TITLE: Standard Operating Procedures	SOP NUMBER: SOP-0102.02	EFFECTIVE DATE:	PAGE 1 of 6

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 creating (content and format), and managing (approval, circulation, distribution and storage) 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 preclinical products, clinical trial materials and other products that are regulated by Good Manufacturing Practices only when an instance of InstantGMP™ is used for manufacturing.

Sponsors, Vendors and Manufacturers are responsible for complying with this SOP when an instance of InstantGMP™ is used except that Sponsors, Vendors or Manufacturers shall use their quality system management,

document management, training, equipment, facility, safety, material handling and labeling, and shipping SOPs.

3. REPONSIBILITIES

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. Quality Assurance Management is responsible for ensuring that the review, approval and management of the training program for all SOPs, Working Instructions and associated cGxP Form(s) and cGxP Template(s) is performed.

3.3. Department Heads are responsible for the review and approval of SOPs (and any related cGxP Forms & Templates) that affect their departmental area and the Working Instructions (and any related cGxP Forms & Templates) that apply to their specific department.

3.4. Document Control Manager is responsible for the review, approval, setting the effective dates, setting retirement dates and training program for all the SOPs and Working Instructions. Document Control is also responsible for managing the biennial review of SOPs and Working Instructions.

4. REFERENCES

N/A

5. BUSINESS REQUIREMENTS

5.1. SOP and Working Instruction Content:

5.1.1. Header – Title, Document Number and Revision Number. Font will be Arial 12pt.

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

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

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

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

5.1.6. Business Requirements – Describe 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 – Describe in block format what to do in a chronological manner or document a systematic approach for following the SOP or Work Instruction. Identify 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 – Identify and define any words or acronyms that require clarity within the procedure.

5.1.9. Forms

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

5.2. Printed procedure will have a watermark identifying the date and expiration of the printed copy.

5.3. Review of SOPs and Working Instructions:

5.3.1. 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.

5.3.2. Working Instructions will be managed by each department biennially (every two years) from the end of the calendar month that the latest revision was placed in effect.

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

6. PROCEDURE

Responsible Party	Action Step
	Creation and Routing of an SOP and/or Working Instruction
Initiator	1. Draft the procedure following the guidelines in the Business Requirements Section, after obtaining input from key personnel impacted by the procedure.
Document Control Manager	2. Determine if the procedure is warranted and, if so, assign a number.
	3. Notify the Initiator of the number.
Initiator	4. 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.
Department Head	5. Review and comment on the SOP.
Quality Manager	6. Review and comment on the SOP.
Initiator	7. Once the draft has been reviewed by affected personnel and is ready for approval;

Responsible Party	Action Step
	sign and date as the author.
	8. Obtain the approval signatures of the Quality Manager and Department Head (or delegate).
	Revising and Routing of an SOP and/or Working Instruction
Initiator	9. Submit a request to change an SOP to the Quality Department through the applicable change procedure.
	10. Incorporate the updates to the SOP and/or Working Instruction revision of the word document.
	11. Route the draft SOP for comments to affected personnel. Always include the Quality Manager, Document Control Manager and the Departmental Head in the route.
	Approving an SOP and/or Working Instruction
Department Head	12. Approve the procedure.
	13. Select the individuals that require training on the procedure and notify the Document Control Manager.
	14. Determine if a formal training session is required.
Quality Manager	15. Approve the procedure.
Document Control Manager	16. If required, set up a training session for the procedure(s) and notify the trainees.
	17. Set the effective date for the procedure(s). In general, allow two weeks so that training can occur. Each employee, associate or user must be trained before they can use the System or use the SOP.

7. DEFINITIONS/ACRONYMS

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

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

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

7.4. Working Instruction – Step by step instructions of how to complete a task within the procedure for a specific situation. For example, a procedure step may say to "route the SOP for approval by Department Heads and Quality". The working instruction will give step by step instructions on how to do that in a particular document management system.

8. FORMS

N/A

VERSION HISTORY

VERSION	EFFECTIVE DATE	DESCRIPTION OF CHANGE
00		New SOP