

Standard Operating Procedure

SOP-IT-010: Document Template Standard

Document ID:	SOP-IT-010	Version:	1.0
Effective Date:	YYYY-MM-DD	Review Date:	YYYY-MM-DD

1. Purpose

This SOP establishes the standard template and formatting requirements for all FDA-regulated SOP documents.

2. Scope

This SOP applies to all Standard Operating Procedures, Work Instructions, Forms, and Appendices in the quality management system.

3. Required Document Sections

All SOPs must include:

- 1. Purpose - Why this SOP exists
- 2. Scope - What/who it applies to
- 3. Responsibilities - Who does what
- 4. Procedure - Step-by-step process
- 5. References - Related documents
- 6. Approvals - Signature table

4. Document Control Table

Every SOP must have header table with:

- Document ID (e.g., SOP-IT-001)
- Version number (e.g., 1.0, 1.1, 2.0)
- Effective Date (when approved and active)
- Review Date (annual review required)

5. Formatting Standards

- Font: Arial, 11pt body text
- Headings: Arial Bold, 14pt (H1), 12pt (H2)
- Margins: 1 inch all sides
- Page numbers: Footer, centered
- Tables: Borders visible, header row shaded

5. Approval Requirements

- **3-signature minimum: Author, Reviewer, Approver**
- Approver must be Quality Manager
- Electronic signatures via DocuSign Business Pro
- Signed PDF archived to SharePoint

6. Approvals

This document requires electronic signature approval via DocuSign (21 CFR Part 11 compliant).

Role	Name	Signature & Date
Author	[Name]	[DocuSign]
Reviewer (QA Lead)	[Name]	[DocuSign]
Approver (Quality Manager)	[Name]	[DocuSign]