AI Work Authorization Toolkit User Guide

Reference v4.2

How to use ten downloadable items: eight connected records, the companion white paper, and the Release Notes / Verification Summary to decide what AI-supported work may proceed, preserve the evidence for that decision, test whether the controls work in practice, and return organizational findings to affected workflows.

Reference operating aid. Adapt and approve within the applicable quality system before use. These files are not regulatory forms, validation results, authorizations, or substitutes for site procedures.

Artifact crosswalk

Every artifact in this toolkit supports one decision: whether a defined AI-supported workflow may proceed, under what limits, and what finding would require restriction or withdrawal. Use this page to find the record that answers the control question in front of you. No single artifact authorizes a workflow or demonstrates continuing effectiveness.

Control need	Record or context	Output or decision supported
Understand the method	Companion white paper (context)	Control basis, operating method, and authorization-cycle rationale.
Identify actual work	AI Use Inventory	Owned use record, initial risk and disposition.
Test the workflow	Workflow Evaluation Scoring Sheet	Representative-case evidence, breakdowns, and gate recommendation.
Authorize the bounded use	Gate Decision Record	Decision, Authority Envelope, accepted residual risk, and triggers.
See the organizational state	AI Authorization Register	Current authorization status, Decision history, and Management actions.
Test control effectiveness	Independent Effectiveness Review Record	Independent findings, effectiveness conclusion, and required action.
Adjudication Protocol	adjudication-protocol-reference-v4.2.pdf	adjudication-protocol-reference-v4.2.docx
Implement consistently	User Guide	Connected sequence, roles, record boundaries, and reconciliation.
Act by role	Role Quick-Start Cards	Role-specific responsibilities, evidence, escalation, and handoffs.
Verify the release	Release Notes / Verification Summary (release documentation)	Included files, verification status, and the checksum-manifest boundary.

1 Package contents and control model

The toolkit is one control system. No single file authorizes a workflow or demonstrates continuing effectiveness.

Record	Purpose	Authoritative boundary
AI Use Inventory	Current inventory of actual bounded uses, including unapproved use	Does not authorize
Gate Decision Record	Connects evidence to a bounded authorization, restriction, or retirement decision	Authoritative decision only when approved in the organization's controlled system
Workflow Evaluation Scoring Sheet	Tests the complete workflow against predefined criteria and protected holdout evidence	Supports a gate review; does not authorize
AI Authorization Register	Current portfolio view plus append-only decision history and management actions	Indexes controlled source records; does not replace them
Independent Effectiveness Review Record	Tests whether authorization and monitoring controls work in practice	Independent conclusion; management action remains controlled separately
User Guide	Operating sequence, reconciliation, and responsibilities	Reference guidance
Role Quick-Start Cards	Role-specific duties and prohibitions	Reference guidance

2 The operating sequence

1. Inventory the bounded use and assign process, quality, system, and data owners.
2. Define the work, baseline process, failure consequences, risk, and evidence boundary.
3. Set the Authority Envelope, record requirements, security and privacy controls, prohibited actions, stop controls, and change triggers.
4. Freeze the evaluation design, test the complete workflow, protect holdout evidence, and examine automation bias and reviewer performance.
5. Approve the Gate Decision Record. Anything not written in the authorized scope is not authorized.
6. Update the AI Use Inventory, append the decision to Decision history, and reconcile the Authorization register current-state row.
7. Monitor actual operation. Record incidents, near misses, overrides, unsupported acceptances, workload, changes, and source or supplier failures.
8. Perform independent effectiveness review using source evidence and actual use, not document presence alone.
9. Escalate material findings to pharmaceutical quality-system management review and create controlled actions.
10. Feed actions back through a new GDR, restriction, change control, deviation, CAPA, requalification, supplier action, retirement, or other applicable record; then verify effectiveness.

