



Synergy Upgrade Accelerator

Synergy Installation Qualification (IQ) Template for Validated Life Sciences Environments

1. Introduction

This Installation Qualification (IQ) documents the controlled installation and upgrade of the OpenText Content Server environment using the **Synergy Upgrade Accelerator**, a validated-environment-compatible upgrade mechanism designed to streamline and modernize Content Server deployments.

This IQ demonstrates that the installation and upgrade were performed in accordance with approved procedures, vendor documentation, and applicable regulatory expectations, including 21 CFR Part 11 and data integrity principles.

2. System Overview

- **System Name:** OpenText Content Server
- **Vendor:** OpenText
- **Upgrade Method:** Synergy Upgrade Accelerator
- **GxP Classification:** GAMP 5 Category 4/5
- **Intended Use:** Controlled document management, quality workflows, regulated records, R&D documentation, or other GxP-relevant processes.
- **Regulatory Context:** System operates within a validated environment supporting FDA-regulated activities.

3. Validation Strategy

This IQ is executed under an approved Change Control and follows the organization's Validation Plan (VP) or Validation Master Plan (VMP).

The upgrade has been assessed for risk and determined to be:

- **Infrastructure-impacting** (typical for Upgrade Accelerator use), or
- **Functionality-impacting** (if applicable, requiring expanded OQ/PQ testing).

The Synergy Upgrade Accelerator is used as a **controlled installation mechanism**, and its internal logic is not subject to customer validation. The customer validates the **outcome**, not the vendor's internal process.

4. Prerequisites

The following items must be approved and available before execution:

- Approved Change Control
- Synergy Upgrade Accelerator documentation
- OpenText release notes and installation guides
- Internal SOPs for installation, validation, and change management
- Verified system backups and restore procedures
- Validated test environment (if applicable)
- Required infrastructure (OS, DB, application servers, integrations)

5. Installation Activities

The following installation elements are verified as part of the IQ:

- Application binaries installed correctly
- Configuration files deployed and version-controlled
- Database schema version matches expected post-upgrade version
- System services installed, configured, and running
- Environment variables and paths validated
- Logging enabled and functional
- LDAP/AD, SMTP, and SSO integrations verified
- Time synchronization validated
- Backup/restore capability confirmed

These steps remain consistent whether using the standard OpenText upgrade method or the Synergy Upgrade Accelerator.

6. Use of Synergy Upgrade Accelerator

6.1 Description of Upgrade Method

The Synergy Upgrade Accelerator is a vendor-supported upgrade mechanism that enables controlled, efficient, and repeatable upgrades of OpenText Content Server, including single-hop and zero-downtime upgrade scenarios.

It replaces the standard OpenText Out-of-the-Box upgrade procedure and is executed under approved change control.

6.2 Customer Responsibilities

The customer is responsible for verifying that:

- The Upgrade Accelerator was executed according to Syntergy documentation
- The upgrade did not alter validated functionality
- Data integrity and audit trail continuity were maintained
- No required controls were bypassed
- The system remains in a validated state post-upgrade

6.3 Evidence Collected

The following evidence is typically included:

- Confirmation that the Upgrade Accelerator package is approved and version-controlled
- Execution logs or screenshots showing successful completion
- Pre- and post-upgrade version verification
- Confirmation of no data loss or corruption
- Confirmation that system availability was maintained (if zero-downtime was used)
- Review of Upgrade Accelerator logs for errors or warnings

6.4 IQ Test Steps Specific to Upgrade Accelerator

- Verify the presence and version of Syntergy Upgrade Accelerator
- Verify execution of the Upgrade Accelerator per vendor instructions
- Verify successful completion via logs or output
- Verify post-upgrade system version matches expected target
- Verify no critical errors or warnings in Upgrade Accelerator logs

These steps confirm controlled use of the upgrade method without validating the vendor's internal engineering.

7. Post-Installation Verification

The following items are verified to ensure the system is ready for OQ/PQ or return to validated use:

- Application launches without errors

- User authentication (LDAP/AD/SSO) functions correctly
- Audit trails remain intact
- Critical workflows perform as expected (high-level smoke test)
- Integrations operate normally
- Permissions and roles remain unchanged

8. Deviations

Any deviations encountered during installation or testing are documented, assessed for impact on the validated state, and resolved before approval.

9. Acceptance Criteria

- All IQ steps executed successfully
- No unresolved deviations
- Installation meets requirements to proceed to OQ/PQ or return to validated state
- Upgrade Accelerator execution confirmed and documented

10. Approval Signatures

- System Owner
- Quality Assurance / CSV
- IT Lead
- Syntergy Representative (optional)