TITLE: Standard Operating Procedures	SOP NUMBER: SOP-0102	EFFECTIVE DATE:	PAGE 1 of 7

APPROVAL BLOCK

APPROVALS	TITLE	SIGNATURE/DATE
Prepared By:		
Reviewed By:		
Approved By:		

1. PURPOSE

The purpose of this procedure is to outline the process for creation (content and format), and approval of Standard Operating Procedures (SOPs).

2. SCOPE

This procedure applies to SOPs written or revised following the effective date of this procedure.

The Quality System is designed to support manufacturing of APIs, drug products, clinical trial materials, dietary supplements, medical devices and other products that are regulated by Good Manufacturing Practices.

Sponsors, Vendors and Manufacturers are responsible for complying with this SOP is used except that Vendors or Manufacturers shall use their quality system management, document management, training, equipment, facility, safety, material handling and labeling, and shipping SOPs.

3. RESPONSIBILITIES

3.1. Initiators are responsible for the creation of the draft procedure using the appropriate template and routing the SOP and/or Working Instruction for review.

3.2. Management is responsible for the review and approval of, employee training on and adherence to SOPs (and any related cGMP Forms & Templates).

3.3. Quality Manager (QADC) is responsible for assuring that the review, approval, setting of effective dates and retirement dates of all the SOPs and Working Instructions as well as associated cGMP Form(s) and cGMP Template(s) is performed.

3.4. Quality Manager (QADC) and department heads are responsible for managing the periodic review of SOPs and Working Instructions and ensuring that only up-to date procedures are accessible to/in use by operators and that paper copies were dated at the time of printing and used before expire one month later.

4. REFERENCES

POL-0122 – Written Procedures Policy

SOP-0103 – Document Management System

SOP-0104 – Change Control

5. BUSINESS REQUIREMENTS

5.1. SOPs will use the following naming conventions and format for content:

5.1.1. For document file names: SOP-XXXX-abbreviated title Header – Title, Document Number and Revision Number. Font will be Arial 12pt. For SOP titles inside the header: SOP-XXXX.YY where XXXX is the sequential number of the policy and YY is the sequential version number.

5.1.2. Purpose – Provides more detail on what the procedure will cover, expanding upon the title.

5.1.3. Scope – Describes to whom and what the procedure applies and any limits of this application.

5.1.4. Responsibilities – Identifies the personnel role responsible for ensuring the procedure reflects the current practice. Describes who is responsible for the performance of the procedure and states that training on the procedure is necessary before performing described actions. Describes other specific responsibilities that are most critical to the performance of the procedure, when appropriate.

5.1.5. References – Identifies any policies, procedures, work instructions or regulations that may require cross-referencing while performing the procedure.

5.1.6. Business Requirements – Describes information that broadly applies to the procedure. If there is not general information that pertains to the procedure, this section can be left out. Use active tense.

5.1.7. Procedure – Describes clearly and unambiguously in block format what to do in a chronological manner or document a systematic approach for following the SOP or Work Instruction. Details a workflow that can yields reproducible results. Identifies functional titles of personnel responsible for performing tasks. Use command statements (e.g. “Discuss details with the Quality Manager; Finalize the Quality Agreement; Approve the SOP”).

5.1.8. Definitions/Acronyms – Identifies and defines any words or acronyms that require clarity within the procedure.

5.1.9. Forms – Related forms necessary for performing the actions outlined in the procedure should be attached to the SOP and labeled as such with cross reference to the SOP apparent in the title or number.

For Form Titles the following conventions will be applied:

For Form titles inside the header: abbreviated title

For SOP Form file names: SOP-XXXX-abbreviated title- Form

5.1.10. Version History – Summarizes the revision history of the procedure. If the procedure replaces another SOP, note it in the "Description of Change" section.

5.2. Review of SOPs and Working Instructions:

5.2.1. SOPs will be managed and reviewed by Quality biennially (every two years) from the end of the calendar month that the latest revision was placed in effect, or sooner if necessary.

Note: Any Forms and/or Templates associated with the SOPs will be evaluated for review at the same time.

5.2.2. Working Instructions will be managed by each department that initiated them.

6. PROCEDURE

Responsible Party	Action Step
	Creation and Routing of an SOP and/or Working Instruction
PM (Initiator/Department manager of affected department)	1. Request SOP number assignment based on proposed purpose and scope from QM (QADC)
QM (QA/ Document Control Manager)	2. Determine if the procedure is warranted and, if so, assign a number as outlined in business requirements.
	3. Notify the Initiator of the number and provide proper template.
PM (Initiator/Department manager of affected department)	4. Draft the procedure following the guidelines in the Business Requirements Section, after obtaining input from key personnel impacted by the procedure. 5. Route the draft SOP for comments to all personnel impacted by the procedure. Always include the Document Control Manager, the Quality Manager, and the Departmental Head in the route.

Responsible Party	Action Step
PM (Department Head)	6. Review and comment on the SOP.
QM (Quality Manager)	7. Review and comment on the SOP.
PM (Initiator/Department manager of affected department)	8. Once the draft has been reviewed by affected personnel and is ready for approval, sign and date as the author.
	9. Route to Quality Manager (or designee).
QM (Quality Manager)	10. Signs on document or routes for necessary edits.
	Revising and Routing of an SOP and/or Working Instruction
PM (Initiator/Department manager of affected department)	11. Submit a request to change an SOP to the Quality Department with *SOP-0104-Change Control-Form.*
QM (QADC)	12. Creates new version of document according to SOP-0103 Document Management System and routes new version to initiator.
PM (Initiator/Department manager of affected department)	13. Edit word document with necessary changes. 14. Route the draft SOP for comments to affected personnel. Always include Quality and management in the route.
QM (Quality Manager)	15. Approve document or route for necessary edits.
	Approval follow up of first or updated version of SOP and/or Working Instruction
PM (Affected Department Management)	16. Determine if a formal training session is required. 17. Select an effective date. 18. Select the individuals that require training and facilitate training.

Responsible Party	Action Step
QM (QADC/ Training)	19. Obtain training documentation of affected employees. 20. Save the new signed version with effective date in active folder and move the superseded document to the archive folder. 21. Follow SOP- 3103 Document Management System to a. file document and b. control superseded version and c. create and file a new working copy of the document.

7. DEFINITIONS/ACRONYMS

7.1. cGMP – Current Good Laboratory Practices, Good Manufacturing Practices and Good Clinical Practices.

7.2. cGMP Form – Controlled document Forms incorporating GxP's. The general structure of the document should not be altered.

7.3. cGMP Template – Controlled document Templates incorporating GxP's The general structure of the document can be altered with pertinent information.

7.4. QADC – Quality Assurance Document Control

8. FORMS

N/A

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VERSION HISTORY

VERSION	EFFECTIVE DATE	DESCRIPTION OF CHANGE
00		New SOP