

## **Standard Operating Procedure**

### **SOP-IT-010: Document Template Standard**

<b>Document ID:</b>	SOP-IT-010	<b>Version:</b>	1.0
<b>Effective Date:</b>	YYYY-MM-DD	<b>Review Date:</b>	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).

<b>Role</b>	<b>Name</b>	<b>Signature &amp; Date</b>
Author	[Name]	[DocuSign]
Reviewer (QA Lead)	[Name]	[DocuSign]
Approver (Quality Manager)	[Name]	[DocuSign]