3 Rules that apply to every workflow

Rule	Operational meaning
Authorize work, not a product label	Define person, system, version, use case, sources, output, downstream decision, and authority.
Capability is not permission	Enforce allowed and prohibited actions technically. A prompt is not an access control.
A score is not authorization	Only an approved GDR grants the bounded decision recorded in it.
Human review must be tested	Test forced verification, AI-exposure timing, certainty labels, review time, workload, queue, rotation, competence, and practical escalation authority.
Reviewer burden is an operating limit	Measure the current process before it changes. Before evaluation, set and approve the review-effort performance limit, monitoring window, summary measure, and action threshold. The baseline informs the limit but does not determine it. Record actual burden during Stage 4 monitoring and restrict or escalate when the defined rule is met.
Critical failures are not averaged away	Predefine them before testing and stop, restrict, correct, or gather further evidence when they occur.
Holdout evidence is protected Adjudication sequence protects the evidence Before holdout scoring, write and approve an Adjudication Protocol that defines the critical-omission definition, rubric, evidence hierarchy, reviewer qualifications, independence, blinding, disagreement process, calibration collection, and reliability criterion. Calibrate first on the separate seeded collection, freeze the method and acceptance criterion, then apply the frozen method to the untouched holdout. A calibration collection is not authorization evidence.	Freeze cases, inclusion rules, expected findings, versions, instructions, thresholds, and mappings before reading results.
Every decision enters history	Append every issued GDR to Decision history; never rewrite earlier decisions into the current state.
Monitoring must produce action	Material findings enter independent review and management review and return to affected workflows through controlled records.

4 Roles and accountability

Role	Owns	Must not do
Process owner	Task, baseline, acceptable outcome, review design, operating capacity	Treat reviewer presence as evidence of effective review
Quality owner	Evidence sufficiency, thresholds, records, authorization co-approval, escalation	Approve after results are seen without predefined criteria
System owner	Configuration baseline, identity, permissions, technical enforcement, recovery	Rely on prompt instructions to prohibit available actions
Data owner	Source boundary, classification, inclusion rules, evidence identity	Allow undocumented or superseded sources into scope
Evaluation owner	Frozen design, cases, scoring administration, reconciliation to the GDR	Confirm their own critical-failure mapping as the only reviewer
Assessor	Independent case scoring and documented evidence basis	See another assessor's answer before independent scoring
AI governance lead	Inventory completeness, register reconciliation, decision history, overdue actions	Substitute portfolio governance for local accountability
Independent reviewer	Risk-based testing of authorization and monitoring effectiveness	Review a workflow they designed, operate, own, or approved without disclosed and accepted safeguards
Management-review chair	Decisions, resources, priorities, accountable actions, and effectiveness follow-up	Close a material finding because it appears on a dashboard

5 Before first use

11. Assign local document and record identifiers, owners, approval routes, effective dates, review cycles, retention rules, and repositories.
12. Define the risk-based criteria for the GDR light path and full path. Any GxP-consequential output, write or execute authority, Part 11 record, or agent normally requires the full path.
13. Approve the controlled vocabularies, finding classifications, escalation thresholds, immediate-containment authority, and management-review cadence.
14. Decide whether completed spreadsheets are working aids or quality records. If they are records, control them in a system with appropriate audit trail, access, backup, retention, and electronic-signature controls.
15. Replace the supplied worksheet-protection passwords and confirm the intended Excel version. Worksheet protection prevents accidental edits; it is not a Part 11 or data-integrity control.
16. Clear worked example data before production use. Preserve the blank masters under document control.

6 AI Use Inventory

Create one row per bounded use. A new task, site, product, source collection, user group, authority level, or materially changed configuration may require a new Use ID or a documented change assessment.

