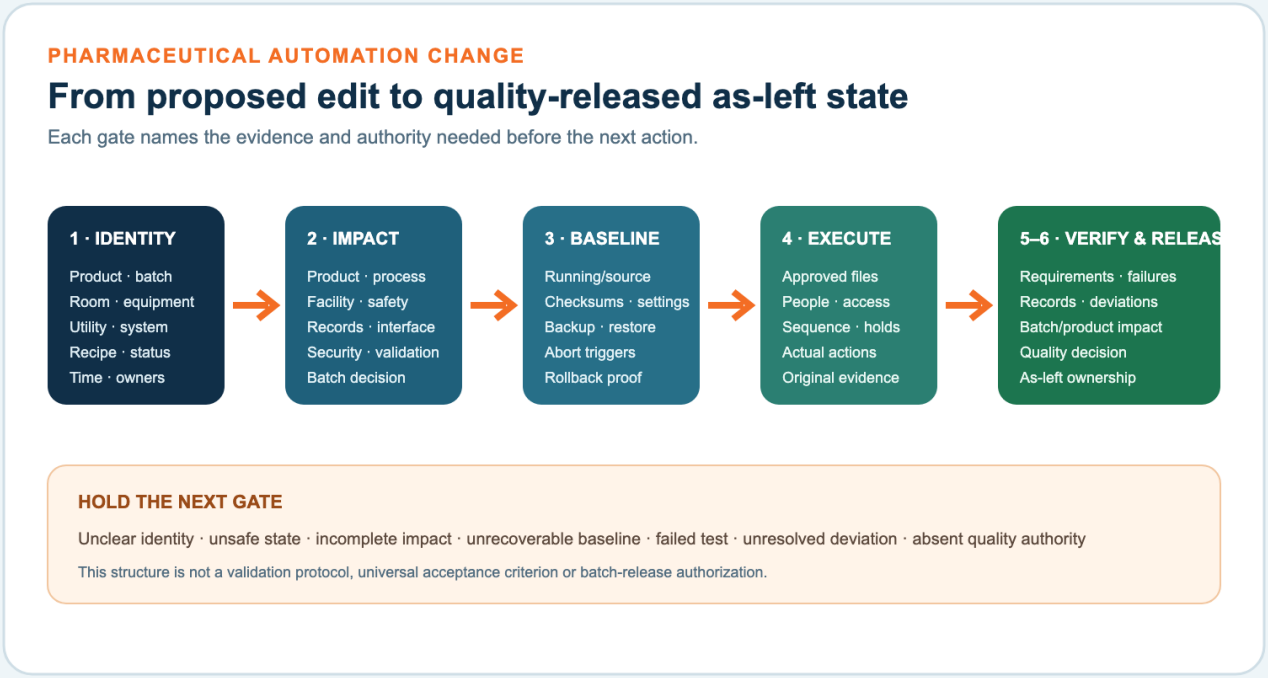
EN-GUIDE-07 | PHARMACEUTICAL AUTOMATION CHANGE

Pharmaceutical Automation Change Control: Impact, Validation, Rollback & Quality Release Evidence

A successful PLC download, SCADA edit, recipe revision or server change does not by itself prove validated operation or release a batch. Fix the operating identity, bound the full impact, protect the approved baseline, verify intended and unintended behavior, resolve deviations and hand over the exact quality-released as-left state.

Reviewed	23 July 2026	**Audience**	Process, automation, CSV, engineering and quality teams
System	PLC, HMI, SCADA, MES, recipes, alarms and infrastructure	**Output**	Approved as-left change and release package



Decision summary

A technically successful implementation is not a validated or quality-released change.
Fix identity, approve impact and requirements, protect the baseline and rollback, record actual execution, verify the required behaviors, control deviations and accept only the named as-left scope.

OBSERVABLE TRIGGERS

Open a controlled change boundary when any of these appear

- A PLC, HMI, SCADA, historian, MES interface, recipe, alarm, network, account, server or infrastructure revision is proposed.
- An online fix is requested while the affected product, batch, room, utility, record or quality boundary remains unclear.
- The running application, source project, approved version, backup and field state do not match.
- A vendor or cybersecurity update changes services, time, identity, authentication, logging, backup or recovery behavior.
- The test proves one intended function but omits interlocks, alarms, records, failure behavior, restart or rollback.
- Implementation completes while deviations, temporary modes, open items or quality release remain outside handover.

STOP-WORK CONDITIONS

Hold implementation or release whenever the evidence chain is incomplete

Identity unclear	Product, batch, room, equipment, utility, system, recipe, process step or owner cannot be fixed.
Safety open	Energy, contamination control, interlock, permit, access, automatic action or affected personnel is unresolved.
Baseline at risk	Approved source, running state, backup, restore proof, license, certificate, credential or data is missing.
Impact incomplete	Product, process, facility, record, interface, security, validation or batch impact is omitted.
Evidence threatened	Original audit trails, electronic records, events, trends, configuration or time provenance may be overwritten.
Authority absent	A failed test, deviation, temporary state, rollback decision or named quality approval is open.

