

Standard Operating Procedure

SOP-IT-005: Incident & Deviation Management

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1. Purpose

This SOP defines the process for managing incidents, deviations, and implementing Corrective and Preventive Actions (CAPA) in IT systems.

2. Scope

This SOP applies to all IT-related incidents and deviations that may affect product quality, data integrity, or regulatory compliance.

3. Incident Classification

Critical (P1):

- System down affecting production
- Data integrity compromise

High (P2):

- Significant functionality degraded

Medium (P3):

- Minor issues, workaround available

4. CAPA Process

- Step 1: Root cause analysis (5 Whys, Fishbone)
- Step 2: Corrective action implementation
- Step 3: Preventive measures deployment
- Step 4: Effectiveness verification
- Step 5: Documentation and closure

5. Documentation Requirements

- **All incidents logged in GitHub Issues**
- Critical incidents require CAPA report
- Quality Manager approval for closure

6. Approvals

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

Role	Name	Signature & Date
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