

Standard Operating Procedure

SOP-106: Document Control

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1. Purpose

This procedure defines the Document Lifecycle using GitHub, Confluence, and SharePoint to ensure FDA compliance (21 CFR Part 11 and Part 820).

2. Three-System Approach

GitHub (Version Control & Audit Trail):

- All SOPs authored in Markdown format
- Immutable commit history with cryptographic signatures
- Pull Request workflow for document review

Confluence (Collaboration & Workflows):

- Auto-published from GitHub for team access
- Workflow management and review process
- DHF/DMR structure and organization

SharePoint (Final Regulatory Records):

- Signed and approved PDFs only
- Immutable archival with 7+ year retention
- 21 CFR Part 11 compliant e-signatures via DocuSign

3. Document Lifecycle

- Step 1: Draft in GitHub feature branch
- Step 2: Create Pull Request for review
- Step 3: Quality Manager approval → merge to main
- Step 4: Auto-publish to Confluence
- Step 5: Generate PDF and sign via DocuSign
- Step 6: Archive signed PDF to SharePoint

4. Critical Controls

- **Branch protection on main branch (no direct commits)**
- **Minimum 2 reviewers for document Pull Requests**

- Quality Manager must approve before merge
- Only signed PDFs stored in SharePoint
- SharePoint records are immutable after signing