GMP DOCUMENT CONTROL

SOP vs Work Instruction Checklist

Choose the Right GMP Document

A practical guide for QA teams, document owners, production supervisors, and pharmaceutical learners.

Why document selection matters in GMP

Wrong document choices can create confusion, inconsistent execution, and audit findings.

RISK 01

Confusing process control

Teams may not know who owns, reviews, or approves the activity.

RISK 02

Creating execution gaps

Operators may miss exact steps, settings, or point-of-use guidance.

RISK 03

Weakening audit evidence

Records, references, and training links may not support the actual work.

Match the document to the risk

SOP vs. work instruction in one minute

An SOP governs a process. A work instruction guides a task.

SOP

Controls the complete process

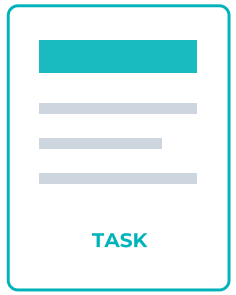
- Purpose, scope, and responsibilities
- Process stages and review points
- Required records and approvals

Governance

Work Instruction

Guides one specific task

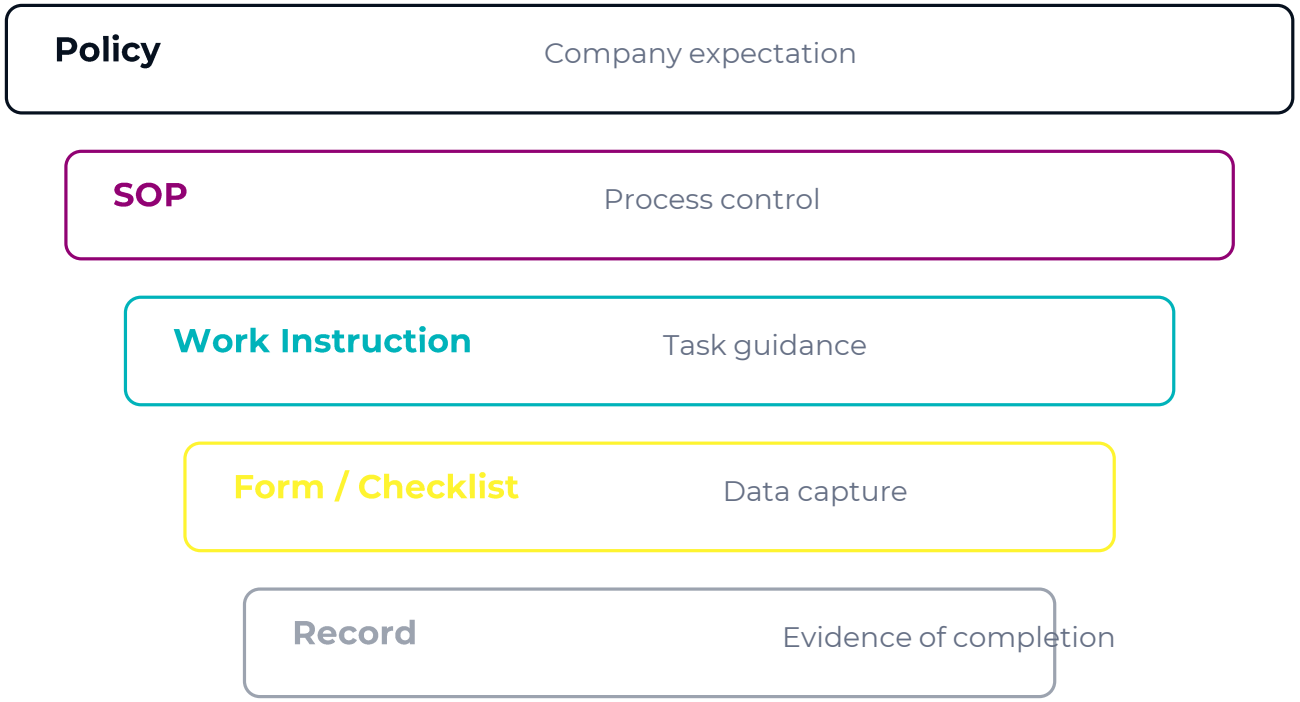
- Numbered steps and sequence
- Settings, screenshots, or measurements
- Point-of-use task guidance



Execution

GMP documentation hierarchy

Each document type has a clear level and purpose.



Key idea

SOPs should not contain every operational detail. Work instructions should not replace process governance.

Use forms and records to prove the work was completed.

What belongs in an SOP

Use an SOP when the document controls a complete GMP process.

1

Purpose & scope

Why the process exists and where it applies

2

Roles & approvals

Who performs, reviews, approves, and records

3

Process stages

Main steps, decision points, and controls

4

Records

Forms, logs, reports, or evidence required

SOP = Process governance

Examples: deviation management, batch release, complaint handling, equipment cleaning.

What belongs in a work instruction

Use a work instruction when consistent task execution needs exact detail.

1

Numbered steps

Fixed sequence, clear actions

2

Exact settings

Parameters, times, volumes, temperatures

3

Visual guidance

Screenshots, photos, diagrams, warnings

4

Point-of-use detail

Designed for operators at the task location

WI = Task execution

Examples: entering a deviation in eQMS, setting up a balance, sampling a defined location.

