Standard Operating Procedure

SOP-IT-001: Master IT Governance

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1. Purpose

This SOP establishes the overall IT governance framework for the organization, defining how IT systems support FDA-regulated medical device operations while maintaining compliance with 21 CFR Part 11 and Part 820.

2. Scope

This SOP applies to all IT systems, infrastructure, and personnel supporting medical device development, testing, and production.

3. IT Governance Structure

- **Quality Manager: Final approval for all IT changes affecting product quality**
- Development Lead: Technical architecture and development standards
- QA Lead: Independent validation and compliance verification
- SRE Lead: Infrastructure, security, and operational reliability

4. Core IT Processes

- Change Control (SOP-IT-002)
- Code & Commit Policy (SOP-IT-003)
- Document Control (SOP-IT-004)
- Incident Management (SOP-IT-005, SOP-IT-009)
- Training & Competency (SOP-IT-006)
- Access & Security (SOP-IT-007)
- Backup & DR (SOP-IT-008)

5. Critical Requirements

- **All IT systems must maintain audit trails (21 CFR Part 11)**
- **Electronic signatures required for critical approvals**
- **Segregation of Duties enforced across all processes**
- **Computer System Validation (CSV) for GxP systems**

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]
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