AI Work Authorization Toolkit Role Quick-Start Cards

Reference v4.2.1

Role-specific duties, required evidence, and prohibitions for the eight roles that operate the toolkit. Each card states what the role does, what evidence it must be able to show, and what it must never do. Use the numbered duties continuously across all cards because they form one connected sequence.

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.

Item	Release
Architecture reference	Governing AI in Pharmaceutical Operations v4.2
Toolkit release	v4.2
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Owner	Brian Drapeau, GxP Frame

1 Process owner

Own the work and acceptable outcome.

Requirement	Detail
Do this	• Define the bounded task, baseline process, downstream decision, failure consequences, and whether the GDR light path or full path applies. • Design review capacity, forced verification, AI-exposure timing, certainty-label use, queue limits, reviewer rotation, and escalation authority as controls for automation bias. • Co-approve the GDR and its Authority Envelope; ensure operating conditions match the authorized scope. • Escalate material deterioration, incidents, unsupported acceptance, and workload failures.
Evidence you should be able to show	Bounded task, baseline, selected record path, approved GDR and Authority Envelope, review design, workload limits, monitoring, and current register state.
Never	• Authorize through an inventory or register entry alone. • Accept reviewer presence as evidence that review works. • Expand scope before a new decision.

Operating boundary: This card is a role-specific prompt. The approved GDR, Authority Envelope, controlled records, and local quality system govern the work.

2 Quality owner or quality unit

Decide whether evidence and controls support the regulated use.

Requirement	Detail
Do this	• Approve the GDR light path or full path, thresholds, holdout design, critical-failure mapping, Adjudication Protocol, reliability criterion, and condition being authorized before results are examined. • Do not accept a critical-omission bound without the calibration record showing the pre-stated reliability criterion was met before holdout scoring. • Confirm records, retention, Part 11 determination, the Authority Envelope, accepted residual risk and accepting owner, and stop criteria. • Co-approve every GDR and require a new decision for expansion or material change. • Escalate material independent-review findings into the pharmaceutical quality system. • Do not accept a Stage 3 decision unless the measured baseline, review-effort performance limit, monitoring window, action threshold, and evidence reference are stated before results are examined.
Evidence you should be able to show	Approved path and thresholds, holdout and mapping evidence, GDR approval, accepted residual risk, Authority Envelope, escalation, and effectiveness closure.
Never	• Approve after-the-fact criteria. • Let a favorable average offset a critical failure. • Close an action before effectiveness is demonstrated.

Operating boundary: This card is a role-specific prompt. The approved GDR, Authority Envelope, controlled records, and local quality system govern the work.

3 System, data, security, and privacy owners

Define and enforce what the workflow may access and do.

Requirement	Detail
Do this	• Maintain and technically enforce the approved Authority Envelope, including configuration identity, source boundary, classification, service identity, least privilege, and prohibited actions. • Test negative actions, stale approvals, duplicates, interruption, partial success, recovery, and out-of-hours escalation. • Raise change triggers for model, prompt, source, interface, permission, supplier, user-role, product, or site changes. • Preserve decision provenance and investigation access without uncontrolled copies.
Evidence you should be able to show	Approved Authority Envelope, configuration baseline, access and service-identity evidence, negative and recovery tests, source map, and change records.
Never	• Rely on a prompt to prohibit an available action. • Run an agent on the initiating user's credentials. • Expand permissions before a new GDR.

Operating boundary: This card is a role-specific prompt. The approved GDR, Authority Envelope, controlled records, and local quality system govern the work.

4 Evaluation owner

Run the scoring sheet and produce Stage 3 evidence.

