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# PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the procedures and responsibilities for management of Standard Operating Procedures used to support computerized systems.

# SOP SCOPE

This SOP applies to personnel and procedures supporting computerized systems.

# DEFINITIONS

A Standard Operating Procedure (SOP) is a set of written instructions followed by an organization when performing routine or repetitive activities.

# RESPONSIBILITIES

The Quality Assurance Manager and staff are responsible for

* Ensuring that SOPs meet the compliance standards
* Approving new SOPs and revisions to existing SOPs
* Initiating and participating in the periodic review of existing SOPs

The Information Technology Manager and staff are responsible for

* Ensuring that SOPs meet the technical standards
* Approving new SOPs and revisions to existing SOPs
* Participating in the periodic review of existing SOPs

The Document Administrator is responsible for

* Management of SOPs and SOP Change Requests in the company document management system

# PROCEDURES

## SOP Preparation

SOPs will be written by individuals knowledgeable in the activity.

SOPs will be written with sufficient detail so that someone with limited experience with or knowledge of the procedure, but with a basic understanding, can successfully reproduce the procedure when unsupervised.

SOPs will be written in the standard SOP Template which includes these components and sections:

| **Section** | **Description** |
| --- | --- |
| Title | The SOP name |
| SOP Number | Unique SOP number |
| Effective Date | The date the SOP became operational |
| Version | SOP version number |
| Purpose | Describes the purpose and objective(s) of the procedure |
| Scope | Describes the scope of the procedure, such as to which processes and personnel the procedure applies |
| Definitions | Defines any unique or unfamiliar terms used within the procedure |
| Responsibilities | Describes the responsibilities of individuals and organizations involved in executing the procedures |
| Procedures | Defines the steps of the procedure |
| References | Identifies any reference document utilized in writing the procedure |

Each SOP will be given a unique name that describes the content of the procedures. For example, this SOP is titled “Document Management”.

Each SOP will be given a unique 3-digit number.

## Change Requests

Each request for SOP creation, revision, retirement, or periodic review will be formally documented using the Standard Operating Procedure Change Request form, Attachment A, following these instructions:

| **Information** | **Instruction** |
| --- | --- |
| **Change Request ID** | Assign a Change Request ID using format SOP-CR-YYYYMMDD-nnn.   * YYYY = current year * MM = current month * DD = current day * nnn = sequential number, starting at 001 each day |
| **SOP Name** | * Record the name of the SOP associated with the requested change. |
| **SOP Version** | * Record the current SOP version number. If new, enter “n/a” * Record the SOP version number upon approval of the CR. SOP version numbers are incremented by 1.   **NOTE:** The current and new version number could be the same in the case of Periodic Review |
| **Effective Date** | * Record the effective date of the current SOP version number. If new, enter “n/a” * Record the effective date of the new or changed SOP.   **NOTE:** The current and new effective date could be the same in the case of Periodic Review |
| **Change Request Date** | * Record the current date. |
| **Requested by** | * Record the name of the person requesting the change. |
| **Author** | * Record the name of the person authoring, updating, retiring, or reviewing the SOP. |
| **Change Type** | * Check each box that applies to the requested change. |
| **Change Description** | * Describe the requested change. * If multiple changes are requested, provide a list containing a description of each change. |
| **Change Rationale** | * Provide the reason for the requested change. * If multiple changes are requested, provide a list containing the reason for each change. |

The completed Change Request and associated SOP will be sent to the Information Technology Manager and the Quality Manager for review and authorization.

## SOP Review and Approval

The Information Technology Manager and the Quality Manager will review the new or modified SOP and the SOP Change Request form. Each manager will sign and record his/her decision on whether or not to authorize the change on the Change Request Authorization form.

## Periodic SOP Review

Each SOP will be reviewed every 3 years to ensure its continued accuracy and relevance.

SOPs that have not been modified within a 3 year time frame will be formally reviewed by the Information Technology Manager and the Quality Manager. The review will be initiated by the Quality Manager.

The Periodic Review will be documented using the Change Request Authorization form in Attachment A.

## SOP Access and Retention

Employees will access SOPs through the “Software SOPs” folder in the company document management system.

* Current versions of approved SOPs will be available in the “Current SOPs” folder within the “Software SOPs” folder of the company document management system.
* Superseded versions of approved SOPs will be retained for 3 years in the “Obsolete SOPs” folder within the “Software SOPs” folder of the company document management system.
* Unapproved (e.g., draft) versions of SOPs will be available in the “Draft SOPs” folder within the “Software SOPs” folder of the company document management system.

The Document Administrator will be responsible for moving documents to the “Current SOPs” and “Obsolete SOPs” folders. The SOPs in these folders will be secured from modification by anyone other than the Document Administrator.

## CR Retention

Approved SOP Change Requests will scanned and retained in the “SOP Change Request” folder within the “Software SOPs” folder of the company document management system. CRs will be retained for as long as the SOP version associated with the CR.

The Document Administrator will be responsible for moving completed change requests to the “SOP Change Request” folder. The CRs in this folder will be secured from modification by anyone other than the Document Administrator.

## Personnel Training on SOPs

Personnel involved in the design, construction, testing, quality assurance and deployment of the computerized system shall be trained in the procedure, *SOP Software Quality Assurance*, and all other SOPs mentioned within that SOP.

Training will take place prior to the SOP’s effective date. For new personnel, training will take place within the first 30 days of employment.

A record of this training will be stored with the company documentation management system.

**References:**

*21 CFR Part 11, Electronic Records; Electronic Signatures*, FDA, March 20, 1997

# ATTACHMENT A: Standard Operating Procedure Change Request

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Change Request ID** | |  | | | | |
| **SOP Name** | |  | | | | |
| **SOP Version** | | Current version \_\_\_\_\_\_\_\_\_ New version \_\_\_\_\_\_\_\_\_ | | | | |
| **Effective Date** | | Current effective date \_\_\_\_\_\_\_\_\_ New effective date \_\_\_\_\_\_\_\_\_ | | | | |
| **Change Request Date** | |  | | | | |
| **Requested By** | |  | | | | |
| **Author** | |  | | | | |
| SOP Change Request Description | | | | | | |
| **Change Type** | | *Check all that apply:* | | | | |
| New SOP  SOP Retirement | | SOP Modification  Periodic Review | | |
|  | | | | |
| **Change Description** | | *Describe requested change(s):* | | | | |
| **Change Rationale** | | *Provide reason for requested change(s):* | | | | |
| Authorization of Change | | | | | | |
| **Role** | **Decision** | | **Name** | | **Signature** | **Date** |
| Quality Manager |  Approve  Reject | |  | |  |  |
| IT Manager |  Approve  Reject | |  | |  |  |