

## **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).

<b>Role</b>	<b>Name</b>	<b>Signature &amp; Date</b>
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