Independent Effectiveness Review Record

REFERENCE TEMPLATE V4.2 - ADAPT AND APPROVE WITHIN THE APPLICABLE QUALITY SYSTEM

Use this form to test whether workflow authorization and monitoring controls work in practice. The review must examine source evidence and actual use, not only the presence of completed records. This reference template does not establish a mandatory review interval, finding classification, retention period, approval route, or regulatory conclusion. The organization must define those elements in its approved quality system.

1 Review identification and independence

Review record ID	[Assign under the approved document or record system]
Review type and trigger	[Scheduled, event-driven, management-requested, or other]
Review period	[Start date] through [end date]
Lead reviewer	[Name and function]
Additional reviewers	[Names and functions or not applicable]
Independence statement	[Describe separation from workflow design, operation, ownership, and approval]
Conflict or limitation	[Record conflicts, incentives, access limitations, or none identified]
AI Authorization Register snapshot	[Controlled identifier, date, and repository]
Related management review	[Reference or pending]

2 Scope and sampling rationale

Review objective	[State what control effectiveness the review will test]
Population	[Define the workflow population and applicable period]
Sample selected	[List workflow IDs and Gate Decision Record IDs]
Risk-based selection basis	[Explain why the sample can test the material risks]
Excluded items and reason	[Identify exclusions and justify them]
Evidence limitations	[State missing, inaccessible, or uncertain evidence]

3 Evidence examined

Evidence class	Review purpose	Controlled reference	Status and limitation
AI Authorization Register	Portfolio snapshot and linked workflow identifiers	[Reference]	[Status]
Gate Decision Records	Decision basis, Authority Envelope, conditions, accepted residual risk, stop triggers, and review date	[Reference]	[Status]
Monitoring and human-review evidence	Errors, omissions, overrides, review time, queue size, automation-bias controls, detection, and escalation	[Reference]	[Status]

Evidence class	Review purpose	Controlled reference	Status and limitation
Incidents, near misses, changes, and CAPA	Failure mechanisms, scope, restrictions, corrections, and effectiveness checks	[Reference]	[Status]
Supplier and configuration evidence	Version, retrieval, interface, integration, and permission changes	[Reference]	[Status]
Qualification evidence	Role-specific challenge cases and reassessment after material change	[Reference]	[Status]

4 Effectiveness tests

Control objective	Procedure performed	Evidence and result	Conclusion
Authorized scope versus actual use	Compare system and access evidence with the Gate Decision Record; examine exceptions and shadow use.	[Evidence and result]	[Conclusion]
Decision reconstruction	Trace the decision from the Authorization register and append-only Decision history to evidence, rationale, conditions, accepted residual risk, accountable approver, and resulting system state.	[Evidence and result]	[Conclusion]
Stop and restriction triggers	Identify trigger events and determine whether required restriction, notification, and decision records were timely.	[Evidence and result]	[Conclusion]
Monitoring detectability	Determine whether monitoring identified material deterioration before unacceptable downstream reliance.	[Evidence and result]	[Conclusion]
Human-review effectiveness	Examine detection rate, unsupported acceptance, overrides, workload, queue, rotation, and practical authority to escalate.	[Evidence and result]	[Conclusion]
Reviewer-burden control effectiveness	Confirm the measured baseline, pre-set review-effort performance limit, monitoring window, summary measure, action threshold, and evidence basis. Test whether actual burden remained within the limit and whether restriction or escalation occurred when the defined rule was met.	[Evidence and result]	[Conclusion]

Control objective	Procedure performed	Evidence and result	Conclusion
Critical-omission adjudication integrity	Confirm the Adjudication Protocol was approved before calibration; test that reviewer independence, blinding, calibration reliability, method freeze, and protected-holdout separation are evidenced and that post-freeze changes were controlled.	[Evidence and result]	[Conclusion]
Corrective-action effectiveness	Test the failure mechanism on fresh cases and check unaffected cases for regression.	[Evidence and result]	[Conclusion]
Change and reauthorization	Confirm that material configuration, source, interface, staffing, and authority changes received impact assessment.	[Evidence and result]	[Conclusion]

5 Findings and immediate control

Finding ID	Affected workflow	Classification	Observation and evidence	Immediate control	Owner and record
[ID]	[Workflow IDs]	[Use approved classification]	[Observation and source evidence]	[Containment or none]	[Owner and record reference]
[ID]	[Workflow IDs]	[Use approved classification]	[Observation and source evidence]	[Containment or none]	[Owner and record reference]

6 Overall conclusion and management-review escalation

Overall conclusion	☐ Effective ☐ Effective with conditions ☐ Partially effective ☐ Ineffective ☐ Unable to determine
Conclusion rationale	[Explain how the evidence supports the conclusion and identify contrary evidence]
Material systemic themes	[Repeated failure mechanisms, common suppliers, workload, permissions, or none identified]
Immediate restrictions	[Restrictions, suspensions, or none]
Management decision required	[Decision, information, or resource required]
Management-review reference	[Controlled reference or pending]
AI Authorization Register update	[Current-state row and append-only Decision history updated by/date, or pending with owner and due date]
Resulting authorization records	[New, restricted, suspended, retired, or superseding Gate Decision Record IDs]
Management action records	[Management actions tab action IDs and linked deviation, CAPA, change control, requalification, training, supplier, restriction, retirement, or other controlled records]

7 Actions, effectiveness follow-up, and register reconciliation

Action ID	Action	Owner	Due date	Affected records	Effectiveness check	Status, closure, and register update
[ID]	[Action]	[Owner]	[Site-assigned date]	[Affected records]	[Effectiveness check]	[Status/reference]
[ID]	[Action]	[Owner]	[Site-assigned date]	[Affected records]	[Effectiveness check]	[Status/reference]

8 Review and decision fields

Role	Name and title	Decision or signature reference	Date
Lead independent reviewer	[Name and title]	[Conclusion/signature reference]	[Date]
Quality owner	[Name and title]	[Decision/signature reference]	[Date]
AI governance or portfolio owner	[Name and title]	[Acknowledgment/action reference]	[Date]
Management-review chair or designee	[Name and title]	[Management decision reference]	[Date]

Use the organization's approved approval and electronic-signature system where required. This Word reference template is not configured or validated as an electronic record or signature system.

9 Open items for site confirmation

- Document and record identifiers, approval route, and controlled repository.
- Review triggers, cadence, sampling method, and required independence.
- Finding classifications, escalation thresholds, and immediate-containment authority.
- Applicable retention, privacy, confidentiality, and electronic-record requirements.
- Interfaces with internal audit, management review, deviation, CAPA, change control, and training systems.

10 Source register and authority status

Source	Authority status	Use in this reference template	Link
ICH Q10 Pharmaceutical Quality System	Harmonised quality-system guideline	Supports management review, performance indicators, escalation, resource action, and continual improvement. Applicability and implementation remain subject to the organization's quality system.	Read source
NIST AI RMF 1.0	Voluntary risk-management framework	Supports inventory, roles, periodic review, executive responsibility, monitoring, training, and safe decommissioning. It is not a pharmaceutical authorization or compliance determination.	Read source
ISO/IEC 42001:2023	Voluntary certifiable management-system standard	Supports an organizational AI management system and continual improvement. Certification does not establish acceptable performance for a particular GxP workflow.	Read source

Source	Authority status	Use in this reference template	Link
Governing AI in Pharmaceutical Operations, Version 4.2	GxP Frame proposed operating method	Defines the AI-Supported Work Authorization Cycle. It is not a regulation, approval, validation result, or substitute for site procedures.	Read source