Requirement	Detail
Do this	• Link the draft GDR, approve thresholds and the Adjudication Protocol, then calibrate on the separate seeded collection. • Freeze the definition, rubric, evidence hierarchy, reviewer qualifications, disagreement process, and reliability criterion before holdout scoring. • Use two qualified adjudicators independent of the workflow outcome, blinded to condition and each other; retain their decisions and rationale. • A qualified tiebreaker who did not author the rubric and is independent of the workflow owner resolves disagreements. • Separate tuning from holdout and record all withdrawals, incomplete cases, deviations, strata, and dates scored. • Capture AI-exposure timing, review time, second-assessor results, forced verification, certainty-label presentation, workload, rotation criteria, and automation bias controls. • Stop testing and escalate immediately when a critical failure or freeze-sequence breach occurs. • Record the measured baseline and pre-set review-effort performance limit, including the monitoring window, summary measure, and action threshold. • Do not treat a passing omission bound as sufficient when review burden exceeds the defined operating limit.
Evidence you should be able to show	Frozen design, scoring sheet, holdout integrity, Breakdowns tab, deviations, independent mapping confirmation, automation bias controls, and GDR reconciliation.
Never	• Confirm your own mapping as the only reviewer. • Score the holdout before calibration is complete and the method is frozen. • Change the design after results without a Version log entry.

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5 Assessor or operational reviewer

Judge the evidence independently and document the basis.

Requirement	Detail
Do this	• Complete the independent assessment before seeing the AI conclusion when the protocol requires it. • Perform forced source verification and apply the approved rubric and certainty-label presentation protocol. • Record review time, detected errors, unsupported acceptance, overrides, escalation, workload limitations, and signs of automation bias. • Reject, restrict, or escalate when evidence or authority is insufficient.
Evidence you should be able to show	Independent assessment, source checks, rubric scores, review time, errors detected, escalations, and limitations.
Never	• Score tone or polish instead of evidence and action appropriateness. • See another assessor's result before independent scoring. • Accept a high-confidence output without verification.

Operating boundary: This card is a role-specific prompt. The approved GDR, Authority Envelope, controlled records, and local quality system govern the work.

6 AI governance or portfolio owner

Keep organizational evidence complete, current, and traceable.

Requirement	Detail
Do this	• Review systemic themes, shared dependencies, trends, overdue actions, restrictions, accepted residual risk, and unresolved uncertainty. • Review portfolio burden signals against the recorded performance limits and require restriction, resourcing, redesign, or requalification when a defined limit is exceeded.
Evidence you should be able to show	Inventory, current register, immutable Decision history, open Management actions, reconciliation evidence, and portfolio analysis.
Never	• Replace local process and quality owners. • Overwrite prior decisions with the current state. • Treat a dashboard entry as action closure.

Operating boundary: This card is a role-specific prompt. The approved GDR, Authority Envelope, controlled records, and local quality system govern the work.

7 Independent effectiveness reviewer

Test whether authorization and monitoring controls work in practice.

Requirement	Detail
Do this	• Document independence, conflicts, population, risk-based sample, exclusions, and evidence limitations. • Test actual use against the Authority Envelope and authorized scope; reconstruct decisions, stop triggers, monitoring detectability, and human-review effectiveness. • Test corrective actions on fresh cases and check unaffected cases for regression. • Escalate material findings and confirm the register, GDR, Decision history, and Management actions records are reconciled.
Evidence you should be able to show	Independence statement, sample basis, source evidence, test procedures, findings, restrictions, escalation, and effectiveness follow-up.
Never	• Review only whether forms exist. • Review work you designed or operate without disclosed safeguards. • Close findings without source evidence and effectiveness follow-up.

Operating boundary: This card is a role-specific prompt. The approved GDR, Authority Envelope, controlled records, and local quality system govern the work.

8 Management review chair or designee

Convert organizational evidence into accountable decisions and resources.

Requirement	Detail
Do this	• Review systemic themes, shared dependencies, trends, overdue actions, restrictions, accepted residual risk, and unresolved uncertainty. • Review portfolio burden signals against the recorded performance limits and require restriction, resourcing, redesign, or requalification when a defined limit is exceeded. • Decide whether to restrict, suspend, requalify, change, investigate, resource, renegotiate, or retire affected workflows. • Assign action IDs, owners, due dates, affected records, and effectiveness checks in the Management actions tab. • Require updates to the Authorization register, GDRs, Decision history, change control, CAPA, training, supplier, and retirement records as applicable.
Evidence you should be able to show	Management decision, action IDs, resources, owners, due dates, affected workflows, controlled outputs, and effectiveness decisions.
Never	• Accept a portfolio average that hides a failed subgroup. • Close action because a due date passed. • Delegate accountability without naming an owner and controlled output.

Operating boundary: This card is a role-specific prompt. The approved GDR, Authority Envelope, controlled records, and local quality system govern the work.