TITLE: Document Management System	POLICY NUMBER: SOP-0103.00	EFFECTIVE DATE:	PAGE 1 of 8

APPROVAL BLOCK

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

1. PURPOSE

This procedure describes the activities necessary to control and file cGMP documents used and generated at the InstantGMP™ Manufacturing Site.

2. SCOPE

This procedure applies to electronic and hard copy cGMP documents at the InstantGMP™ Manufacturing Site. It applies to all personnel assigned to work in the InstantGMP™ Manufacturing Site.

Sponsors, vendors and manufacturers are responsible for complying with this SOP when an instance of InstantGMP™ is used for manufacturing, except that Sponsors, vendors or manufacturers may use their document management system if available. Responsibilities will be defined in a Quality Agreement.

3. REPONSIBILITIES

3.1. The Quality Manager is responsible to assure this procedure is followed, remains consistent with current practices and is reviewed and updated as necessary.

4. REFERENCES

4.1. POL-0500 – Document Storage Policy

4.2. SOP-0104 – Change Control

4.3. SOP-0221 – Documentation Practices

5. BUSINESS REQUIREMENTS

5.1. Official copies of all documents will be electronic copies. Paper copies will be dated at the time of printing and expire one month later.

5.2. Controlled Documents are defined as those documents that fall under the Change Control system.

6. PROCEDURE

Responsible Party	Action Step
	Controlled Documents and Forms (SOP, MPR, Policies, Clinical Shipping Forms)
User	1. If a hard copy of an executed form or document is required: a. Print from the appropriate Master file. b. Stamp as “COPY”. c. Initial and date. NOTE: the copy is only good for one month.
	2. If creating a new controlled document follow the appropriate SOP.
	3. If revising a controlled document: a. Make a copy from the Working Copy folder and revise according to SOP-0104, *Change Control* and the appropriate SOP.

Responsible Party	Action Step
	4. Place the final reviewed version in the electronic Final Revision folder Notify the Document Manager that the document is in the Final Revision folder.
Project Manager	5. When a controlled document has been placed in the Final Revision folder: a. Designate as “read only”. b. Compare the new electronic version with the previous version (if not new) and ensure that the changes correspond to the appropriate approved change control form. Ensure that any changes are documented in the change history. c. Ensure that new documents correspond to the approved new document form. d. If a form or guide is included in the original document, create an identical interactive form/ guide locking the information on the form where it cannot be changed.
	6. When the document has been checked and is ready for signatures a. Assign an effective date as indicated by Quality Manager. b. Convert the Word Document to a PDF file. c. Move the PDF file and any interactive form/guides to the Signature folder.
Quality Manager	7. Ensure that the form/guide in the form/guide folder corresponds to the form/guide in the document.
	8. Sign and date the approval page approving both the form/guide and the SOP document.
Project Manager	9. When approval signatures are on the document: a. Move any forms/guides to the SOP - Finals Folder within the SOP folder and then file per POL-0500, *Document Storage Policy*. b. Ensure that only the effective version is available for use. Place the superseded version in the Archive folder.

	Maintaining Logs
Project Manager	10. Create logs in the appropriate vault in Master Control.
	11. When a number is requested, ensure that the number given is the next in sequence.
	Filing Executed Documents and ancillary information
Project Manager	12. Scan document into PDF file and place in appropriate “read only” file using Attachment II as a guide. In general, file documents specific to a part number, Equipment, number or room number in the folders with those numbers. If document applies to more than one part#, equipment #, or room #, file in specific SOP # folders. Equipment and Facility Manuals should be filed according to S405 Equipment Receipt and System Manuals. NOTE: If a Study is blinded, do not open sealed envelopes before filing.
	Filing Quality Agreements
	13. File Quality Agreements in accordance with the site’s document storage policy.
	Filing Training Records
	14. File Training Records in accordance with the site’s document storage policy.
	Filing Regulatory or Client Inspection Reports
	15. File Inspection Reports in accordance with the site’s document storage policy.
	Filing Deviation Reports
	16. File Deviation Reports in accordance with the site’s document storage policy.
	Filing Document Review Forms

	17. File Document Review Forms in accordance with the site's document storage policy.
	Filing Batch Specific Information
	18. File Batch Information that is not electronically stored in an instance of InstantGMP in accordance with the site's document storage policy.
	Filing Part Number Specific Information
	19. File Part Number specific Information that is not electronically stored in an instance of InstantGMP in accordance with the site's document storage policy.

