

## SOP-001 v1.0 – VDC System Governance and Validation

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### 1. Purpose

The purpose of this SOP is to define the governance model, validation approach, and lifecycle controls for the Validated Document Control (VDC) system hosted at <https://williamoconnellpmp.com>. This SOP ensures the system is fit for intended use and compliant with applicable GxP and 21 CFR Part 11 requirements for electronic records and audit trails.

### 2. Scope

This SOP applies to:

- The production VDC application and supporting AWS services (e.g., Cognito, API Gateway, Lambda, S3, CloudFront).
- All VDC-related validation activities (URS, FS, RTM, IQ/OQ/PQ or equivalent).
- All personnel involved in design, development, validation, operation, and support of VDC.

It does not cover business process content of documents themselves; those are governed by functional area procedures.

### 3. Definitions

- VDC: Validated Document Control system at [williamoconnellpmp.com](https://williamoconnellpmp.com).
- Computerized System: A system including hardware, software, and associated documentation.
- Validation: Documented evidence that a system consistently performs as intended.
- Part 11: 21 CFR Part 11, Electronic Records; Electronic Signatures.

### 4. Roles and Responsibilities

- System Owner
  - Overall accountability for VDC.
  - Approves validation strategy and final validation package.
  - Ensures SOPs and training are in place and maintained.
- QA / Compliance

- Reviews and approves validation deliverables and key configuration decisions.
- Assesses compliance impact of changes and deviations.
- System Administrator
  - Implements and maintains technical configuration of VDC and AWS resources.
  - Executes backups/restores per SOP-008.
  - Maintains system technical documentation.
- Developers / Technical Support
  - Implement changes under SOP-004.
  - Execute and document technical tests.
- End Users (Submitters, Approvers, Viewers)
  - Use the system in accordance with approved procedures and training.
  - Report incidents/deviations per SOP-005.

## 5. System Description

- Web-based application accessed via <https://williamoconnellpmp.com>.
- Users authenticate via AWS Cognito-hosted login pages.
- Functional capabilities:
  - Upload and registration of documents and metadata.
  - Workflow states: Draft → Submitted / Pending → Approved / Rejected.
  - Controlled download of approved copies.
  - Immutable audit trail of key events (submit, approve, reject, download, configuration events).
- Data storage:
  - Application state and metadata in managed back-end components.
  - Documents stored in S3 buckets with integrity and access controls.
  - Audit events retained and queryable as part of the VDC evidence set.

## 6. Validation Approach

6.1 Lifecycle Model VDC is managed under a defined system lifecycle:

- Concept → Requirements → Design → Build/Configure → Test → Release → Operation → Retirement.

6.2 Key Validation Deliverables At minimum, the following documents must exist and be maintained as part of the VDC Validation Package:

- User Requirements Specification (URS).
- Functional Specification (FS) / Design Description.
- Risk Assessment (if separate).
- Traceability Matrix (RTM) linking URS → FS → test cases.

- Qualification Protocols and Reports (IQ/OQ/PQ or equivalent).
- Deviation and CAPA records.
- SOPs governing use and technical operations of VDC (this SOP set).

### 6.3 Risk-Based Approach

- System functions and data are assessed for GxP and data integrity impact.
- Validation depth is commensurate with risk (e.g., more rigorous testing for workflow, approvals, and audit trail than for cosmetic UI elements).

### 6.4 Validation Acceptance

- QA/Compliance and System Owner review:
  - Complete and approved validation deliverables.
  - Successful execution of test protocols with resolved deviations.
- Written approval is required before VDC may be used for regulated records.

## 7. Documentation and Record Management

- All validation documents must be:
  - Version-controlled.
  - Approved by authorized signatories.
  - Stored in a controlled repository with read-only final copies.
- Records generated by VDC (documents, audit trails, logs) are retained per SOP-008.

## 8. Operation and Maintenance

- Ongoing operation of VDC must follow:
  - SOP-002 (User Management and Access Control).
  - SOP-003 (Document Lifecycle and Workflow).
  - SOP-004 (Change Control).
  - SOP-005 (Incident/Deviation/CAPA).
  - SOP-007 (Periodic Review and Audit Trail Review).
  - SOP-008 (Data Retention, Backup, and Restore).

## 9. Periodic Review and Revalidation

- At least annually, the System Owner and QA perform a Periodic Review (per SOP-007) to confirm:
  - Validation status remains current.
  - System changes are properly controlled and tested.
  - No new regulatory or business requirements necessitate additional validation.
- Revalidation (partial or full) is performed when:

- Major system changes introduce new functionality or architecture.
- Significant issues or regulatory interpretations require reassessment.

## 10. References

- 21 CFR Part 11.
- GAMP 5, "A Risk-Based Approach to Compliant GxP Computerized Systems".
- Internal quality policies on computerized system validation.