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. |
| **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

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| --- | --- | --- | --- |
| Version | Date | Change Description | Approved By |
|  |  |  | [Name / Title] |