1. PURPOSE

This procedure describes the activities necessary to update and controlled documents in the InstantQMS (iQMS) Electronic Quality Management System.

2. SCOPE

2.1. This procedure applies to all Company controlled documents including but not limited to:

- Standard Operating Procedures (SOPs)
- Policies
- Forms
- Templates
- Reports
- Protocols
- Study Plans
- Study Protocols
- Stability Protocols
- Specifications
- Testing Methods
- Quality Manual
- Technical Reports and Memos
- Audit Reports
- Incident Reports
- Change Requests
- Work Instructions
- Material safety data sheets
- Investigator Brochure

that comprise the Company Quality Management System maintained in the iQMS.

3. RESPONSIBILITIES

3.1. The Document Manager will maintain a Master Table of Contents for Controlled Documents in the iQMS.

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

4. REFERENCES

4.1. SOP-002 Standard Operating Procedures

4.2. SOP-019 Change Control

4.3. WKI-005 Use of Document Management System

5. BUSINESS REQUIREMENTS

5.1. Official copies of all controlled documents will be electronic copies.

5.2. For controlled documents, the following naming conventions will be applied:

Document ID	Code
Standard Operating Procedures (SOPs)	SOP
Policies	POL
Forms	SOP xxx Fy
Templates	TMPL
Reports	REP
Protocols	PRO
Study Plans	SPL
Study Protocols	SPR
Stability Protocols	STP
Specifications	SPC

Testing Methods	TES
Quality Manual	QMA
Technical Reports and Memos	TRM
Audit Reports	ART
Incident Reports	IRT
Change Requests	CRQ
Material Safety Data Sheets	MSDS
Work Instructions	WKI
Training	TRN

5.3. Document Classification and Document Type are used to provide a Document Number. Document Classification and Type are established in the iQMS setup process and will automatically create the Document Number based on the abbreviations that are supplied. Refer to WKI-005.

5.4. Management of Controlled documents

5.4.1. Document Identification: Refer to SOP 002 Standard Operation Procedure

5.4.2. Electronic Copy Control (document dependent):

5.4.2.1. Maintained in the iQMS Document Management System (DMS)

5.4.2.2. DMS will convert Word docs to PDF and retain original Word file.

5.4.2.3. Forms and Template should not be converted to PDF.

5.4.3. Control of Superseded Documents-Archiving

5.4.3.1. Changes are tracked by:

5.4.3.1.1. Archive of original superseded documents are stored in Document Management System. The document is retained per section 5.4.5. Record Retention.

5.4.4. External Documents:

5.4.4.1. External documents received are provided to Quality for input into a change control log. A Document Change Request (DCR) is not required for the external document to be entered into the electronic document management system.

5.4.4.2. Examples include calibration certificates, specifications, an international standard that may be used or referenced.

5.4.4.3. External documents that are superseded by another revision are removed from distribution. Documents are stored in a hidden state in the Document Management System.

5.4.5. Document and Records Retention

5.4.5.1. The storage locations and retention periods of all controlled documents and records.

5.4.5.2. All records shall be retained for a period of time equivalent to the design and expected life of product/device, but in no case less than 2 years from date of release for commercial distribution by the manufacturer.

5.4.5.3. Trial related records should be stored for 2 years after approval of the investigation drug by FDA or for 2 years after the study is discontinued and FDA is notified.

5.4.5.4. Sponsor specific essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical trials.

5.4.5.4.1. IRB/EC records must be retained for at least 3 years after the completion of research.

5.4.6. DMS Document(s) – The document may have been replaced by another document or is no longer applicable or in use. Documents in the DMS can be superseded (new version approved), Rejected or Hidden.

5.4.6.1. Documents are removed from all points of use and otherwise prevented from unintended use and are stored in a hidden state in the Document Management System.

6. PROCEDURE

Responsible Party	Action Step
Document Change Request: New Document	
Requestor	1. Contact the Document Manager and request a new document record to be initiated.
	2. Provide the Title, and Document ID and list of reviewers and approvers.
Document Manager	3. Generate new document record in iQMS. 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 Reviewers, 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. Review document. Prior to approval, turn off “Track Changes”. 17. Sign on Approval tab.

Responsible Party	Action Step
	18. When all approvers have signed, the system will automatically lock the document and show the status as “Approved”.
Document Change Request: Document Revision	
Initiator	19. Contact the Document Manager and request the document record requiring revision. 20. Open a Change Control Log record for the document and identify all the actions required which are associated with the revision of an existing SOP. 21. Check for the following: a. If there are associated forms b. If other SOPs or forms impacted by the change (1) Initiate change to SOPs/forms as required and route through the review and approval process c. If a template update is required d. If update to training curricula is required
Document Manager	22. On request create new version of document record in iQMS. 23. Retrieve document file that supersedes current version. a. If a PDF file is versioned up, the Word Document must be retrieved from the most recent superseded version and uploaded to the new revision b. If Word Document, turn on “Track Changes”. 24. Upload the document file. 25. Identify Reviewers, Approvers, and Titles. 26. Sign the record. 27. Submit for review. 28. Monitor document to ensure reviewers complete review in a timely manner.
Initiator	29. Include proposed updates to the controlled document using track changes in word and forward to the Document Manager for upload and review. a. Add comment indicating that your editing is completed. 30. Sign on the Submit for Review tab when completed.
Reviewers	Follow steps 11 thru 15.

Responsible Party	Action Step
Approvers	Follow steps 16 thru 18.

7. DEFINITIONS/ACRONYMS

7.1. iQMS – InstantQMS: an electronic quality management system for managing document release, changes, and storage of documents.

7.2. Quality Controlled Document – Any written or electronic document that is traceable and formally maintained and updated through a review process

7.3. Tracked (Changes) - Reviewing procedure that can be enabled within the Microsoft Word program to enable the visualization of changes being made within a document.

7.4. SOP - Standard Operating Procedure is a controlled document which details, instructions to achieve uniformity of the performance of a specific function. The procedure should describe required actions in a step by step manner utilizing an outline format and focusing on methods, performance, and accountability. Deviations from these procedures must be documented.

7.5. Controlled - A document that is maintained and updated. Controlled documents are formally approved, and their distribution is traceable to enable changes to be executed.

7.6. Archived - Process of storing a superseded document or retired document within a restricted folder.

7.7. External Document - A document of external origin that provides information or direction for the performance of activities within the scope of the quality management system.

7.8. Document Change Request (DCR) - Request by an author or user of a document submitted to QA.

7.9. Regulatory Forms - Forms used to document processes described in the SOP (e.g. report forms, templates, logs, etc.)

7.10. Effective Date - Date assigned when the newly approved document becomes effective in the Document Control System (training should be completed within the specified period after this date).

7.11. Change Request (CRQ) - Request by an author or user of a document submitted to QA

8. FORMS/ATTACHMENTS

N/A