- Record unapproved or consumer-tool use when found; do not wait for procurement reconciliation.
- Describe the work and downstream decision, not the vendor or model alone.
- Name process, quality, system, and data owners before the use leaves Stage 0.
- Record the GDR ID, decision date, next review date, evidence repository, trigger event, and last update.
- Use the New entry checks before transferring a row to the inventory; resolve or explicitly document every accepted gap.
- Update the inventory on access, source, interface, model, prompt, supplier, role, product, site, incident, near miss, or retirement changes.

7 Workflow Evaluation Scoring Sheet

17. Create the draft GDR and enter its ID on Gate summary.
18. Approve minimum case counts, average score, critical-failure allowance, tolerable upper bound, holdout minimum, and the condition being authorized before testing.
19. Freeze the collection, inclusion rules, expected findings, configuration, reviewer instructions, rubric, critical-failure mapping, and thresholds. Record the date and independent confirmation in the GDR.
20. Mark every case Tuning or Holdout. Tuning cases may improve the workflow; holdout cases support authorization.
21. Record strata, whether the AI conclusion was shown before independent assessment, review time, second-assessor score, and date scored.
22. Treat forced-verification failures, high-confidence misses, unsupported acceptance, workload deterioration, and ineffective escalation as control findings even when the average score is high.
23. Read every Breakdowns section before the gate decision. A favorable average cannot authorize a failed subgroup.

8 Gate Decision Record

Open a new GDR for every gate decision, including registration, containment, pilot, routine use, expansion, restriction, suspension, reinstatement, and retirement.

- Identify the inventory entry, stage, requested decision, effective period, record path, and preparer.
- Define the bounded use and approved Authority Envelope with technical enforcement evidence.
- Cite the scoring sheet, freeze, holdout result, limitations, reviewer-performance evidence, and contrary evidence.
- Record the authorized scope, conditions, accepted residual risk and accepting owner, monitoring, stop criteria, change triggers, records, retention, and investigation access.
- Obtain accountable process and quality approval in the organization's approved system.
- Transfer defined fields to the Authorization register current-state row and append the GDR to Decision history.
- Record whether independent review is required and how management escalation and controlled actions will be referenced.

9 AI Authorization Register

Use the register as an index and aggregation layer, not as a substitute for controlled source records.

Tab	Row grain	Required practice
Authorization register	One row per current bounded workflow	Update from the latest approved GDR and monitoring records
Decision history	One immutable row per issued GDR	Append; never overwrite or delete prior decision events
Management actions	One row per management action	Track owner, due date, affected workflows, controlled records, effectiveness check, closure, and register reconciliation
Guidance	Reference instructions	Adapt responsibilities, cadence, and escalation rules locally

- Stratify portfolio analysis when averages could conceal site, product, role, supplier, authority, or failure-class problems.
- Treat missing independent-review conclusions and pending management-escalation decisions as open items.
- Keep protected evidence in approved repositories; store only identifiers, controlled links, summaries, and decisions in the register.

10 Independent Effectiveness Review

24. Establish reviewer independence from workflow design, operation, ownership, and approval. Record conflicts and access limitations.
25. Define the population, period, risk-based sample, exclusions, and evidence limitations.
26. Examine the register, GDRs, monitoring, human-review evidence, incidents, near misses, changes, CAPAs, suppliers, configurations, and qualification evidence.
27. Test actual scope against authorized scope, reconstruct decisions, test stop triggers, evaluate monitoring detectability, and assess human-review and corrective-action effectiveness.
28. Classify findings under the organization's approved system and impose immediate restrictions when necessary.
29. Escalate material systemic themes and required decisions to management review.
30. Confirm the register, affected GDRs, and management-action records were updated; then test effectiveness on fresh evidence.

11 Management review and action

The organizational loop is complete only when evidence changes a controlled state, resource decision, or accountable action and the result is checked.

