Standard Operating Procedure

SOP Title: Change Control SOP
Document Code: SOP-VA-103
Effective Date: 05May2025
Supersedes: [Previous Version if applicable]
Approved By: [Name / Title]
Review Date: [Annually or as needed]

1. Purpose

To establish a formal system for initiating, evaluating, approving, implementing, and documenting all changes that could impact product quality, safety, regulatory compliance, or the Quality Management System (QMS).

2. Scope

Applies to changes in:

- **Documents** (SOPs, forms, specifications, batch records)
- **Processes or Equipment** (manufacturing, testing, cleaning)
- **Materials or Suppliers**
- **Computerized Systems / Seed-to-Sale Software**
- **Facilities, Utilities, Environmental Controls**

3. Definitions

Term	Definition
Change Request (CR)	Formal record that describes the proposed change and its justification.
Impact Assessment (IA)	Evaluation of potential effects on quality, validation status, and compliance.
Change Control Board (CCB)	Cross-functional team (QA, Production, Engineering, Compliance) that reviews and approves changes.

Term	Definition
Minor Change	Low-risk alteration not affecting critical quality attributes (e.g., typo correction).
Major Change	Any change that can affect product quality, safety, or regulatory filings; requires full IA.

4. Responsibilities

Role	Key Responsibilities
Initiator (SME / Dept. Manager)	Drafts the CR, completes preliminary IA, and proposes implementation plan.
Quality Assurance (QA)	Manages the Change Control log, facilitates CCB review, and verifies closure documentation.
Change Control Board (CCB)	Reviews IA, classifies change risk (minor/major), approves or rejects CR, assigns target dates.
Engineering / Validation	Assesses equipment or process validation impact and executes requalification if required.
Regulatory / Compliance	Confirms changes align with CCA and cGMP requirements; updates filings if needed.

5. Procedure

5.1 Change Request Initiation

1. Initiator completes *Change Request Form* (FORM-VA-###).
2. Provide description, reason/justification, and proposed implementation timeline.
3. Submit CR to QA for logging and CCB scheduling.

5.2 Impact Assessment (IA)

- Identify affected SOPs, validations, training, materials, or regulatory submissions.
- Evaluate risk to product quality and patient safety.

- Determine classification: **Minor** (low-risk, expedited) or **Major** (full CCB review).

5.3 CCB Review & Approval

- CCB meetings held at least monthly or ad hoc for urgent changes.
- Outcomes recorded: *Approved*, *Rejected*, or *More Information Required*.
- For Major changes, assign Action Items (e.g., protocol drafting, validation, training).

5.4 Implementation

- Responsible departments execute tasks by assigned due dates.
- QA monitors progress; deviations trigger CAPA per SOP-VA-104.
- Update all affected documents via Document Control SOP (SOP-VA-101).
- Perform required re-validation or re-qualification activities.
- Train personnel before "go-live."

5.5 Verification & Closure

- QA reviews evidence (updated SOPs, validation reports, training records).
- If all acceptance criteria met, QA signs the *Change Request Form* as "Closed."
- Closed CRs archived; open CRs tracked until completion.

6. Records

- Change Request Form with IA section
- CCB meeting minutes
- Validation / re-qualification reports
- Updated documents and training records
- Change Control Log (master spreadsheet or database)

Retention: **5 years** minimum (or per Record Retention Policy SOP-VA-108).

7. References

- 21 CFR 211.100–115 (Production & Process Controls)

- ISO 9001:2023 – Clause 8.5.6 Control of Changes

- Virginia CCA Regulations – Change Management Requirements

- SOP-VA-101 Document Control SOP

- SOP-VA-104 Deviation & CAPA SOP

- QM-VA-001 Quality Manual

8. Revision History

Version	Date	Change Description	Approved By
			[Name / Title]