Stop means preserve and escalate

Maintain the approved safe and GMP state, protect original evidence and return the decision to the named site authority. This guide does not authorize online edits, bypasses, access, validation approval or batch release.

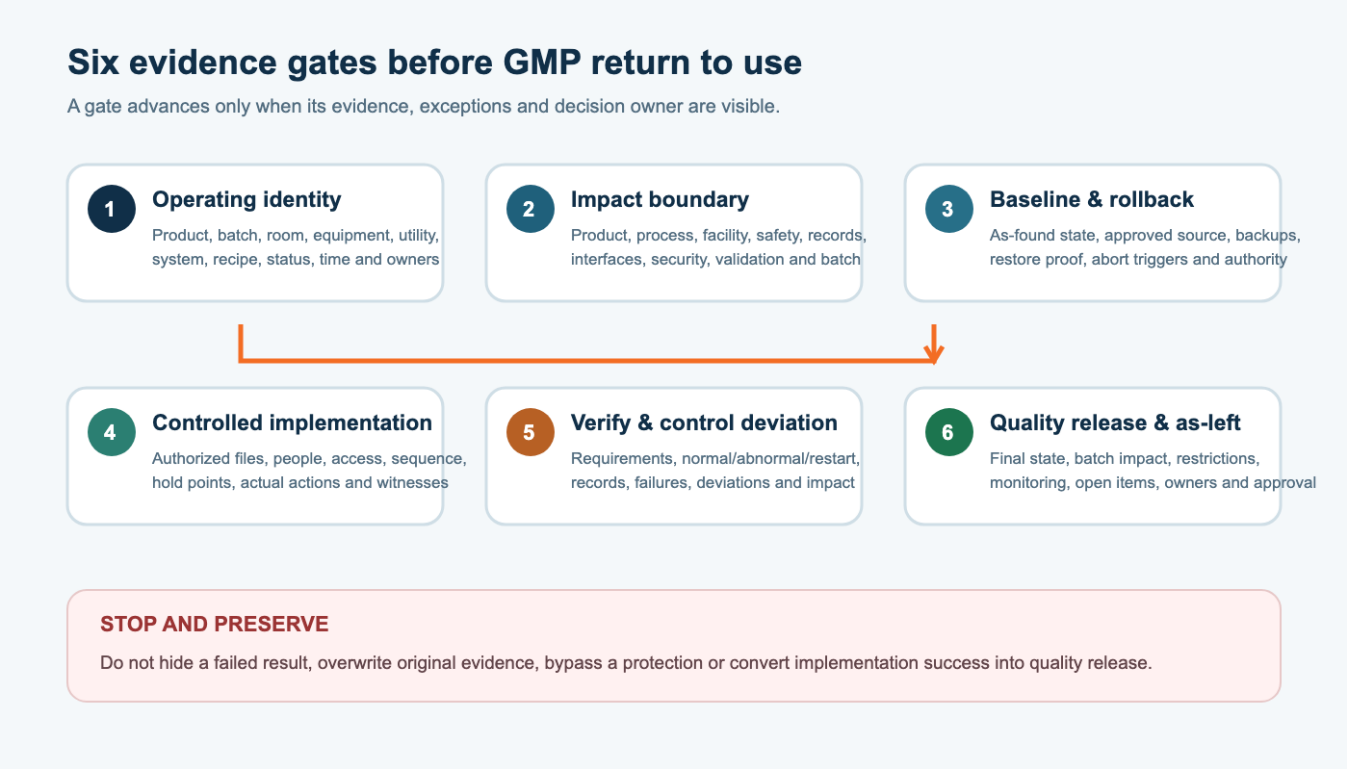
DATA TO COLLECT

Make the change traceable to one operating identity and one approved boundary

Evidence group	Minimum record	Decision supported
Operating identity	Site, product, batch, room, equipment, utility, system, recipe, mode, status, time and owners	Fixes exact operating and quality boundary.
Change request	Problem, outcome, requirement, reason, urgency, affected assets, exclusions and approvals	Prevents an undefined small edit.
As-found baseline	Running/source versions, checksums, hardware/firmware, settings, accounts, network, field state and restore proof	Establishes comparison and recovery.
Impact and risk	Product, CPP/CQA, process, facility, safety, records, interfaces, security, training, validation and batch	Defines review depth and owners.
Implementation plan	Authorized files, sequence, access, outage, prerequisites, holds, witnesses, abort and rollback	Bounds execution before change.
Verification plan	Requirements, normal/abnormal/restart tests, expected results, acceptance source and witnesses	Separates evidence from assumption.
Actual execution	Who, when, where, files/checksums, commands, responses, deviations and raw records	Shows what actually changed.
As-left release	Final versions, restore proof, open items, temporary states, monitoring, batch impact, quality decision and owners	Defines the exact released state.

