

SOP-003 v1.0 – Document Lifecycle and Workflow in VDC

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Title: Document Lifecycle and Workflow in VDC

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1. Purpose

To define how documents are created, reviewed, approved, distributed, and retired within the VDC system, ensuring control over GxP-relevant documentation and traceable approval records.

2. Scope

Applies to all documents managed in VDC that are designated as controlled documents (e.g., validation evidence, SOPs, specifications) and to any user performing document-related actions in VDC production.

3. Definitions

- **Controlled Document:** Any document designated as requiring formal approval and version control.
- **Controlled Copy:** Approved document version downloaded from VDC and used for operational purposes.
- **Metadata:** Structured attributes stored with each document (title, owner, type, status, timestamps, etc.).

4. Document States

VDC supports, at minimum, the following states:

- **Draft** – Document created or edited by Submitter; not yet routed for approval.
- **Submitted / Pending Approval** – Document locked for editing and awaiting Approver decision.
- **Approved** – Document formally approved; content and metadata locked (except fields designated as administrative).
- **Rejected** – Document rejected by Approver with justification; returned to Submitter for revision or withdrawal.
- **Superseded / Retired** – Older versions made obsolete by a newer approved version or taken out of use.

5. Document Creation and Drafting

5.1 Creation

- Submitter logs into VDC and selects Upload or equivalent function.
- Submitter provides:
 - File to be registered.
 - Required metadata (e.g., title, category, process area, owner/submitter).
- The document is created in Draft state.

5.2 Editing Drafts

- Submitter may revise content (by re-uploading a file) and update metadata while in Draft state.
- Drafts are not to be used as official controlled copies.

6. Submission for Approval

- When content and metadata are complete, Submitter selects Submit for Approval.
- Prior to submission, Submitter must confirm:
 - The document correctly reflects the intended content.
 - Required metadata are accurate and complete.
- On submission, the system:
 - Changes state to Submitted / Pending Approval.
 - Records user, timestamp, and relevant details in the audit trail.
 - Routes the document to designated Approver(s) as configured.

7. Review, Approval, and Rejection

7.1 Review

- Approver opens the document and reviews:
 - Content for completeness, accuracy, and compliance.
 - Metadata for correctness (e.g., classification, owner, effective date, where applicable).

7.2 Approval

- If acceptable, Approver selects Approve and may enter a comment.
- System actions:
 - Sets state to Approved.
 - Locks the document content, preventing further modification.
 - Records approving user, timestamp, and outcome in the audit trail.

7.3 Rejection

- If not acceptable, Approver selects Reject and enters a clear justification.

- System actions:
 - Sets state to Rejected.
 - Returns document to Submitter for revision.
 - Records rejection event, user, timestamp, and comment in the audit trail.

7.4 Resubmission

- Submitter corrects issues, updates content/metadata, and resubmits following Section 6.

8. Controlled Copies and Distribution

- Approved documents can be accessed via Open controlled copy or similar function.
- Download events:
 - Are logged with user, timestamp, and document identifier.
 - Are considered evidence that a controlled copy was accessed.
- Users must ensure printed or offline controlled copies are labeled and managed according to applicable quality procedures (outside the scope of this SOP).

9. Versioning and Supersession

- Each new approved revision of a document should be stored as a new version.
- When a new version is approved:
 - Prior version is marked Superseded or Retired but not deleted.
 - Links between versions (e.g., previous version ID) should be maintained where supported.
- Users must ensure that only the current approved version is used operationally.

10. Archiving and Retirement

- Documents that are no longer in use but need to be retained (e.g., for regulatory or business reasons) are moved to Retired state.
- Retired documents remain available for read-only access and audit purposes until their retention period (per SOP-008) has elapsed.

11. Audit Trail

- The following events must be captured at minimum:
 - Creation, upload, and modification of documents and key metadata.
 - Submissions, approvals, rejections, and comments.
 - Downloads of approved copies.
- Audit trail entries must include:
 - Actor identifier (user), timestamp (UTC), event type, and relevant details.
- Audit trails are reviewed periodically as defined in SOP-007.

12. Deviations

- Any instance where the document process does not follow this SOP (e.g., use of uncontrolled copies, bypass of approval workflow) must be recorded as a deviation and managed under SOP-005.