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1. Purpose

The purpose of this procedure is to ensure that GxP documents and records are appropriately created, captured, accessed, managed, and stored in a manner that reflects the business, corporate, and regulatory compliance requirements.

2. Scope

This procedure applies to all company ***GxP*** documentation and records. In more detail, the document control process applies to Policies, Manuals, Standard Operating Procedures, Job Aids, Templates and Supporting Documents (e.g. quality system controlled documents) that are governed by the QMS quality management system.

3. Roles and Responsibilities

Managing Director (most senior person)

- Ensuring the effective implementation of the document and records management system;
- Ensuring that appropriate resources are provided for the management of documents and records;
- Ensuring information, training and instruction is provided on the document and records management system; and
- The review and final approval of all GxP company documentation.

Document Controller Manager

- Oversee the daily operations of the document control process
- Update the document control process and procedural documents to maintain currency with best practices and requirements
- Manage controlled documents in accordance with approved procedures for document control
- Managing the document control and records management process;
- Checking the quality of documents;
- Ensuring documents are developed using correct styles and format;
- Maintaining the document register;
- Maintaining all GxP records;
- Ensuring that only approved current versions of documents are available for use; and
- Archiving of all obsolete documents and records.

Employees and Contractors

- Follow approved procedures for creating, revising, reviewing, approving, controlling, and accessing controlled documents
- Participate in the controlled document review and approval process.
- Obtaining documents from the approved location;
- Not making copies (uncontrolled documents) of documents; and
- Participating in reviews of documents as required.

Quality Assurance

- Establish and operate the Document Control System
- Function as the document owner for the Document Control policies, processes and procedures
- Participate in the controlled document review and approval process
- Establish and manage a system and procedures for managing controlled documents throughout the document lifecycle
- Maintain the quality record for the document control system in accordance with SOP Record Management

4. Definitions

Term	Definition
Author	The actual author of the document.
Controlled Document	Any GxP document for which distribution and status are required to be kept current to ensure authorized users have the most current version. A document that is reviewed and approved before use, version-controlled and has a life cycle.
Data	Information used to control the process that affects the final product (e.g. reference values, benchmarks).
Document Control	The process established in this procedure to define controls needed for the management of Quality Managementdocumentation.
Document Control Form	The Form used to create or change a document.
Document Control Number	The number assigned to a document when it is entered into the document register as a controlled document. This number will always be the next sequential number in the register. This number is to be recorded on the controlled document in the ***(e.g. top left corner of the header)***.
Document Control Register	A list that identifies all company GxP documents and includes current revision status.
EDMS	Electronic Document Management System (EDMS)

Uncontrolled Document	A copy of a controlled document. Uncontrolled documents may not be the latest version. Any copy of a controlled document that exists outside of the company document control management system. Examples include desk copies and copies that are transported away from the controlled source in any manner to any location.
Approved	The status of an item (e.g., controlled document, controlled record) that has been reviewed, found acceptable and documented as acceptable by all approvers.
Archive:	1.) A collection, usually of records, that is stored and maintained for historic reference. 2.) A lasting collection of system data or other records that are in long term storage.
Change Control	The process of identifying, documenting, verifying, reviewing and approving changes before their implementation.
Document Control System	The processes that govern the controlled document lifecycle.
Quality System Controlled Document (aka Quality System Document)	Controlled documents whose existence is mandated by the quality management system requirements. Typically, quality system controlled documents consist of policies, manuals, plans, standard operating procedures, work instructions, forms, and templates.
Record (aka Quality Record)	Any written or electronic documentation providing evidence that activities were performed and their results. Records include original documents, accurate reproductions of original documents, electronic data and files. Records do not exist until the activity has been performed.
Record Management	The policies and procedures that govern systematic control of all records from their creation, or receipt, through their processing, distribution, organization, storage, retrieval, retention and ultimate disposition.