

TITLE: Electronic Document Management	POLICY NUMBER: SOP-0116	PAGE 1 of 3
--	----------------------------	-------------

1. PURPOSE

This procedure describes the activities necessary to update and control documents in the InstantGMP electronic Document Management System (eDMS).

2. SCOPE

This procedure applies to all controlled documents and corresponding forms and templates.

RESPONSIBILITIES

- 2.1. The Document Manager will maintain a Master Table of Contents for Controlled Documents.
- 2.2. The Document Manager will generate and manage controlled document records in the eDMS.
- 2.3. The Quality Assurance Unit is responsible to assure this procedure is followed, remains consistent with current practices and is reviewed and updated as necessary.

3. REFERENCES

- 3.1. N/A

4. BUSINESS REQUIREMENTS

- 4.1. Official copies of all controlled documents will be electronic copies.
- 4.2. Controlled Documents are defined as those documents that are managed by this Change Control Document:
- 4.3. For Policy, SOP and Working Instruction documents the following naming conventions will be applied:

Document Type	Code
Policy	POL

TITLE: Electronic Document Management	POLICY NUMBER: SOP-0116	PAGE 2 of 3
--	----------------------------	-------------

Standard Operating Procedure	SOP
Template	TMPL
Working Instructions	WKI

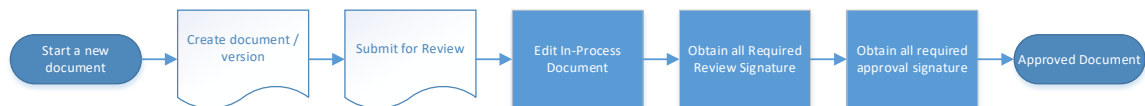
- DMS Document ID: SSS-TTT where SSS = Code, TTTT is the number assigned in the Master Table of Contents, e.g. POL-0100.
- DMS Document Title: SSS-TTTT-Title of Document where SSS=Code and TTTT is the assigned number e.g. POL-0100-General Policies.
- Title inside document header: Title of document, e.g. General Policies.
- Document ID inside document header: Same as DMS Document ID.
- Document File Name: Same as DMS Document Title.

4.4. For Training document the following naming conventions will be applied:

Document Type	Code
Training	TRN

- DMS Document ID: SSS-TTT-Y.YYY.ZZZ where SSS = Code, TTTT is the number assigned in the Master Table of Contents, Y.YYY is the software version and ZZZ is the build number, e.g. TRN-1000-3.000.000.
- DMS Document Title: SSS-TTTT-Title of Document where SSS=Code and TTTT is the assigned number e.g. TRN-1000-Orientation Slides.
- Title inside document header: Title of document, e.g. Orientation Slides.
- Document ID inside document header: Same as DMS Document ID.
- Document File Name: Same as DMS Document Title.

5. PROCEDURE



Responsible Party	Action Step
Requestor	1) Contact the Document Manager and request a new document record be started.
	2) Provide the Title, and Document ID and list of approvers.

TITLE: Electronic Document Management	POLICY NUMBER: SOP-0116	PAGE 3 of 3
--	----------------------------	-------------

Responsible Party	Action Step
Document Manager	3) Generate new document record in eDMS. 4) Use the naming conventions in the Business Requirements to name the documents and files. 5) If Word Document, turn on "Track Changes". 6) Upload the document file. 7) Enter the document name. 8) Identify Approvers and titles. 9) Sign the record. 10) Submit for Review.
Reviewers	11) Edit word documents with "Track Changes" on. 12) Use the ADD CHANGES function to record the changes made in a document. 13) Add Comment indicating that your editing is completed. 14) Sign on the Submit for Review tab when completed
	15) When all reviewers have signed the system will automatically "Submit for Approval" and send e-mail notifications to all Approvers
Approvers	16) Sign on Approval tab.
	17) When all approvers have signed, the system will automatically lock the document and show the status as "Approved".

6. DEFINITIONS/ACRONYMS

n/a

7. FORMS

n/a