7. DEFINITIONS/ACRONYMS

N/A

8. FORMS

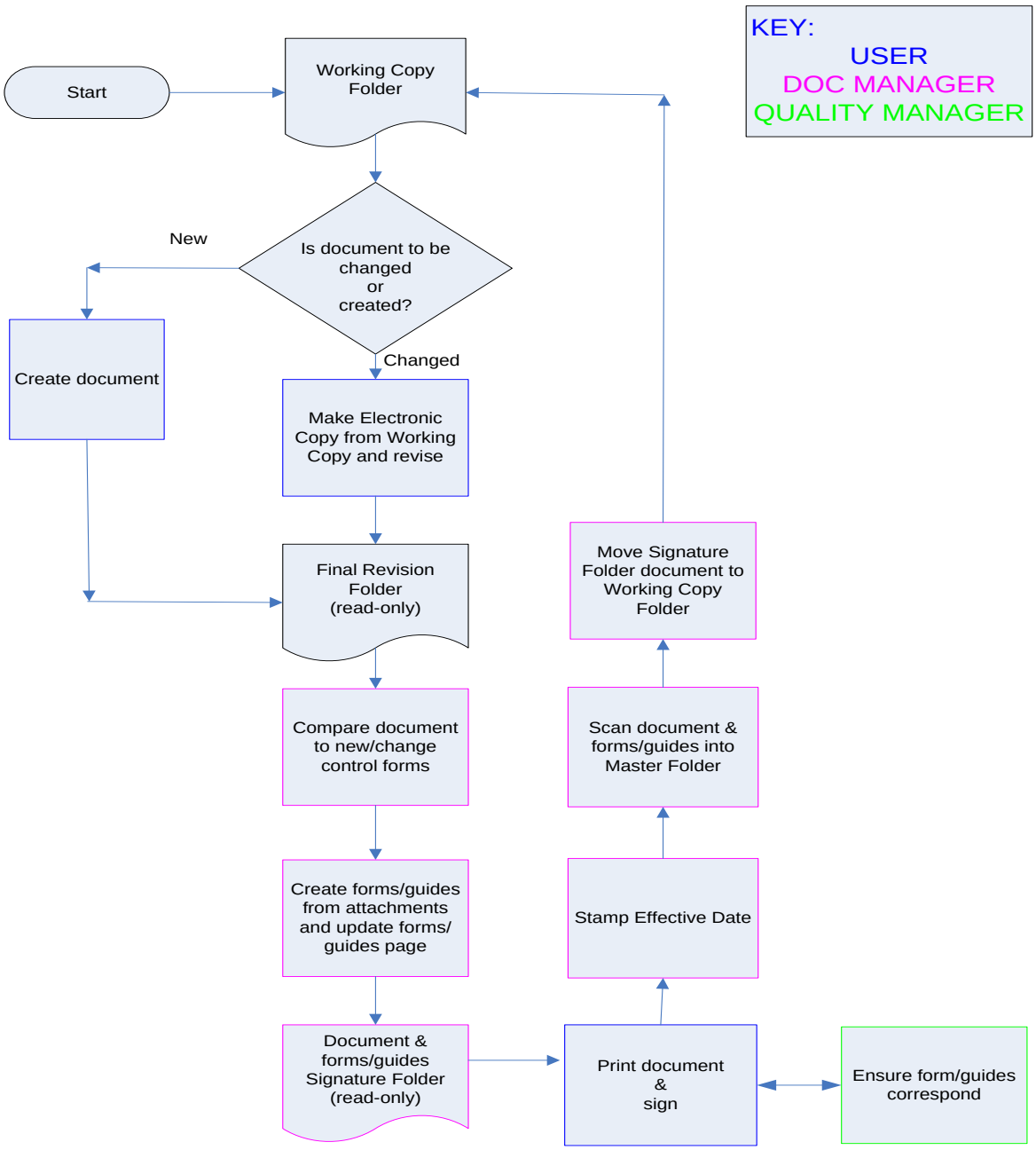
8.1. Attachment I: Flow Chart for Controlled Documents

8.2. Attachment II: Filing Guide

VERSION HISTORY

VERSION	EFFECTIVE DATE	DESCRIPTION OF CHANGE
00		New SOP.

Attachment I: Flow Chart for Controlled Documents



Attachment II: Filing Guide

Master File	(Level 1)	(Level 2)
SOP	Table of Contents	
	Individual SOP	
		Master
		Working Copy
		Final Revision
		Information specific to each SOP
Signature	SOP's	
	Policy's	
	Specifications	
Logs	CAPA Log	
	Change Control Log	
	Deviation/Inspection Log	
	SAE Log	
Policies	Table of Contents	
	Individual Policies	Master
		Working Copy
		Final Revision
Part #	Specifications	Master
		Working Copy
		Final Revision
	MPR	Master
		Working Copy
		Final Revision
	Vendor Qualification	
	Receiv./ Batch Number	C of A/ C of C
		Test/ inspection results
		Shipping info
		Material request info
		Inventory control &rec.
		Disposition

Master File	(Level 1)	(Level 2)
Equipment #	Protocols	
	Work order/calibration documents	
Room #	Protocols	
	Work order/calibration documents	
Project #	Project related info	