

# MASINOVA Example SOP

## Standard Operating Procedure Development, Review, Approval, Issuance, and Periodic Review

### Illustrative example only.

This document is provided as a public example of MASINOVA’s SOP writing style and document-control approach. It is not a controlled internal record and is published for informational purposes only.

**Document Number:** QMS-SOP-001

**Version:** 1.0

**Effective Date:** [DD-MMM-YYYY]

**Review Date:** [DD-MMM-YYYY]

**Document Owner:** Quality Assurance

**Approved By:** [Title / Function]

**Document Status:** Public example for website publication

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## Introduction

At MASINOVA, Standard Operating Procedures are written to ensure clarity, consistency, accountability, and quality across all regulated and development-stage activities. A well-written SOP should define what must be done, who is responsible, how the activity is controlled, and how the document is maintained over time.

The following example reflects the structure, tone, and quality standards MASINOVA applies when developing SOPs for operational, technical, quality, and regulatory use.

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# 1. Purpose

This Standard Operating Procedure defines the process for drafting, reviewing, approving, issuing, training on, maintaining, revising, and retiring SOPs within the MASINOVA Quality Management System.

The purpose of this procedure is to ensure that all SOPs are:

- clear and actionable;
- technically accurate;
- appropriately reviewed and approved;
- traceable through formal document control;
- maintained in a current and compliant state.

Consistent SOP governance supports operational reliability, regulatory readiness, and quality system integrity.

# 2. Scope

This SOP applies to all MASINOVA personnel, departments, and authorized contractors involved in the lifecycle management of controlled SOPs and related quality documents.

This procedure covers:

- creation of new SOPs;
- revision of existing SOPs;
- functional and quality review;
- formal approval;
- document issuance and controlled distribution;
- training, where applicable;
- periodic review;
- retirement and archival.

This SOP applies only to controlled documents managed within MASINOVA's approved document-control system. It does not apply to informal notes, working drafts, temporary reference materials, or uncontrolled communications.

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## **3. Responsibilities**

### **3.1 Document Owner**

The Document Owner is responsible for the content, technical accuracy, and continued maintenance of the SOP. The Document Owner ensures the procedure reflects current practice and business needs.

### **3.2 SOP Author**

The SOP Author prepares the draft using the approved template, incorporates required inputs, and updates the document in response to review comments.

### **3.3 Functional Reviewers**

Functional reviewers assess the SOP for scientific, technical, operational, and cross-functional accuracy. Reviewers confirm that the content is practical, consistent, and suitable for implementation.

### **3.4 Quality Assurance**

Quality Assurance reviews the SOP for compliance with formatting, document-control requirements, clarity, consistency, and QMS alignment. QA ensures that the document meets internal quality standards before approval.

### **3.5 Approver(s)**

Approver(s) provide final authorization for implementation. Approval confirms that the SOP has been adequately reviewed and is suitable for controlled issuance.

### **3.6 Document Control**

Document Control assigns document numbers, maintains version history, issues approved documents, removes superseded versions from active use, and archives obsolete copies in accordance with retention requirements.

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### **3.7 Line Management / Training Function**

Line management or the designated training function ensures that affected personnel complete required training before or by the effective date, where applicable, and that training records are maintained.

## **4. Definitions**

### **Controlled Document**

A document managed under the Quality Management System with defined requirements for approval, versioning, access, and retention.

### **Document Owner**

The individual or function accountable for the content, accuracy, and maintenance of a controlled document.

### **Effective Date**

The date on which an approved document becomes active for operational use.

### **Obsolete Document**

A superseded or retired document that is no longer approved for current use but is retained for archival purposes.

### **Periodic Review**

A scheduled assessment performed to confirm that a document remains accurate, current, and fit for purpose.

### **Revision**

A change to an approved document resulting in a new version.

## **5. Procedure**

### **5.1 Initiation**

The need for a new SOP or a revision to an existing SOP may arise from:

- new or changed processes;
- quality events, CAPAs, or audit observations;
- regulatory updates;
- organizational changes;
- process improvements;
- scheduled periodic review.

The initiating function shall notify the Document Owner or Quality Assurance and provide the rationale for the proposed document action.

