

Standard Operating Procedure

SOP-IT-008: Backup & Disaster Recovery

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1. Purpose

This SOP establishes backup procedures and disaster recovery protocols to ensure business continuity and data protection for FDA-regulated systems.

2. Scope

This SOP applies to all critical IT systems, databases, and data storage containing GxP-relevant information.

3. Backup Strategy

Database Backups:

- Full backup: Daily at 2 AM UTC
- Incremental backup: Every 6 hours
- Retention: 30 days recent, 7 years compliance data

Code & Documentation:

- GitHub: Automatic replication to secondary region
- SharePoint: Microsoft 365 built-in redundancy

Configuration & Infrastructure:

- Infrastructure as Code (IaC) in GitHub
- AWS snapshot policy: Daily with 30-day retention

4. Disaster Recovery

Recovery Time Objective (RTO):

- Critical systems: 4 hours
- Non-critical systems: 24 hours

Recovery Point Objective (RPO):

- Database: 6 hours (incremental backup interval)
- Code: Near-zero (GitHub replication)

5. Testing Requirements

- **Restore test: Monthly**

- **Full DR drill: Annually**
- Results documented and reviewed by Quality Manager

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] |
| Approver (Quality Manager) | [Name] | [DocuSign] |