

Training Document Authoring Methodology

A customer template for preparing procedures, work instructions, training materials, and job aids

GxP Frame | CUSTOMER TEMPLATE | SITE APPROVAL REQUIRED | Version 1.0

This method helps an authoring team turn approved process knowledge into clear, usable documents. It is a customizable reference package. The purchasing organization must adapt it to its approved document-control, quality, training, and change processes before operational use.

1. Intended outcome

The outcome is a document that enables the intended user to perform or explain a defined task, makes decision points visible, and gives reviewers a coherent basis for technical and quality review. The document should be specific enough for its intended work and remain within the approved source material.

Document type	Primary reader task	Typical evidence of use
Procedure or SOP	Understand the controlled sequence and decision points	Approved source, review record, change history
Work instruction	Perform a defined task consistently	Step completion, observation, or execution record
Training material	Build understanding before supervised or independent work	Training record and an appropriate learning check
Job aid or checklist	Retrieve critical information during work	Completed checklist or referenced aid where required

2. Authoring workflow

1. Define the intended user, the task boundary, and the decision the document must support.
2. Collect the approved source material. Identify gaps, conflicts, and assumptions before drafting.
3. Map the work in sequence: trigger, inputs, core actions, decisions, exceptions, outputs, and records.
4. Draft the first usable version in plain language. Keep one action or decision per step where possible.
5. Ask technical reviewers to verify accuracy and quality reviewers to verify control boundaries and record expectations.
6. Resolve comments through the site's approved review process. Do not treat a draft as an approved instruction.
7. Prepare accompanying training material only after the procedure's meaning is stable, then manage revisions through the site process.

Authoring principle

A document is useful when a trained reader can identify what to do, when to stop, who decides an exception, and what record supports the action.

3. Build from approved knowledge

Start with the current approved sources that describe the work. Those may include approved procedures, validated system specifications, batch or laboratory records, controlled forms, equipment instructions, process maps, and documented decisions. The author records any source conflict or missing decision for resolution by the appropriate subject-matter owner.

Before drafting	Check	Record or escalation
Scope	What task, user group, product, system, or process is in scope?	State the boundary in the draft.
Authority	Which source is current and approved for the claim?	List the source or raise a gap.
Sequence	What happens before, during, and after the task?	Use a process map or numbered outline.
Exceptions	What stops work, requires escalation, or changes the path?	Identify condition, decision maker, action, and record.
Terminology	Which terms have a site-defined meaning?	Use the approved term or define it.

4. Write for execution

Use the reader's work sequence as the document structure. Lead with the trigger, then state each action in the order a user performs it. Use an imperative verb. State the responsible role. Identify the required record where the action needs evidence. Put conditions and exceptions next to the step they govern.

Weak phrasing	Executable phrasing
"Ensure the record is complete."	"The performer reviews the required fields before submission and records any exception in the designated system field."
"Escalate issues as appropriate."	"If the specified acceptance condition is not met, the performer stops the activity and notifies the designated reviewer under the site escalation process."
"Follow applicable procedures."	"List the procedure or define the decision that sends the user to it."

5. Make decisions visible

A reader should not have to infer a critical decision from surrounding prose. For each meaningful branch, state the condition, decision-maker, action, record, and escalation route. Use a table only when it makes paths easier to compare.

Condition	Decision owner	Required action	Evidence
Required input is unavailable	Role defined by site process	Stop or use the approved exception route	Exception or deviation record, where required
Step result is unclear	Technical or quality reviewer	Clarify before proceeding	Review comment or decision

9. Source and decision record

Use this table before drafting. Enter the current approved source, its version or effective date, its owner, and the specific step or decision it supports. Record conflicts and open questions for the accountable site owner. Do not resolve a missing requirement by assumption.

Claim or step	Approved source and version	Source owner	Open item / disposition
[Describe action or decision]	[Document ID, version, date]	[Role/name]	[Decision, date, record]
[Describe exception]	[Document ID, version, date]	[Role/name]	[Decision, date, record]

10. Task and exception map

Map the work before writing prose. Show the trigger, responsible role, needed inputs, action, decision condition, exception route, output, and required record. Confirm the map with a person who performs the work and the accountable process owner.

Trigger / role	Action and decision condition	Exception / stop point	Output and record
[When and who]	[Action; acceptance condition]	[If not met, stop and notify role]	[Record/system]
[Next step]	[Action; decision]	[Escalation route]	[Handoff evidence]

11. Drafting rules

- Use one clear actor and action per step. Separate required actions from explanatory background.
- Place a condition next to the step it controls. State what the reader does when the condition fails.
- Name records and systems exactly as the approved site source does. Do not invent acceptance limits.
- Distinguish an example from an approved instruction. Remove placeholders before site release.
- Check document accessibility, numbering, tables, links, and printable layout with intended users.

12. Review and disposition log

Use the site's approved review tool where required. This table is a planning aid for tracking whether technical, quality, training, and document-control comments were actually resolved.

Reviewer / role	Comment and affected section	Disposition and approved source	Owner / date / evidence
[Technical reviewer]	[Specific issue]	[Resolution or escalation]	[Name, date, record]
[Quality reviewer]	[Control or record issue]	[Resolution or escalation]	[Name, date, record]