves a specific purpose and provides different levels of detail.

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Three-tier documentation system



Policies, procedures and work instructions, and records form the three tiers described in these notes

Tier 1: Policies

Definition

- Policies are high-level documents that describe the overall intentions, principles, and quality objectives of an organization.

Characteristics

- Policies explain what the organization intends to achieve.
- Policies provide direction for all employees.
- Policies are approved by senior management.

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Examples

- Quality Policy.
- Data Integrity Policy.
- Environmental Health and Safety Policy.
- Documentation Control Policy.

Tier 2: Procedures and Work Instructions

Definition

- Procedures and work instructions describe how activities should be performed.

Characteristics

- Procedures explain the sequence of activities.
- Work instructions provide detailed operational guidance.
- These documents ensure uniformity in operations.

Examples

- Standard Operating Procedures (SOPs).
- Equipment Cleaning Procedures.

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- Sampling Procedures.
- Analytical Testing Procedures.
- Calibration Work Instructions.

Tier 3: Records and Forms

Definition

- Records provide documented evidence that activities were performed according to approved procedures.

Characteristics

- Records are generated during actual operations.
- Records demonstrate compliance with requirements.
- Records cannot be altered without proper authorization.

Examples

- Batch Manufacturing Records.
- Laboratory Test Reports.
- Equipment Logbooks.
- Calibration Records.
- Training Records.

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Relationship Between the Three Tiers

- Policies define what the organization aims to achieve.
- Procedures and work instructions explain how activities should be performed.
- Records provide evidence that activities were actually completed.

Policy, Procedures and Work Instructions

Policy

Definition

- A policy is a formal statement issued by management that establishes the organization's intentions and quality commitments.

Purpose

- To provide direction and guidance.
- To support regulatory compliance.
- To establish quality objectives.

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Characteristics

- Policies are broad and general.
- Policies are approved by top management.
- Policies apply throughout the organization.

Example

- A quality policy may state that all products will be manufactured according to GMP requirements to ensure patient safety.

Procedures

Definition

- Procedures are written documents that describe the steps required to perform a specific activity.

Purpose

- To ensure consistency and standardization.
- To reduce variability and errors.
- To ensure compliance with regulations.

Characteristics

- Procedures describe who performs an activity.
- Procedures describe when and where an activity should occur.
- Procedures describe the sequence of operations.

Example

- SOP for handling out-of-specification laboratory results.
- SOP for equipment cleaning.
- SOP for deviation management.

Work Instructions

Definition

- Work instructions provide detailed step-by-step guidance for carrying out specific tasks.

Purpose

- To ensure tasks are performed correctly.
- To provide operational details beyond those found in procedures.

Characteristics

- Work instructions are highly detailed.

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- Work instructions focus on individual tasks.
- Work instructions are usually used by operators and technicians.

Example

- Detailed instructions for operating a High-Performance Liquid Chromatography (HPLC) system.
- Detailed instructions for weighing raw materials.
- Detailed instructions for equipment setup.

Records (Formats)

- Records are documents that provide evidence of activities performed and results obtained.
- Formats are pre-designed templates used to record information consistently and accurately.

Purpose of Records

- To demonstrate compliance with approved procedures.
- To maintain traceability of activities.
- To support quality investigations.
- To provide evidence during inspections and audits.

Characteristics of Good Records

- Records should be accurate.
- Records should be complete.
- Records should be legible.
- Records should be contemporaneous, meaning information is recorded at the time of activity.
- Records should be attributable to the person who performed the activity.

Common Types of Records

1. **Batch Manufacturing Records**
   - These records document all manufacturing activities for a specific batch.
2. **Batch Packaging Records**
   - These records document packaging operations.
3. **Laboratory Records**
   - These records include analytical test results and observations.
4. **Equipment Logbooks**
   - These records document equipment usage, cleaning, and maintenance.

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