

Standard Operating Procedure

SOP-IT-006: Training & Competency

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1. Purpose

This SOP establishes training requirements and competency assessment for personnel working with FDA-regulated IT systems.

2. Scope

This SOP applies to all personnel requiring access to GxP-critical IT systems and processes.

3. Training Requirements

Initial Training (all personnel):

- 21 CFR Part 11 overview
- Segregation of Duties (A-02)
- Document Control (SOP-IT-004)
- GitHub workflow (SOP-IT-003)

Role-Specific Training:

- Developers: Change Control (SOP-IT-002), Code Policy (SOP-IT-003)
- QA Lead: Validation, IQ/OQ/PQ procedures
- SRE: Backup & DR (SOP-IT-008), Incident Response (SOP-IT-009)

4. Competency Assessment

- Written test (80% pass score)
- Practical demonstration
- Annual recertification required
- Training records maintained 7+ years

5. Training Records

- **Stored in SharePoint Training Records library**
- Signed by trainer and trainee
- Accessible for FDA inspection

6. Approvals

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

Role	Name	Signature & Date
Author	[Name]	[DocuSign]
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