Input	Management decision	Controlled output
Systemic failure or deteriorating control	Restrict, suspend, narrow, investigate, or retire	New GDR plus incident, deviation, CAPA, or retirement record
Shared supplier or configuration weakness	Change supplier terms, technical controls, sources, or monitoring	Change control, supplier action, regression test, requalification
Reviewer workload or automation bias	Change presentation, forced verification, staffing, queue limits, rotation, or qualification	Procedure/training change, requalification, monitoring update
Resource or governance gap	Assign owner, budget, system support, or review capacity	Management action with due date and effectiveness measure

12 Reconciliation and timing

Event	Required same-cycle updates
GDR approved	Inventory decision fields; Authorization register current-state row; Decision history entry
Material change	Inventory trigger; impact assessment; restricted state if needed; new or superseding GDR; regression evidence
Incident or critical failure	Immediate containment; inventory/register status; investigation; affected scope; GDR restriction or suspension
Independent review completed	Register conclusion; findings; management escalation; affected GDRs and actions
Management action issued	Management actions tab; controlled implementation records; affected authorization states
Effectiveness check completed	Action closure; review conclusion; register reconciliation; further action if ineffective

13 Record and electronic-signature boundaries

- The supplied Word and Excel files are not configured or validated as Part 11 systems.
- Use the organization's approved record and electronic-signature system when a signature or regulated record is required.
- Retain enough evidence to reconstruct the decision: inputs, versions, retrievals, outputs, human changes and reasons, approvals, system actions, resulting state, and linked investigations.
- Do not indiscriminately log protected content or copy evidence into uncontrolled files. Use controlled identifiers and repository references.
- Document supersession and preserve prior decisions. Never make the current register state the only surviving evidence of earlier authorization.

14 Release contents by component

Only the files in the Public protected preview column are included in this download. The DOCX files and editable workbook masters in the Licensed editable master column are available only with the separately licensed package.

Component	Public protected preview	Licensed editable master
White paper	governing-ai-in-pharmaceutical-operations-v4.2.pdf	governing-ai-in-pharmaceutical-operations-v4.2.docx
AI Use Inventory	ai-use-inventory-reference-v4.2.xlsx	ai-use-inventory-reference-v4.2.xlsx
Gate Decision Record	ai-gate-decision-record-reference-v4.2.pdf	ai-gate-decision-record-reference-v4.2.docx
Evaluation Scoring Sheet	ai-workflow-evaluation-scoring-sheet-reference-v4.2.xlsx	ai-workflow-evaluation-scoring-sheet-reference-v4.2.xlsx
AI Authorization Register	ai-authorization-register-reference-v4.2.xlsx	ai-authorization-register-reference-v4.2.xlsx
Independent Effectiveness Review Record	independent-effectiveness-review-record-reference-v4.2.pdf	independent-effectiveness-review-record-reference-v4.2.docx
User Guide	ai-work-authorization-toolkit-user-guide-v4.2.pdf	ai-work-authorization-toolkit-user-guide-v4.2.docx
Role cards	ai-work-authorization-toolkit-role-quick-start-cards-v4.2.pdf	ai-work-authorization-toolkit-role-quick-start-cards-v4.2.docx

15 Source and authority statement

The operating method is a GxP Frame proposal informed by established quality and AI risk-management principles. The adopting organization remains responsible for determining applicable requirements, approving local procedures and records, and establishing evidence that each particular workflow is fit for its intended use.

Source	Use in the toolkit	Boundary
ICH Q9(R1)	Risk-based effort, formality, and documentation	Does not authorize a particular AI workflow
ICH Q10	Management review, escalation, resources, action, and continual improvement	Implementation remains subject to the organization's PQS
NIST AI RMF 1.0	Inventory, roles, monitoring, review, and decommissioning concepts	Voluntary; not a pharmaceutical compliance determination
ISO/IEC 42001:2023	Organizational AI management-system concepts	Certification does not establish acceptable performance for a specific GxP workflow
Governing AI in Pharmaceutical Operations v4.2	AI-Supported Work Authorization Cycle	Proposed operating method; not regulation, approval, or validation evidence