### **5.2 Drafting**

The SOP Author shall prepare the document using the current approved SOP template.

The draft shall:

- use clear, precise, and unambiguous language;
- define purpose, scope, responsibilities, and procedural requirements;
- reflect actual approved practice;
- avoid duplication of requirements already governed elsewhere unless cross-reference is necessary;
- include linked forms, records, templates, or work instructions where relevant.

SOPs shall be written in a way that supports consistent execution by trained personnel.

### **5.3 Functional Review**

The draft SOP shall be reviewed by appropriate subject matter experts and impacted functions.

The review shall confirm:

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- technical and scientific accuracy;
- operational practicality;
- consistency with related procedures;
- alignment with assigned responsibilities;
- suitability for the intended use.

The SOP Author shall incorporate agreed comments and revise the draft as necessary.

## **5.4 Quality Review**

Quality Assurance shall review the revised draft for:

- compliance with document structure and formatting standards;
- clarity and readability;
- consistency of terminology;
- alignment with QMS requirements;
- adequacy of document-control elements.

QA may return the draft for correction before approval if deficiencies are identified.

## **5.5 Approval**

After completion of review, the SOP shall be submitted for formal approval by the designated approver(s).

The approved SOP shall include, at minimum:

- document title;
- document number;
- version number;
- effective date;
- approval identification.

No SOP shall be issued for operational use prior to approval.

## **5.6 Issuance and Distribution**

Following approval, Document Control shall issue the SOP through the approved document management process.

Document Control shall ensure that:

- only the current approved version is available for routine use;
- superseded versions are withdrawn from active circulation;
- archived versions remain protected and traceable;
- document status is clearly indicated.

Any printed or exported copy shall be considered uncontrolled unless specifically managed as a controlled copy.

## **5.7 Training and Implementation**

The Document Owner, in coordination with QA and line management where appropriate, shall determine whether training is required before the SOP becomes effective.

Where training is required:

- affected personnel shall complete training before or by the effective date;
- training completion shall be documented;
- implementation shall occur only when the organization is operationally ready.

The effective date shall allow sufficient time for training and implementation planning.

## **5.8 Periodic Review**

Each SOP shall be reviewed at a defined interval or sooner if triggered by material process, quality, regulatory, or organizational change.

Periodic review shall confirm whether the SOP:

- remains accurate and current;
- reflects actual practice;
- remains fit for purpose;
- requires revision, continuation without change, or retirement.

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The review outcome shall be documented in accordance with document-control requirements.

## **5.9 Revision**

Where revision is required, the SOP shall be updated through the same controlled process used for initial approval.

The revised document shall:

- receive a new version number;
- identify the effective date;
- record the reason for change or revision summary, where applicable.

Retraining shall be conducted when revisions affect responsibilities, critical steps, compliance expectations, or system use.

## **5.10 Retirement and Archival**

When an SOP is no longer required, it shall be formally retired.

Retired SOPs shall be:

- marked as obsolete or inactive;
- removed from current operational access;
- archived in accordance with applicable retention requirements.

Archived copies shall remain legible, traceable, and protected from unauthorized modification.

# **6. Document Writing Principles**

MASINOVA SOPs should be written according to the following principles:

- Write for execution, not decoration.
- Use precise and direct language.
- Assign responsibilities clearly.

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- Keep scope aligned to the procedure purpose.
- Avoid vague wording such as “as needed” unless criteria are defined.
- Use consistent terminology throughout the document.
- Ensure the procedure reflects the actual controlled process.
- Review for readability before approval.

## 7. References

This SOP should be read together with applicable internal procedures governing:

- document control;
- training management;
- record retention;
- change control;
- quality system governance.

Applicable external standards and expectations may include GxP principles and relevant regulatory quality-system expectations, as appropriate to the document context.

## 8. Records

Records generated through execution of this procedure may include:

- SOP draft and review history;
- approval records;
- training records;
- periodic review records;
- revision history;
- archival records.

All records shall be retained in accordance with the applicable record-retention requirements.

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## **9. Attachments**

**Attachment 1:** SOP Template

**Attachment 2:** SOP Review Checklist

**Attachment 3:** Training Acknowledgement Record

**Attachment 4:** Periodic Review Form

**Attachment 5:** Revision History Log