SIX EVIDENCE GATES

Keep implementation success separate from GMP release



Gate	Evidence to close	Named output
1. Identity	Product, batch, room, equipment, utility, system, recipe, status, time and owners agree.	Fixed operating boundary.
2. Impact	Product, process, facility, safety, records, interfaces, security, validation and batch are reviewed.	Approved scope and depth.
3. Baseline and rollback	As-found state, approved source, backups, restore method, abort triggers and rollback test exist.	Recoverable starting state.
4. Controlled implementation	Authorized files, people, access, sequence, holds, actual actions and witnesses are recorded.	Traceable executed change.
5. Verification and deviation	Requirements, normal/abnormal/restart, alarms, records, interfaces, failures and deviations are reviewed.	Test result and controlled exceptions.
6. Quality release and as-left	Final state, batch impact, restrictions, monitoring, open items, rollback and approvals are accepted.	Released scope and owners.

EIGHT-STEP CHANGE PROCEDURE

Build the evidence chain before touching the system

01	**Fix operating and batch identity.** Name the product/batch, process step, room, equipment, utilities, automation layers, recipe, mode, time and owners.
02	**Preserve as-found state and raw records.** Capture running/source versions, checksums, settings, interfaces, audit trails, alarms, events, trends and field state.
03	**Translate the request into requirements.** Define outcome, functions, exclusions, acceptance-source references and evidence owners.
04	**Assess cross-system and GMP impact.** Review product, batch, process, facility, utilities, safety, records, data integrity, security, training and validation.
05	**Prove rollback before implementation.** Verify backups, restore dependencies, licenses, certificates, credentials, data compatibility, abort triggers and authority.
06	**Execute only the authorized scope.** Use approved files and sequence, record actual actions and stop at hold points when evidence differs.
07	**Verify requirements and failure behavior.** Test normal, abnormal, alarm, interlock, interface, restart and recovery paths; control every deviation.
08	**Release and hand over as-left.** Reconcile final versions, restore proof, open items, monitoring, batch impact and engineering/CSV/quality acceptance.

EXPERT REVIEW

Questions before a change becomes operating authority

- Does the live system, approved source, as-found evidence and request describe the same equipment and revision?
- Can the site explain product, batch, process, facility, data and validation impact for every changed object?
- Are audit trails, electronic records and time provenance preserved before reset, migration or restore?
- Does rollback include data, interfaces, licenses, certificates, accounts and field state - not only a project file?
- Were abnormal, restart, alarm, interlock, interface and record behaviors tested under the approved plan?
- Are deviations, temporary modes, restrictions, monitoring and owners visible to the quality release decision?

AS-LEFT HANDOVER

Transfer the operating state that actually exists

Identity and evidence	Verification and ownership
- Change, product and batch identity - As-found/as-left versions and checksums - Backups, restore proof and interfaces - Audit trails, records and physical state	- Requirement traceability and actual tests - Failures, deviations and product impact - Temporary states and restrictions - Monitoring, rollback, open items, owners and approvals

Release record

Name the released product, batch, equipment, utility, automation layer, recipe and operating scope. Record every excluded boundary, residual restriction, monitoring condition, rollback state and accountable owner.

OFFICIAL PRIMARY SOURCES

Use each source within its published jurisdiction and document scope

1. **eCFR 21 CFR Part 211**
   https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211
   United States CGMP requirements for finished pharmaceuticals.
2. **FDA Process Validation**
   https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-validation-general-principles-and-practices
   FDA lifecycle principles for process validation in drug and biological-product manufacture.
3. **FDA Data Integrity and Drug CGMP**
   https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-integrity-and-compliance-drug-cgmp-questions-and-answers
   FDA guidance on reliable and accurate data and risk-based data-integrity management.
4. **European Commission EudraLex Volume 4**
   https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
   European Union GMP legislation and guidance, including Annex 11 and Annex 15.
5. **NIST SP 800-82 Rev. 3**
   https://csrc.nist.gov/pubs/sp/800/82/r3/final
   Operational technology security guidance, including system lifecycle, change and recovery considerations.

Application limit

FDA guidance and eCFR describe United States regulatory or guidance scope. EudraLex describes European Union GMP scope. NIST SP 800-82 is OT security guidance. These sources are not interchangeable national rules, site validation protocols, universal process values or batch-release authority. Confirm country, product authorization, pharmacopoeia, AHJ, site quality system, approved SOPs, validation strategy, permits, OEM requirements, qualified personnel and named quality authority.

Field Electric Guide | Reviewed 23 July 2026 |
https://field-electric-guide.pages.dev/en/guides/pharmaceutical-automation-change-control-impact-validation-rollback-release-evidence