The five-question document decision test

Answer these questions before creating or revising a controlled document.

1. **Does it control an entire process?**
2. **Does it assign responsibilities or approvals?**
3. **Does it require exact settings or numbered actions?**
4. **Could inconsistent execution affect quality or patient safety?**
5. **Does the employee need it at the point of use?**

Mostly YES to Q1–Q2

Create an SOP

Mostly YES to Q3–Q5

Create a WI

When an SOP is enough

A high-level process document can be enough when task detail is already controlled elsewhere.

Use an SOP alone when employees already understand the technical task and the main need is governance.

- The process spans multiple roles or departments
- The activity requires review or approval points
- The exact technique is simple, stable, or covered by training
- The records and responsibilities are the main risk controls

SOP ONLY

Example: document control procedure with defined review, approval, and periodic review rules.

When a work instruction is required

A work instruction adds practical detail when an SOP cannot safely carry every step.

Create a WI when variation during execution could cause errors, rework, or weak GMP evidence.

- Steps must follow a fixed sequence
- Equipment settings or system fields must be exact
- Operators need guidance at the task location
- Visual examples improve consistency

WI REQUIRED

Example: balance calibration check steps with exact weights, sequence, entries, and acceptance limits.

When both documents are necessary

Many GMP activities need governance and precise task guidance.

SOP

Defines responsibilities, frequency, review, deviations, records, and approval requirements.

BOTH

WI

Explains the exact sequence, measurements, settings, screenshots, or point-of-use steps.

Best fit: high-risk activities where the process and task must both be controlled.

Equipment-cleaning example

The SOP controls the cleaning program. The WI controls exact execution.

Cleaning SOP

- Defines cleaning frequency
- Assigns production and QA roles
- Defines records and review
- Controls deviations and re-cleaning

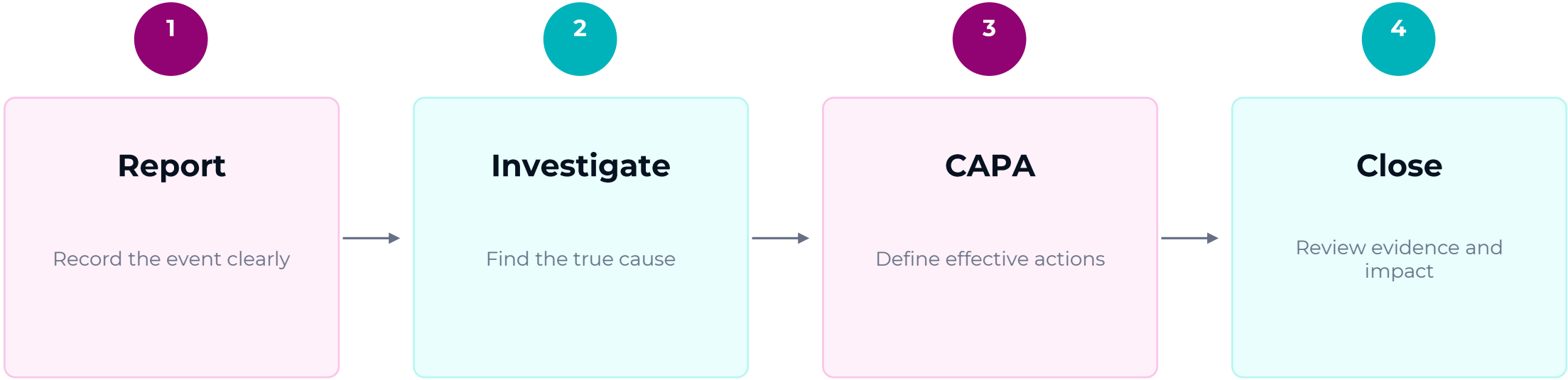
Cleaning WI

- Lists cleaning sequence
- States detergent concentration
- Sets contact time and rinse steps
- Shows equipment settings

Result: fewer execution gaps and stronger inspection-ready evidence.

Deviation-management example

The SOP describes the investigation lifecycle. The WI helps users operate the eQMS.



SOP Process rules, roles, timelines, approvals

WI How to enter, update, and close records in eQMS

Common SOP–WI alignment failures

Misalignment makes documents harder to use and harder to defend.

Duplicate content

Same steps copied into both documents

Conflicting instructions

Different sequence, limits, or terminology

Broken references

WI does not link to the controlling SOP

Training gaps

Users trained on one document but not the other

Correction principle: one source of truth, clear references, synchronized revisions, and role-based training.

Pre-approval document checklist

Use this checklist before releasing an SOP or work instruction.

- ✓ **Title matches activity**
- ✓ **Steps and sequence are logical**
- ✓ **Purpose and scope are clear**
- ✓ **References and forms are linked**
- ✓ **Responsibilities are correct**
- ✓ **Version and training needs are defined**

Before approval, ask: will this document help the right user perform the right work in the right way?

Final one-page decision matrix

Choose an SOP, a work instruction, or both using one practical view.

SOP

Complete process
Roles and approvals
Records and governance

WI

One specific task
Exact steps or settings
Point-of-use execution

BOTH

High-risk activity
Process + task control
Reduced variation

Pharmuni CTA

Use this checklist to review your next SOP or work instruction before approval.

Explore Pharmuni courses and toolkits to strengthen GMP documentation skills.